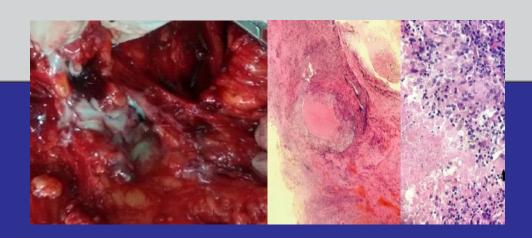


# THE SRI LANKA JOURNAL OF SURGERY

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#### In this issue

- Is laparoscopic appendicectomy safe in the hands of trainees?
- Surgical treatment for valvular heart disease experience from Sri Lanka
- Burns in Sri Lanka: pattern and initial management steps
- Burden of Functional gastrointestinal disorders
- Critical care management in burns: a review of current evidence and guidelines

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# A centre dedicated for men's health and wellbeing for the first time in Sri Lanka - End your suffering with an effective treatment for Erectile Dysfunction

Lanka Hospitals PLC, a premier health care provider in Sri Lanka, announces its latest addition to the Centres of Excellence- the Male Wellness Centre (MWC) – in a bid to offer services to improve health and wellbeing of men. It's also significant that a fully-fledged wellness centre dedicated solely for men has been established for the first time in Sri Lanka.

The MWC caters to a host of services including Personnel fitness scheduling and programming, Sport health and injury management, Dietary & Nutritional advices, Pre-marital counseling and health screening, Management of premature ejaculation, Management of Erectile dysfunction, Cosmetic surgeries (Bariatric / Ocular / Dental). In addition to the General health screening, patients can obtain screening for Liver, Kidney, Respiratory, Cardiac, Diabetic, Endocrine-Hormonal, Cancer and Sexually Transmitted Diseases in addition to Substances and Alcohol abuses. Furthermore, apart from leading physicians MWC offers the service of competent consultant specialists such as Cardiologist, Endocrinologist, Diabetologist, Venerologist, Urologist, Nephrologist, Oncologist, Surgeon, Vascular Surgeon, Psychiatrist as well as Counsellor.

Erectile Dysfunction (Impotence) is a common health issue suffered by men, defined by the difficulty in achieving and maintaining a penile erection during sexual intercourse. In the Sri Lankan context, the issue is hardly brought into light especially by those who suffer and often show reluctance to seeking proper medical attention. Often, incorrect and misleading advice not only aggravates the issue, but also lead them to face unwanted complications. A special Shock Wave Therapy unit was established within the Male Wellness Centre by the Lanka Hospitals to specifically treat impotence.

The Centre conducts in-depth studies and comprehensive medical analysis to precisely identify the causes for impotence such as Vascular, Psychogenic, Neurological, Hormonal, Structural and others. Being a newer and less invasive way to treat this common sexual challenge shock wave therapy has proven to be effective even when oral medication has failed. Also known as penile extracorporeal low-intensity shockwave therapy, this method involves the use of low intensity acoustic pulse waves that lead to release of factors which promote growth of new blood vessels in the penis Therapy compromises of a handheld device being angled towards the shaft of the penis. One of the main advantages of this treatment method is that it has no clinically relevant side effects. Each treatment session can last approximately 20 minutes.

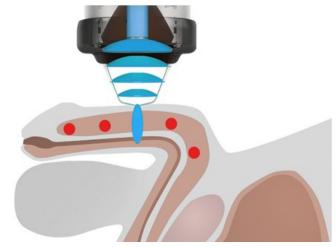


Figure 1. Shock wave therapy

Shock wave treatment is a completely painless way to treat what can be a life altering condition and a regular course of treatment usually comprises of six sessions. The frequency of these session can be tailor made as below and would be decided by the consultant:

- 1) Every day for 6 days
- 2) Every second day over an 11 day period
- 3) Twice a week for 3 weeks

The outcomes include gaining of more frequent erections, more rigid erections, ability to maintain an erection and perform entire act of sexual intercourse and freedom to reduce or omit medication. Therefore the use of a treatment which researchers claim is "really a breakthrough" could be good news for men who have erectile dysfunction.

As a hospital staying abreast with latest medical technology, Lanka Hospitals established Male Wellness Centre in a bid to provide world class health care services to Sri Lankan as well as International patients. Moreover, when catering to health issues and conditions that are highly sensitive and personal, Lanka Hospitals delivers complete confidentiality to its patients with the assistance of its specially trained staff.

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### **MEN'S WELLNESS CENTRE**



## **Erectile Dysfunction Shockwave Therapy (SWT)**

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- Each session duration: 20-30mins
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- The sessions can be tailored on patient preference after discussing with the Consultant Genito-Urinary Surgeon or Physician

### For any information and clarifications

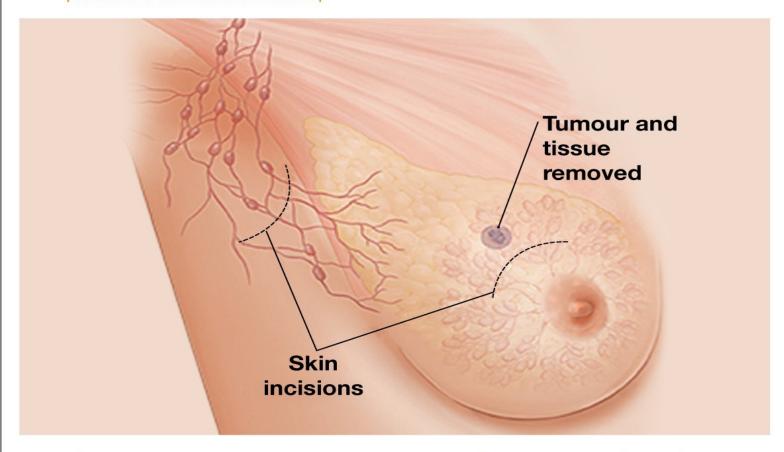










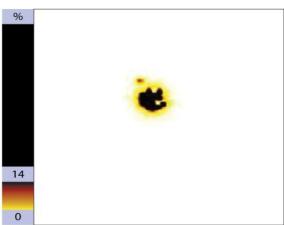


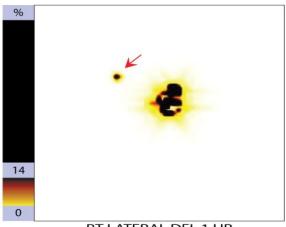
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## SCIENTIFIC ARTICLE

## Is laparoscopic appendicectomy safe in the hands of junior trainees in surgery?

N. Harivallavan<sup>1</sup>, M. D. Jayawardene<sup>1</sup>, S. A. Piyarathne<sup>2</sup>, A Arulprashath<sup>1</sup>, S. D. Iddamalgoda<sup>1</sup>, S. Anton Swarnan<sup>1</sup>, A. A. Pathirana<sup>2</sup>

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**Keywords:** laparoscopic appendicectomy; trainees; safety

#### **Abstract**

#### Introduction

Laparoscopic appendicectomy (LA) is considered as the mainstay of treatment in acute appendicitis. LA is a basic laparoscopic procedure and therefore can be used as a training tool for surgical trainees. It is considered an index operation for junior surgical trainees. This study aims to assess whether LA is safe to be carried out by a junior surgical trainee.

#### Methodology

The study was conducted at a tertiary care unit in Colombo. Data were collected retrospectively. A total of 152 LA (including those which were converted to open appendicectomy) performed between January 2018 to May 2019, by surgical trainees (both junior and senior) were included. Gender, age, initial investigation findings, intraoperative findings, operative time, hospital stay, postoperative complications and histology data were analysed. Findings were compared in two groups – operated by junior and senior surgical trainees.

#### Results

One hundred and three surgeries were performed by junior trainees while 49 were performed by senior trainees. There was no significant difference in complicated appendicitis (21.4% vs 34.7%), operative time (71m vs 68m), conversion rate (12.6% vs 16.3%) and hospital stay (3d vs 3d) between these two groups. The overall complication rate was 3.9%.

#### Conclusion

Our findings were comparable to previously published data and no statistically significant difference was noted between the two trainee groups in terms of operative finding, hospital stay and postoperative complications. The results suggest that LA can safely be performed by the junior surgical trainees with acceptable outcomes.

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#### Introduction

The overall lifetime risk of developing acute appendicitis is 8.6% for males and 6.7% for females; the lifetime risk of appendicectomy is around 12% in males and 23% in females [1]. Despite emerging data on the possibility of managing many patients with acute uncomplicated appendicitis conservatively, appendicectomy is still considered as the mainstay of treatment in most settings in both complicated and uncomplicated cases [2]. There are open and laparoscopic techniques for appendicectomy. With the increasing popularity of minimal access surgeries, laparoscopic appendicectomy (LA) is fast becoming the mainstay of treatment. Appendicectomy is considered an index operation for junior surgical trainees [3]. In the modern era, all surgical trainees are expected to have laparoscopic skills. LA is a basic laparoscopic procedure and therefore can be used as a training tool. But any surgical procedure in the training programme should be monitored for safety.

This study aims to assess whether LA is safe to be carried out by a junior surgical trainee (JT, a first-year trainee in surgery) without much prior experience in minimally invasive surgery.

#### Methodology

This study was conducted at a tertiary care centre in Sri Lanka. A total of 152 cases of laparoscopic appendicectomy (including those which were converted to open appendicectomy) performed between January 2018 and May 2019, by surgical trainees (both junior and senior), were included. A junior trainee (JT) was defined as a surgical registrar in the first year of his/her surgical training. A senior trainee (ST) was defined as a surgical senior registrar (post-MD trainee). Those who had previous surgical experience on laparoscopic surgeries were excluded from the junior trainee group even if he/she were in their first-year pre-MD surgical training (i.e. a previous Senior House Officer in a surgical unit who had performed laparoscopic work).

All junior trainees had undergone initial training in basic laparoscopic skills before starting the MD surgery training program by taking part in a mandatory workshop on Basic Laparoscopic Skills conducted by the College of Surgeons of Sri Lanka. They had assisted for several LA in the initial period of training and subsequently performed the procedure

under the supervision of a consultant. Once confident, junior trainees could perform LA independently, with a senior trainee (ST) present in the theatre.

The basic demographic data (gender, age), initial investigation findings (white cell count, CRP), intraoperative findings (degree of inflammation, amount of blood loss, operative time), hospital stay, postoperative complications and histology of patients who underwent LA during the study period were retrospectively gathered and recorded separately for JT and ST groups. Ethical clearance was obtained from the ethics review committee of the institution. SPSS version 25 was used for data analysis. The Independent t-test was used for quantitative variables and the chi-square test was used for qualitative variables. A p-value of less than 0.05 was considered statistically significant.

#### Results

One hundred and three LA were performed by JT while 49 were performed by ST. There was no statistically significant difference between these two groups in terms of age, gender, pre-operative inflammatory markers, and time duration from onset of symptoms to operation. (Table 1)

There was no significant difference in operative time (71m vs 68m, p=0.58), conversion rate (12.6% vs 16.3%, p=0.53) and hospital stay (3d vs 3d, p=0.13) between these two groups (Table 2). The incidence of abscess formation and perforation of the appendix (complicated appendicitis) was 21.4% and 34.7% in junior and senior trainees' groups respectively, with a p-value of 0.079.

Two incidents of surgical site infection and one case of residual abscess were observed in the JT group. Observed complications in the ST group were one surgical site infection and one paralytic ileus. An inflamed appendix was confirmed histologically in 150 cases, while two appendices were not inflamed. These non-inflamed appendices were in the JT group.

For an unbiased comparison of JT and ST performances, we analysed after the exclusion of appendicectomy done for patients with complicated appendicitis. Subsequent findings showed that there was no statistically significant difference in terms of age, gender, pre-operative inflammatory markers, and time duration from onset of symptoms to operation between these two groups (Table 3). Even after the exclusion of surgeries for complicated appendicitis, the cohort with surgeries for uncomplicated appendicitis did not show any statistically significant difference in operative time, conversion rate, days of hospital stay, or postoperative complications (Table 4).

#### Discussion

Surgical training programmes have indicated index operations which are mandatory to be performed by trainees according to the level of their training. With the development of minimally invasive surgery, the necessary skills to perform these procedures are vital and it is necessary to select operations that are suitable for training the JT. Appendicectomy is a commonly performed procedure in most general surgical units, and performing this with minimally invasive methods is accepted as a safe procedure.

To obtain knowledge, skills, and values of the surgical profession, the workplace remains the principal site. It is believed that the theoretical concept of communities of practice can aptly be applied for surgical training [4].

Lave and Wenger defined the concept of communities of practice in which legitimate peripheral participation is a central notion [5]. A newcomer initially doing tasks peripheral to a community should get meaningful opportunities to interact and learn from the old-timers to be gradually allowed to undertake tasks central to the community [6]. It is the JT that plays this role initially in the setting of a surgical community. JT being a peripheral participant in the surgical community at first, gaining opportunities to perform meaningful surgical tasks in proportion to his/her ability, progressively improves upon developing the knowledge, skills, and confidence in surgical procedures. With time, the JT will move toward the centre of the community where he/she will be allowed to perform the entire surgical procedure. This theoretical basis of workplace learning applies to our study.

JT who has taken part in a basic laparoscopic skills workshop can be allowed to perform components of a minimally invasive procedure under direct supervision. Once confident, a procedure such as laparoscopic appendicectomy can be allowed to be performed by the JT. This helps the JT to gain the necessary skills and more importantly confidence in laparoscopic work, without compromising patient safety.

Our study showed that the outcome of LA done by JT was comparable to those done by ST, strengthening the notion that LA qualifies as a laparoscopic surgery a JT can be offered to perform on their own under senior supervision.

The prevalence of complicated appendicitis was 21.4% and 34.7% in this study in JT and ST groups respectively. The overall prevalence of complicated appendicitis was 25.6% (39/152) which is higher than what had been reported in published studies. Yilmaz M et al showed a complicated

Table 1. Comparison of basic findings (All appendicectomies – uncomplicated & complicated appendicitis)

	Junior Trainee (JT)	Senior Trainee (ST)	p value
No of surgeries	103	49	
Mean Age (Range)	24y (8-62)	27y (8-75)	p=0.23
Gender Male	64	39	p=0.125
Female	24	25	p=0.125
Mean WBC (x103 /mm3) (Range)	14(4-25)	15(7-27)	p=0.548
Mean CRP (mg/dl) (Range)	48(5-276)	61(4-376)	p=0.347
Mean time duration from onset of symptoms to operation (days)(Range)	2.01(1-7)	2.43(1-8)	p=0.249

WBC-White Blood Cells, CRP-C Reactive Protein

**Table 2.** Operative details (All appendicectomies – uncomplicated & complicated appendicitis)

	Junior Trainee (JT)	Senior Trainee (ST)	P value
Mean Operative time (min)	71(25-180)	68(30-150)	p=0.589
(Range)			
Conversion to open	13(12.6%)	8(16.3%)	p=0.536
Incidence of appendicular Abscess and perforation (complicated appendicitis)	22(21.4%)	17(34.7%)	p=0.079
Mean Hospital stay (days)	3(1-7)	3(1-8)	p=0.138
(Range)			
Complications	3	3	p=0.342
Surgical site infection	2	2	
Paralytic ileus	0	1	
Residual abscess	1	0	

**Table 3.** Comparison of basic findings (After exclusion of appendicectomies for complicated appendicitis)

	Junior Trainee (JT)	Senior Trainee (ST)	p value
No of surgeries	81	32	
Mean Age (Range)	26y (9-62)	30y (11-75)	p=0.147
Gender Male	48	17	p=0.552
Female	33	15	
Mean WBC (x103 /mm3) (Range)	14(5-24)	15(7-24)	p=0.324
Mean CRP (mg/dl)(Range)	46(5-252)	41(4-210)	p=0.680

WBC-White Blood Cells, CRP-C Reactive Protein

Table 4. Operative details (After exclusion of appendicectomies for complicated appendicitis)

	Junior Trainee (ЛТ)	Senior Trainee (ST)	P value
Mean Operative time (min)	67(25-165)	60(30-150)	p=0.255
(Range)			
Conversion to open	3(3.7%)	0(0.0%)	p=0.270
Mean Hospital stay (days) (Range)	3(1-7)	2(1-5)	p=0.255
Complications	1	0	p=0.528
Surgical site infection	1	0	
Paralytic ileus	0	0	
Residual abscess	0	0	

appendicitis rate of 17% in a study comprising 1642 cases [7]. In our study, the ST group's complicated appendicitis rate was higher than that for the JT. This is because significantly complicated cases when anticipated pre-operatively were done by the seniors while the JT was given relatively fewer complex cases.

The conversion rate to open was 12.6% versus 16.3% in junior versus senior trainees' groups. A study conducted among the surgical trainees comprising 115 patients showed a conversion rate of 9.2% [8]. Many studies have shown conversion rates of LA to be 9%-12% [9]. Our study presented a slightly higher conversion rate. This might be due to the low threshold to open in complex cases. Even though ST had done more complicated cases of appendicectomy, the difference in the conversion rate was not statistically significant between the two groups in our study. There was another study which had compared a surgical resident and an experienced surgeon in performing LA, where the conversion rates were 7% and 22% respectively with a p-value of 0.04[10]. The difference had stemmed from the fact that the experienced surgeon had performed more complex surgeries.

The mean operative time was 71 minutes and 68 minutes in junior and senior trainees' groups respectively. Lapo Bencini et al reported a mean operative time of 67 minutes and 60 minutes by the surgical resident and the experienced surgeon respectively [10]. This was comparable with our study. Another study indicated a mean operative time of 52 minutes which was less than our study [6]. Their trainees had to perform a minimum of 25 open cases appendicectomy before embarking on LA. On the contrary, our junior trainees did not have comparable experience with open appendicectomy before performing laparoscopic surgery. A couple of studies showed a mean operative time higher than that of our study (96 minutes and 102 minutes) [11, 12].

Our overall complication rate was 3.9% which was less than the published data. Carrasco-Prats M et al showed a 13% complication rate in their study comprising 224 cases and Martin LC et al published a complication rate of 13.1% (81) [9,11]. In our study, the length of hospital stay was three days in both groups. This is like the studies of Carrasco-Prats M et al. and Mutter et al where the hospital stay was an average of 4.9 days [9, 13].

In this retrospective study, we were unable to find consistent data about BMI of patients, position of the appendix, and preoperative abdominal examination findings. As these factors also influence the surgery, comparing the JT and ST groups based on these parameters would have provided more significance to this study. Hence, we consider it as a limitation of our study.

In conclusion, our findings are comparable to previously published data in terms of complicated appendicitis, conversion rates, operative time, hospital stay, and postoperative complications. Therefore, we propose that LA could safely be performed by the junior surgical trainees, who have limited experience in minimal access surgery with acceptable outcomes.

All authors disclose no conflict of interest. The study was conducted in accordance with the ethical standards of the relevant institutional or national ethics committee and the Helsinki Declaration of 1975, as revised in 2000.

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## SCIENTIFIC ARTICLE

## Surgical treatment for valvular heart disease: a single centre experience from Sri Lanka

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**Keywords:** Valvular heart surgery; Sri Lanka; valve replacement; valve repair; warfarin

Abstract

#### Introduction

Valvular heart disease (VHD) is an important cause of morbidity and mortality in the world. Anatomically, it affects mostly the left side of the heart (aortic and mitral valves), but the right side (tricuspid and pulmonary valves) can also be involved.

Etiologically, a variety of underlying mechanisms can damage the heart valves and lead to stenosis, regurgitation, or a combination of both. Although rheumatic heart disease (RHD) has been reduced in the world, it remains the commonest cause of VHD in many countries [1]. It affects 33.4 million people worldwide and its long-term effects on heart valves are still seen in developing countries [2]. RHD, predominantly but not exclusively, affects the mitral valve and can often involve multiple valves [3]. In countries such as the USA and UK, age-associated degeneration of the valves has become the major contributor to valve disease [4]. With better living standards, as the longevity of people increases, the diagnosis and referral of diseases improve. Therefore, overall surgical treatment for VHD in the world is increasing [4]. Degeneration of the aortic valve is mainly caused by calcification, and usually causes aortic stenosis [5], whereas degeneration of the mitral valves tends to be myxomatous, and usually causes mitral valve prolapse, which could subsequently lead to mitral regurgitation [6]. Acute infective endocarditis (IE), caused by a highly virulent organism, can deform a previously normal valve, while endothelial damage present in RHD can predispose to subacute bacterial endocarditis. Congenital valvular disease can involve all four valves and can present at any age, but the congenital bicuspid aortic valve is the commonest type and is present in 1% of the world population [8]. Dilatation of the annulus is the key mechanism of functional regurgitation [9]. Coronary artery disease that causes ischemic changes of the mitral papillary

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muscles can cause ischemic mitral regurgitation [10].

Valve disease is usually progressive, frequently debilitating, and with time, can be life-threatening. While medical management provides an important ancillary treatment, and interventional procedures are important for selected valve diseases, it is surgical therapy that still plays a major role in definitive therapy.

Valvular heart surgeries (VHS) may be in the form of valve repair or valve replacement, the choice depending on the type of valvular lesion, the patient's characteristics, the surgeon's experience and the facilities available at the centre - to name a few. Recently, many modern techniques, including minimally invasive valve surgery [11] and combined surgical and interventional approaches such as Transcatheter Aortic Valve Implantation (TAVI) [12], have become available. However, because of the high costs of these treatment modalities, more traditional surgical options remain the standard of care, especially in parts of the world where resources are limited.

The demography, underlying pathology, aetiology and the outcome of patients undergoing valve surgery have been extensively reviewed in the USA and Europe [4], while data from Sri Lanka is mostly lacking. In this environment, management decisions have been based on "international data" that may not adequately represent local conditions. Therefore, we need to understand the profile of patients undergoing VHS in Sri Lanka, as it will influence our management decisions.

#### Material and Methods

Ethical clearance to do the study was obtained from the local ethical review committee. Permission to do the study was obtained from the head of the institution. No identification details were published or exposed to anyone other than the investigators of the study.

This is a retrospective descriptive cross-sectional study in a single surgeon-led cardiothoracic unit from August 2010 to April 2020. Operation notes, clinical records including microbiological reports, perfusion records and morbidity-mortality records of all patients who had undergone valve operations during the study period were reviewed. The operations included isolated and multiple valve operations

and valve operations done combined with other operations. Valve repairs done as part of major aortic surgery (five aortic dissections/ aneurysm) and valve repairs done as a secondary part of the correction of other congenital defects (two atrioventricular canal defects) were excluded as they constituted quite different clinical and surgical entities. Data was entered on specially designed data extraction forms and transferred onto a Microsoft EXCEL database and analysed.

#### Results

During the study period, a total of 175 patients had undergone VHS which constituted 15.7% (175/1115) of the total workload of this unit. The mean age of patients was 51.5 years (range 6-76 years). There were 105 (60 %) males and 70 (40%) females. There were no referrals of pregnant females for valve surgery in this series.

The majority (151/175; 86.3%) of operations were single valvular heart operations while 21 (12%) were double valve operations and three (1.7%) were triple valve operations. Most (132/175; 75.4%) were isolated valvular procedures while (43/175; 24.6%) were combined valvular procedures. The protocol in this unit is that all patients above the age of 40 years awaiting VHS should routinely undergo coronary angiography. Accordingly, 35/175 (20.5%) patients were found to have coronary artery disease severe enough to warrant concomitant Coronary Artery Bypass Surgery (CABG). Other procedures that were done concomitantly with the VHS were: four ventricular septal defect closures, two atrial septal defect closures, one aortic root replacement and one pericardiectomy.

The commonest valve involved was the mitral valve (117/175; 66.9 %) followed by the aortic (72/175; 41.1%), tricuspid (10/175; 5.7%) and pulmonary valves (3/175; 1.7%). There were differences in their mean ages: 56 (19-76, SD 11.7) years for aortic valve lesions, 52 (7-75, SD 13.5) years for mitral valve lesions, 30 (23-37 SD 7.0) years for pulmonary valve lesions and 26.5 (6-56 SD 21.8) years for tricuspid valve lesions.

The commonest hemodynamic pathology was mitral regurgitation (88/175; 50.3%) present alone or in combination with other valvular pathologies followed by mitral stenosis (38; 21.7%). The commonest aetiology was RHD (76; 43.4%) which was diagnosed based on the past medical history of RHD and was confirmed macroscopically during surgery. In the case of the mitral valve, macroscopic findings typically included thickened, shortened and fused chordae tendinea as well as thickened and fibrosed valve leaflets. In the case of the aortic valve, the typical findings were thickened and fibrosed free edges of the leaflets, fused commissures, a classic "fish mouth" appearance of the aortic

Table 1. The case load and mortality of valvular heart surgery

Type of Surgery	Number of Patients	Deaths
Valve replacement	149 (85.1%)	13 (8.7%)
Valve repair	21 (12%)	1 (4.8%)
Combined valve replacement and repair	5 (2.9%)	1 (20%)
Total	175 (100%)	15 (8.6%)

valve orifice and minimal calcification. The other aetiologies were degenerative (51;29.1%), congenital (28; 16%), acute endocarditis (9; 5.1%), ischemic (6; 3.4%) and functional (5; 2.8%). There were 6/175 redo operations in this series.

Subacute bacterial endocarditis had been present in 14/175 (8%) of these patients; thus, a total of 23/175 (13.2%) had endocarditis at some point of their disease. The mitral valve was involved in 16/23 (69.5%) of patients with endocarditis. The commonest organisms involved were of the Genus Streptococcus. These were all native valve endocarditis. There were no patients with prosthetic valve or intracardiac devise endocarditis.

A total of 195 prostheses were used in this series consisting of 178 valves (153/178; 88.8% mechanical valves, 25/178;14% tissue valves) and 17 rings. The sizes most frequently used were 29 mm for mitral valves, 19 mm for aortic valves and 29 mm for mitral valve rings.

Ten (5.7%) patients had postoperative complications: Reopening for bleeding was the commonest cause of morbidity (5/175; 2.9%). All were resolved successfully.

The overall in-hospital mortality was 15/175 (8.6 %) (Table 1). The mortality of the most frequently performed (60/175; 34.2% %) valve replacement surgery, mitral valve replacement, was 8.3 % and that of the most frequently performed (9/26; 34%) valve repair surgery, isolated MV repair, was zero. It is noteworthy that one third (5/15) of those who died had endocarditis. The endocarditis group had a high mortality 5/23 (23%), especially for those with fungal endocarditis as both patients with candida endocarditis died. Elective valve surgery carried a mortality rate of 5.7% (8/141) while that of non-elective surgery was 20.6% (7/34). There were no deaths (0/6) in the small group of re-do operations.

All patients in this unit routinely undergo a post-operative echocardiogram before discharge. Accordingly, 2/136 (1.5%) patients who were discharged following valve replacements had mild paravalvular leaks that were managed conservatively. The postoperative valve functions of 134/136 (98.5%) of valve replacements and 100% of valve repairs were good. It is the unit's protocol that all patients after VHS are prescribed

warfarin. This is omitted three months after surgery in those who have had a repair or a tissue valve replacement, while those who have had a mechanical valve will essentially continue warfarin for life.

Six patients have died after discharge due to warfarin related issues: Two died due to haemorrhage: one was a 14-year-old who died two years after discharge due to massive intracerebral haemorrhage. The other was an adult who died two months after discharge due to massive generalized haemorrhage after taking four tablets of 5mg warfarin instead of the prescribed four tablets of 1mg warfarin. Four patients have died due to possible thrombotic complications after stopping warfarin: two died within the first year: one when a doctor had stopped warfarin for three days to control an ecchymotic patch and another due to four days of vomiting when he most likely vomited his warfarin tablets. Two patients died five years after discharge due to neglecting their medication amidst family conflicts and social problems.

#### Discussion

VHS is second only to coronary operations in most adult cardiac surgical centres in the world and usually accounts for 20% to 35% of their procedures [13]. As our unit deals with both cardiac and thoracic surgery, VHS accounted for only 15.6% of all operations in our unit and is the third commonest operation next to coronary and thoracic operations.

Rheumatic carditis was the most frequent etiological factor for VHD. According to WHO data published in 2017, the age-adjusted death rate due to rheumatic carditis in Sri Lanka is 1.94 per 100,000 of population and ranks Sri Lanka at number 92 in the world [14].

World data shows that IE is slightly commoner in aortic valves [15]. However, the mitral valve was the commonest valve affected by IE (69.5%) in our series. This is because RHD, a risk factor for IE, predominantly involves the mitral valve and RHD is, by far, the commonest aetiology for VHD in our community. International data shows that most native valve endocarditis is now caused by Streptococcus, Staphylococcus, and Enterococcus [16]. The commonest organisms in our series were Streptococcus and Enterococcus. Fungal endocarditis remains the most serious form of infective endocarditis, with high mortality rates of 44-80% in world series [17] and this dismal prognosis is reflected in our small series as well.

Valve replacement can be done using either a mechanical or tissue valve. In this series, 88.8% of valves used were mechanical. Mechanical valves last a lifetime but have the disadvantage of requiring lifelong anticoagulation, usually with warfarin. Neither tissue valve replacements nor valve

repairs require such long-term warfarin for the valve per se (unless the presence of arrhythmia influences this decision).

Warfarin requirement confers disadvantages to patients in many aspects, especially with regards to pregnancy due to its risks of bleeding and teratogenicity. Patients on warfarin need to have their International Normalized Ratio (INR) measured monthly. The INR can change with alcohol and certain types of food and drugs-all of which can be problematic to patients. Our experience with warfarin is that patients' compliance in the long term is not optimal. There are no home INR testing facilities in Sri Lanka and patients need to travel to a hospital for the test and the medication, and the motivation to do so can dwindle over time. Problems have arisen with dosing as the 1mg, 2mg and 5 mg tablets are all white, of the same size and shape, and are not marked on the tablet. The quality of the warfarin tablets is questionable and tends to crumble when trying to break it into parts. Inadvertent massive overdoses have happened occasionally due to confusion in tablet strength. In this series, the death of six patients after discharge is related to such issues. Authorities need to take action to prevent such complications by marking the strength or colour-coding the warfarin tablets as was done in the past.

One way to overcome these problems during surgery is to use a tissue valve instead of a mechanical one, but as tissue valves last only 10 -15 years, it is usually recommended for the older age group. As the patients' age at surgery shows an increasing trend, the use of tissue valves is increasing in the world [4]. If a young patient opts for a tissue valve (e.g. wishes to become pregnant and avoid warfarin) the chances are that 10 -20 years later, she will need a redo operation. Recent trends in the USA show increasing use of tissue valves even in the 50-60-year age group, but with higher rates of reoperations [18]. Redo operations carries a higher risk than a first-time operation [19]. Despite these problems with warfarin, we use tissue valves only in the above 60-years age group and continue to insert mechanical valves for the younger patients. This is not only to avoid the technical challenges of reoperation but also to avoid an additional operation in an already over-burdened system where the waiting time for any cardiac operation is long.

There has been a strong move in the US and Europe to repair rather than replace valves [20]. Valve repair requires, among many other facilities, the availability of intraoperative transoesophageal echocardiography (TEE), accredited experts to perform it, interpret it and liaise with the surgeon during surgery to ensure a good repair. Our unit does not have TEE, despite yearly efforts by the surgical team to convince the administration to invest in one and highlights how financial issues have a direct impact on therapy in Sri Lanka.

Until TEE is available, we have tried to overcome this problem by performing valve repairs in carefully selected patients with favourable anatomy. The repair is assessed intraoperatively using static water testing, with a low threshold to convert to a replacement on-table should test results be less than ideal. This method has given excellent postoperative echocardiography results and has conferred the advantage of managing selected patients without long term warfarin. However, the zero morbidity and mortality of this small group (9/175; 5.1%) of isolated mitral valve repair patients is perhaps due to our careful selection of uncomplicated patients for repairs. Furthermore, cardiologists refer patients for repairs (as opposed to replacement) earlier - before the onset of complications. Both factors could contribute to a better outcome in the repair group. We continue our efforts to obtain TEE facilities, without which we cannot progress safely with mitral valve repairs.

A large study was done in 2005 of more than 400,000 patients in the Society of Thoracic Surgery (STS) database in the USA over 10 years found an overall mortality of 7.1% [19]. The acute presentation was the most important risk factor to confer high mortality (12.9%) for valve surgery [19]. In this study, the authors urged to refer patients with severe valve lesions under elective and not emergency conditions. Our own unit's mortality reflected a similar trend with 5.7% mortality for routine versus 25% for acute presentations. Therefore, the desirability of early referral and intervention appears to be relevant at present in our setting as well. Given the cost of valve operations (SLR 1-1.3 million) and the added cost of a stormy intensive care stay for compromised patients, fast-tracking valve patients before clinical deterioration should be a topic of discussion between clinicians and administration.

Over time, VHD compromises the myocardial and overall organ functions. Patients who have not undergone surgical correction in time often present late with significant myocardial dysfunction, pulmonary hypertension and cardiac cachexia. Late presentations could be a cause for higher mortality in our setting. However, objective measurements of myocardial compromise such as the ejection fraction, or a complexity scoring were not available in our records. This is a shortcoming in this retrospective study and should be studied in future prospective studies. Furthermore, the long term survival of this cohort merits further study.

#### **Conclusions**

This is the first study of baseline data of patients undergoing VHS in a cardiothoracic unit in Sri Lanka. It has established the workload, demography, aetiology, pathology, trends in surgical treatment and outcome of VHS in the local setting which have important differences from those of international

studies. This has also highlighted aspects of VHS in Sri Lanka that need to be developed and areas that merit further audit and research.

All authors disclose no conflict of interest. The study was conducted in accordance with the ethical standards of the relevant institutional or national ethics committee and the Helsinki Declaration of 1975, as revised in 2000.

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## SCIENTIFIC ARTICLE

## Burns in Sri Lanka: analysis of pattern of burns and initial management steps of patients admitted with burns to Teaching Hospital Kandy

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**Keywords:** Epidemiology of burns; burn injuries; Sri Lanka; initial management

#### **Abstract**

#### Introduction

Burn injuries range from minor superficial burn to a deep lifethreatening injury. Minor burns are treated with first aid, in an out of hospital setting, while major burns require more specialized treatment in specialized centres. Sri Lanka has only one designated "Burns" unit at National Hospital, Colombo, with limited bed capacity. Teaching hospital Kandy is the second-largest hospital in Sri Lanka providing services to a large population within the central province and adjacent provinces. Kandy district accounts for an urban to the rural population distribution of approximately 12.4% to 81.4% with an estate population of 6.2%. With its unique sociocultural, religious and economic inequalities, there is a scarcity of information on the incidence, causes and outcomes after burn injuries. This preliminary survey was to obtain reliable data on the epidemiology of burns victims, the pattern of burn, the circumstances associated with the injury and management steps carried out during the initial period and to justify establishing a unit for the care of patients with burns in Kandy Hospital.

#### Methodology

A prospective observational study was carried out among all patients admitted to Teaching Hospital, Kandy with burn injuries over six months. Data were collected using a pretested questionnaire, completed by the investigators.

Results-Of the 46 victims, the majority were females (74%, p<0.05) and 50% were between the ages 18-55 years. The majority were ethnic Sinhalese (69%) and 52.2% were transferred patients from satellite hospitals.

Most of the burns were accidental (n= 43,93.5%) and 82% occurred in households. 91.3%(n=42) were thermal burns while flame burns caused 54.4%. Electrical(n=3,6.5%) and chemical burns(n=1,2.2%) were rare. Cooking related

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incidents accounted for 65% of the incidents of flame burns. 50% of the adults (n=23) and 83% (n=5) of children sustained major burn injuries. 24% sustained facial burns and 10.8% (n=5) inhalational injuries, 7(25%, p<0.05) required endo-tracheal intubation and management in an intensive care unit.

Over 64% (n=18, p=0.13) of the patients with major burns had not received any form of local first aid care for the injury, and all burns were left uncovered until surgical dressings were applied. Hypothermia prevention strategies were not implemented on 92.8%(p<0.05). Only 67% utilized the Parkland formula to calculate the resuscitation fluid volume.

#### Conclusion

The predominant proportion of patients admitted to Teaching Hospital Kandy were adult females who suffered household accidental flame burns, many of them being classed as major.

Awareness programmes need to be planned and implemented to improve knowledge on the prevention, first aid and initial management of burns for general public and health care workers.

These patients may benefit from a specialized burns unit at Teaching Hospital Kandy.

#### Introduction

Burns is a worldwide health problem, resulting in an estimated 180,000 deaths annually, major proportion taking place in lower-middle-income countries, nearly sixty-five percent occurring in South-East Asia and Africa [1].

An estimate of the incidence of burn injuries in India varies from 100000 to 2 million annually, with approximately 50 000 fatalities. In Pakistan, burns injuries were found to be the second leading cause of disability and the eleventh leading cause of premature death.[2] In Sri Lanka, the estimated burn-related injuries account for 10000 injuries and 100 deaths[3].

Only three published articles from Sri Lanka were available to us. These studies were carried out in the Eastern Province with a marginally different ethnic and socio-economic and cultural environments. Selladorai et al in 2013 studied patients admitted to Batticaloa Hospital-the leading hospital in the

eastern province. In their study, 41% of the burns were of suicidal intent. [4] and deep burns (n=46, 73%) were more frequent. Main sources of accidental burns were traditional lamps (n=18, 51%) and kerosene oil cookers (n=9, 26%). Similar findings were observed in a study conducted by Laloe in 2002 and Lau in 2006[3,8].

A national burn management guideline was published by the College of Surgeons of Sri Lanka in 2007. However, there is no information available on the degree of adherence to these guidelines, nor of outcomes.

With one specialized centre for patients with burn injuries in the country, with a limited number of available beds, most of such patients are treated at major tertiary care centres and peripheral units. This study intended to obtain information on the circumstances associated with the causation of the injury, the epidemiological data of the victims, initial resuscitation and management steps carried out by the emergency department and surgical unit doctors at Teaching Hospital Kandy, and to assess the need for a special burn management unit at Kandy Teaching Hospital to enable clinicians to provide a better quality of care.

#### Methodology

This prospective observational study was carried out among all the patients admitted to the emergency treatment unit, surgical unit, paediatric surgical unit and plastic surgery unit at Teaching Hospital Kandy with burn injuries over six months from 1.2.2019 to 30.7.2019. Data collection was done within 24-48 hours of the admission of the patient to the hospital.

Data on demographic details were collected using a pre-tested questionnaire completed by the investigators interviewing the subjects. Information on initial management steps was obtained by studying their hospital notes, after obtaining informed written consent from the patient or the next of kin.

The first part of the questionnaire covered the following areas: Demographic data of the burn victim, the mechanism, source, pattern and severity of the burn injury. The second part of the questionnaire was designed to identify the initial management steps carried out in the treatment of the burn victim (e.g. first aid, initial management according to ATLS protocol and burn specific management steps).

Statistical analysis was performed using SPSS version 25, in terms of frequencies and percentages for respective categories. Significance was calculated with Pearson's Chisquared test and the Fisher Exact test.

Ethical clearance was obtained from the Ethical committee of Teaching Hospital Kandy (THK/ERC/16/2019).

#### Results

#### Patient demographics

A total number of 46 patients were studied. Demographic data of the study population are given in Table-1. The Demographic data reveals that a significant proportion (p=0.001) of the victims were females (74%, n=34), while males comprised 26% (n=12). Sixty-nine percent were ethnic Sinhalese, while 50% were young and middle-aged adults (18-55 years). Approximately half of the patients (52.2%, n=24, p=0.831) reaching Kandy Hospital were transferred patients from satellite hospitals, while 47.8%(n=22) were direct admissions to the hospital.

**Table 1.** Demographic data of the study population (n=46).

Category		Number (%)
Gender	Male	12(26%)
	Female	34(74%)
Age – range 6	< 10 years	5(10.8)
months to 78 years	10-18	5(10.8)
	18-35	13(28.2)
	35-55	10(21.7)
	55-65	8(17.4)
	>65	5(10.8)
Ethnicity	Sinhalese	32(69.5)
	Tamil	6(13.1)
	Muslim	8(17.4)
Marital status	Married	30(65.2)
	Unmarried	16(34.8)
Occupation	Housewife	20(43.5)
	Unemployed	5(10.8)
	Chef/ cook/helper	3(6.5)
	Self employed	3(6.5)
	Schooling	5(10.8)
	Garment factory workers	2(4.3)
	Drivers	2(4.3)
	Mechanic/ electrician	2(4.3)
Mode of admission	Direct	22(47.8)
to hospital	Transferred	24(52.2)

#### Pattern of Burn Injuries

Data on mechanism of burn injuries, source of burn and the injury pattern observed are presented in table 2,3 and 4 respectively.

Table 2. Mechanism of burn injuries

Category		Total Number	Number of	Number of	Significance
		(Percentage)	males (%)	females (%)	(males and
					females)
Type of burn	Thermal burns	42(91.3)	9(21.4)	33(78.6)	*p=0.0004
	Hot liquids- scalds	19(41.3)	5(26.3)	14(73.7)	*p=0.039
	Flame burns	23(50)	3(13)	21(87)	*p=0.0001
	Contact with hot surfaces	1(2.2)	1(100)	-	
	Electrical burns	3(6.5)	2(66.7)	1(33.3)	-
	Chemical burns	1(2.2)	1(100)	-	-
Mechanism of	Accidental	43(93.5)	10(32.5)	33(67.5)	*p=0.0006
burns	Suicidal	3(6.5)	1(33.3)	2(66.7)	-
Place of burn	Household	38(82.6)	7(18.4)	31(81.6)	*p=0.0001
	Workplace	7(15.2)	5(71.4)	2(28.6)	**p=0.452
	Outdoors	1(2.2)	-	1(100)	-

p value calculated using \*Pearson's chi squared test and \*\*Fisher exact test. p<0.05 considered significant.

Table 3. Source of Burn

Category		Frequency	Major burns	Minor burns	Significanc
		(percentage	frequency	frequency	e- major
		from all	(percentage from	(percentage from	and minor
		burns n= 46)	all burns n=46)	all burns n=46)	burns
Hot liquids	Hot water	14(30.4)	6(13)	8(17.4)	*p=0.791
	Hot oil	5(9.2)	3(6.5)	2(4.3)	**p=0.999
n=19(39.6)					
Flame burns	Kerosene cookers	4(8.7)	2(4.3)	2(4.3)	-
n=22/E0\	Kerosene traditional lamp	3(6.5)	3(6.5)	-	-
n=23(50)	Gas cookers (liquid petroleum)	8(17.3)	6(13)	2(4.3)	**p=0.282
	Wood stove	3(6.5)	2(4.3)	1(2.2)	**p=0.999
	Falls into litter burning pits	2(4.3)	2(4.3)	-	-
	Petrol	1(2.2)	-	1(2.2)	-
	Suicidal attempt with kerosene	2(4.3)	2(4.3)	-	-
Contact with hot surface	Hot oven	1(2.2)	-	1(2.2)	-
Electrical n=3(6.5)	Damaged wire	2(4.3)	2(4.3)	-	-
	High-tension wire associated electrical and flame burn	1(2.2)	1(2.2)	-	-
Chemical n=1(2.1)	Battery acid ingestion	1(2.2)	1(2.2)	-	-

p value calculated by Pearson's chi-squared test and Fisher exact test. P<0.05 was considered as significant BSA- Burn surface area. \*Significance calculated between major burns and minor burns with Pearson's chi square and Fisher's exact test accordingly

Table 4. Injury Pattern

Category		Frequency (Percentage
		from all cases n = 46)
Burn surface area (BSA) – adults	<10 %	6(13)
	10-20%	11(23.9)
	20-30%	6(13)
	30-50%	10(21.7)
	>50%	7(15.2)
Burn surface area – children	<10%	1(2.1)
	10- 20%	5(10.8)
Special areas of burn	Inhalational injury	5(10.8)
	Face	11(23.9)
	Eyes	1(2.1)
	Perineum	4(8.7)
	Hands	14(30.4)
Degree of burns	1º only	2(4.3%)
	1º and 2º	16(34.8%)
	2º and 3º	27(58.7%)
	40	1(2.2%)
Severity of burns - Adults	Burns requiring in hospital	33(79.2%)
	treatment	
	Major burns	23(57.5%)
	Intermediate 10-20% BSA	10(21.7%)
	Minor < 10% BSA	7(15.2%)
Severity of burns — Children	Major >10% BSA	5(10.8%)
(<12 years)	Minor <10% BSA	1(2.1%)

p value calculated by \*Pearson's chi-squared test and \*\*Fisher exact test. P<0.05 was considered significant. BSA- Burn surface area.

**Table** 5. Initial management of major burn victims (n=28)

Management step		Frequency (% form total	Significance
		major burns n=28)	
First aid at the site of injury	Burn cooling with cold running water	9(32.1)	*p=0.131
	Application of aloe vera	1(3.6)	
	None	18(64.3)	
Covering the burn area until	None	28(100)	*p<0.05
proper wound dressing is done			
Analgesia	Morphine	26(92.9)	*p=0.0004
	NSAIDs	5(17.9)	
	Paracetamol	6(21.4)	
Fluid resuscitation – calculation of	Parkland formula used	19(67.8)	*p=0.059
volume	Other non-standard regimes	9(32.1)	
Type of fluids used for initial	Hartmann's solution only	14(50)	*p=0.023 (between
resuscitation (first 24 hours)	Hartmann's solution, albumin and FFP	6(21.4)	Hartmann +/- collois
	0.9% saline only	7(25)	and 0.9% saline +/-
	0.9% saline and dextrose	1(3.6)	dextrose
Wound dressing at ward/	Silver sulfudiazine	15(53.6)	
operating theatre	Acticort	10(35.7)	
	Collagen	3(10.7)	
Escharotomies	Upper limbs	6(21.4)	
	Lower limbs	5(17.9)	
Tetanus toxoid (adults)	Given	15(65.2)	*p=0.144
	Not given	8(34.8)	
Antibiotics	Given	28	p<0.05
Hypothermia prevention	Warm fluids used for resuscitation	2(7.1)	**p=0.0004
	Warming blankets	2(7.1)	
	None	26(92.8)	
Requirement of ICU care	Ventilation and airway protection	7(25)	*p=0.008

 $p\ value\ calculated\ using\ Pearson's\ chi-squared\ test\ or\ Fishers\ exact\ test.\ P<0.05\ was\ considered\ as\ significant.$ 

Table 2- reveals that a significant majority of burns were caused by thermal injuries (91.3%, p<0.05), while significant mechanism being accidental burns (93.5%, p<0.05) occurring in households (82.6%, p<0.05). It is also evident that, in all categories significant majority affected are females.

Table 3- represent data on the source of the burn injury. It is shown that the commonest source of burn injuries was related to cooking (32.5%) that caused flame buns, commonly catching fire onto their loose-fitting garments. Of them the commonest source was the liquid petroleum gas cooker (17.3%). Females were the victims of all the burns related to hot oils, gas cookers and wood stoves. Only females attempted suicide with kerosene oil. Hot liquids were the only source of burn injuries among children <12 years in our study group.

Table 4 - represent the data on pattern of injuries.

Interestingly, significant number of patients admitted 79.2%(p=0.0001) required in-hospital treatment [5] while 50%(n=23) of adult patients admitted to Kandy hospital have sustained major burn injuries, that is they have suffered >20% of the body surface area burn(partial thickness or more) or had burns involving special areas of the body or suffered inhalation injury [5] 25% requiring intubation and ICU care, whom should ideally be managed in a specialized centre for burn management. Approximately 15% suffered >50% burn surface area and 10.8% was associated with inhalational injury, which are predictors of high mortality and poor outcome [6]. Of the children admitted 5(83.3%, p=0.219) had major burns (burn involving >10% BSA or involvement special areas)[5].

#### Initial management of major burns

Data on initial treatment steps within first 24 hours of injury are indicated in table 5.

Remarkably, all patients with major burns were prescribed analgesics, as pain is a significant complication of burns. However, 64% (p=0.13) have not received any form of first aid at the site of injury or the local hospital. Surprisingly, none of the burn areas was covered with sheets though is a recommended method to reduce pain by reducing airplay on the wound. Strategies to prevent hypothermia, which is another common complication with major burns that increase the severity of burns, hence the morbidity,5 were not employed in the initial management of a significant majority of patients (92.8%,p<0.05)in our study population even after the admission to hospital. Though Parkland formula is the recommended formula to guide the fluid requirement in the initial 24 hours, it was used only at 67% of the time while >30% used nonstandard regimes for fluid resuscitation (p=0.023), which could have an impact on the outcome.

Furthermore, >25% had received only 0.9% saline (p= as the resuscitation fluid, though it is Hartmann solution with or without colloids is considered the fluid of choice.[5],[6] Additionally, all patients were prescribed antibiotics even though it is not indicated, however, tetanus toxoid is indicated in all adult patients with burns if not recently immunized,[5] but it was only practised on 65%. Many of these omissions may be attributed to a lack of knowledge and training specific to burn victims' management among first contact health care professionals, which should be addressed accordingly. Significant number of patients (n=7,25%, p<0.05) required ICU admission. Therefore, it would be beneficial and tranquil to train these professionals if a separate unit and staff are allocated for specific management of burns.

#### Discussion

Burn injuries that are the fourth leading cause of traumatic injury worldwide remains a significant, preventable cause of morbidity and mortality in Sri Lanka.[7] Understanding the epidemiology and the socio-economic factors influencing their causation is fundamental to implementing preventive efforts. Though the exact burden is not known, a study published by Lau YS, 2006 suggests that burns account for 10000 injuries and 100 deaths, costing US\$1 million annually in Sri Lanka. [3]

We have studied 46 burn victims who were either directly admitted or referred from hospitals in the periphery of the Teaching Hospital Kandy.

Similarly, to studies conducted in the Eastern Province in Sri Lanka,[3],[4],[8] most burn victims were young (18 to 35 years, 28.2%) or middle (35-55years,21.7%) aged females(p=0.001). Most of the burns, over 80% (p<0.05) were in their homes and over 40 %, while they were cooking. This result might be related to the fact that, culturally, females of this age group do most of the cooking and household chores. This pattern is similar to observations from other regions of South Asia and Oman with adult females being affected at home in their kitchens.[2],[8],[9] Many incidents of flame burns associated with cooking were due to flames spreading to their loose-fitting flammable garments, especially synthetic clothes.[2],[3]

Our study revealed that thermal burns accounted for 91% of the cases. Of them, > 50% (52.2%, p=0.0001) were caused by flame burns. With the common source being kerosene cookers, gas (liquid petroleum) cookers and wood stoves. This was in contrast to the observations of Pirasath et al 2013, Lau 2006, Laloe 2002 (all conducted in Eastern province) that suggested that traditional kerosene lamps were the main source of the fire.[3],[4],[8] In our study, only 3(6.5%) victims had burns from the traditional kerosene lamp. This finding

may be due to differences in the socioeconomic and cultural backgrounds in the two provinces. Ethnically, Eastern Province has most Tamils -39.5%, followed by 36.9% Sri Lankan Moors and 23.2% Sinhalese. In contrast, in the Central province, 65.35% are Sinhalese, 19.92% Indian Tamils and 9.2 % Sri Lankan Moors. [11]The poverty headcount index of 11.3% in Batticaloa-one of the poorest districts (7.3% in the eastern province) and 5.5% in Kandy (5.4% in the central province) reveals the difference in economic status between residents of the two provinces.[12] The lower socioeconomic state and limited availability of electricity in rural areas in the Eastern Province probably necessitate the use of traditional kerosene lamps as the sole means of lighting.[3]

Of note is the burn prevention campaign pioneered by Dr Wijaya Godakumbura that established the safe bottle lamp foundation in Sri Lanka. This expanded world-wide and focused mainly on replacing unsafe kerosene bottle lamps to the safer and inexpensive version designed by him —called this Sudeepa (su -good, Deepa-light). This is an example of aetiology-based approach in the prevention of injuries, highlighting the importance of nationwide epidemiological studies.

Chemical burns(n=1,2.1%) were rare in our study population. Males were among two-thirds of the electrical burn victims and they all occurred at the workplace, suggesting the need for better protection for such workers.[2],[8],[9],[10]

When the circumstance of injury is considered, our study revealed a low incidence of suicidal or deliberate self-harm related burns (6.5% n=3) compared to an alarmingly high rate of suicidal burns (41% [4] and 25% [8]) observed in studies conducted in the Eastern province.[4],[8] This may again be attributed to the socioeconomic status, the general level of trauma experienced during the wartime (Eelam war in Northern and Eastern Provinces of Sri Lanka from1983-2009) and poor coping strategies.

Scalds or the burns related to hot liquids were the only type of injury that was observed among children less than 10 years. Sixty percent of injured children were males. As a group, they constituted only 10.8% of all burns, which is different to results revealed in other previous international studies. Studies conducted by Al-Shaqsi et al 2016 and Li et al 2017 showed that preschool children (under 6 years old-majority males) were at the highest risk of burns (67% and 34.7% respectively).

Primarily these children have also sustained scalds. Their unawareness of the danger, curiosity and easy susceptibility of their skin for burns may be regarded as the factors that contributed.[9,10] Our results have to be taken in the context

that there are reduced numbers of admissions of paediatric patients to TH Kandy. These patients are directed to the Srimavo Bandaranaike Children's' Hospital, located within the province.

In contrast to previous international studies, where a majority of the admissions were due to burns involving less than 20% total body surface area(BSA) [8,9,10], 50% of the victims of our study had suffered over 20 % BSA burns resulting in 57.5% of major burns among adults (BSA >20% and/or involvement of special areas i.e. face, eyes, perineum, joints and hands or presence of inhalational injury) and 80% of the major burns in children <10 years. (BSA>10% and/or involvement of special areas or presence of inhalational injury). More than 58% of the victims suffered full-thickness burns (30 or more), while 7 victims (25% of major burn victims, p<0.05) required ICU care. Additionally, around 80% of the victims required in-hospital treatment(p=0.0001).

This finding may be a reflection of the nature of admission to our hospital in that 52.2% are transferred from satellite hospitals, thus clustering more severely injured patients in this second largest tertiary care facility in Sri Lanka, implying a need for a specialized burn unit to the hospital, for better patient care. However, this need would have properly identified if the outcome of these patients, in terms of mortality, rate of infection and morbidity were studied as well.

Concerning the initial management of major burn victims, striking deficiencies were noted in some areas. Namely, not providing any type of first aid at the site of injury (64.3%, p =0.13)( especially in the form of burn surface cooling, that plays a significant role in reducing pain, depth of injury, oedema formation, infection and morbidity),[5]not covering the burn area for pain relief (to prevent the airplay on the wound) until proper wound scrubbing and dressing is done at the theatre(100%), non-adherence to standard fluid resuscitation regimes (occupying non-standard regimes without using Parkland formula for fluid calculation (42.3% p =0.059) using only 0.9% saline for fluid resuscitation (25%), and ignorance on prevention of hypothermia, in management of a significant proportion of patients (92.8%, p=0.0001).

Reasons for these shortcomings and the non-uniformity of care may be attributed to lack of awareness, lack of knowledge or failure to recognize the importance of these aspects of management by the public in the case of first aid and medical teams at peripheral hospitals. This re-emphasizes the importance of establishing a specialized unit and a dedicated team for better management of burn victims as well as the importance of training and teaching all grades of medical personnel.

Our sample size was small (46) as we limited our study to six months, feasible to the study group given their necessity to move from one hospital to another after a specified period by the Department of Health. One other limitation of the study includes analysing only the management steps during the first 24 hours of the admission due to the same reason of time constraints. It would have been more informative and would have provided a better justification for the need of a specialized unit for burn care to the facility if the subjects' outcome was studied in terms of morbidity and mortality related to the injury.

#### Conclusion

The predominant proportion of patients admitted to Teaching Hospital Kandy are adult females who suffered major accidental flame burns, many of which are preventable. Awareness programmes need to be planned and implemented to improve knowledge on the prevention, first aid and initial management of burns for general public and health care workers serving in peripheral hospitals. These patients may benefit from a specialized burns unit, but further studies should be conducted to analyse the outcome of these patients to justify the requirement of a specialized unit at Teaching Hospital Kandy.

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## SCIENTIFIC ARTICLE

## Burden of functional gastrointestinal disorders in a surgical clinic in Sri Lanka

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**Keywords:** Follow up; functional gastrointestinal disorders; Rome III; symptoms

#### **Abstract**

#### Introduction

Making a positive diagnosis of functional gastrointestinal disorders based on the patterns of symptoms allows the clinician to manage the patients without further investigations (treat and test strategy) to exclude an organic disorder (test and treat strategy).

The objectives were to diagnose and classify the functional gastrointestinal disorders according to Rome III criteria among the patients attending to a Gastrointestinal surgery clinic and to assess the effectiveness of the treat and test strategy.

#### Methodology

In a prospective study data were collected from consecutive patients who were likely to have functional gastrointestinal disorders. Diagnosis and classification were performed by an interviewer administered Rome III questionnaire. They were then treated according to their symptoms and considered for further investigations or only follow up depending on the response.

#### Results

There were 103 patients with "likely FGID" among 665 clinic patients (15.4%) over six-month period. Eighty-two patients fulfilled the Rome III criteria (79.6 %). Forty-nine patients had single FGID (59.7%) whereas 33(40.2%) patients had overlap symptoms. Eighty-one patients (78.6 %) have been followed up for a mean duration of 12.3 months. Sixty-five patients (80.2 %) underwent investigations whereas sixteen patients had only followed up (19.8 %). Three patients (3.7 %) were diagnosed with organic illness during the follow up.

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#### Conclusion

Functional gastrointestinal disorders are common among our patients. Making a positive diagnosis initially can avoid unnecessary investigations. Close follow up is necessary to avoid false negatives if empirical treatment (algorithmic approach) is used in the initial management.

#### Introduction

Functional gastrointestinal disorders (FGID) are a group of chronic disorders of the gastrointestinal (GI) tract arising from multiple factors including gut mucosa and microflora, enteric nervous system and signalling within the brain and spinal cord. They are grouped under the "functional" disorders since there is no demonstrable pathophysiological or biochemical abnormality despite having various symptoms. In the absence of any physical signs and biomarkers, diagnosis and classification of FGID are based on the study of symptom patterns and few basic investigations where relevant and available. For this purpose, Rome classification is very useful since it is a standardized and internationally recognized symptom-based classification. Further, Rome criteria enable the clinician to make a specific diagnosis rather than labelling the patient as having a functional disorder of the GI tract.

This will also provide the clinician with an opportunity to inform the patient of our current understanding of FGID and tailor the available therapeutic options according to the patients' requirements. Most of the studies published in literature address specific FGID such as Irritable Bowel Syndrome (IBS) or Functional dyspepsia (FD) [1]. Other types of FGID have not been investigated as often. Only a few studies surveyed and classified multiple FGID [1].

These studies are either population based or limited to a specific group of population [1]. Use of Rome criteria in a clinical setting not only can make the diagnostic process more efficient but also reduce the unnecessary diagnostic procedures and related costs. This is especially true in a third world country like us where health resources are scarce. The usefulness of symptom-based criteria to make a positive diagnosis of specific FGID s in clinical practice has been studied. Majority of them have focused on detecting IBS among the patients with lower GI symptoms or diagnosing

functional dyspepsia among the patients with upper GI symptoms [2, 3]. There are several studies on the spectrum of the FGID diagnosed by Rome criteria in tertiary care centres [4].

#### **Objectives**

This study aimed to establish a positive clinical diagnosis and analyse the spectra of functional gastrointestinal disorders (FGID) in a Gastrointestinal surgery outpatient clinic using Rome III criteria and to assess the effectiveness of the treat and test strategy in reducing the number of patients undergoing investigations.

Patients who visited the outpatient clinic of the Gastrointestinal surgery clinic (a tertiary referral centre) were investigated. Ethical clearance for this study was obtained from the ethical committee of the Hospital. Written consent was obtained from the patients after explaining the nature of the study. A detailed history taking, and thorough clinical examination was performed and those with "likely FGID" were recruited. Patients who had alarm signs or diagnosed with the organic disease were excluded. The Rome III Diagnostic questionnaire for adult functional GI disorders was used among patients with "likely FGID" as an interviewer administered questionnaire by two investigators who were familiar with it. The questionnaire was translated into one of the two native languages by the interviewer and the answers were recorded in the printed form. It was tested in 10 patients prior to the study to assess the clarity, understandability and the appropriateness of the translation. Those in whom the diagnosis of FGID was made were reassured and treated according to their symptoms. They were then reassessed after two to four weeks. Patients who did not respond to the treatment were considered for further investigations if deemed necessary. Responders were followed at regular intervals up to one year.

Since the oesophageal PH monitoring and manometry were not freely available in our institution, the differentiation between the Gastroesophageal reflux disease (GERD) and functional heartburn was based on the response to proton pump inhibitors (PPI).

#### Statistical analysis

Continuous variables were presented as mean  $\pm$  standard deviation, and categorical data were presented as numbers and percentages.

#### Results

#### **Demography**

Total of 665 patients was seen in our clinic for over 6 months. After excluding patients with the organic disorder and alarm features, 103 (15.4 %) patients were recruited for the study.

Demographic criteria of these patients are seen in table 1.

Presenting symptoms and the duration of symptoms of the study group are shown in table -2. Eighty-two patients fulfilled Rome III criteria (79.6 %). Prevalence of deferent FGIDs is listed in table 3. Forty-nine patients had single FGID (59.7%) whereas 33(40.2%) patients had overlap symptoms (table -4). The two most commonly overlapping symptoms were Functional bloating and Unspecified functional bowel disorder (FBD) (n=6; 7.3%).

#### Follow up

Follow up data of 81 patients (78.6 %) were available for the analysis. Mean follow up duration was 12.3 months ( $\pm$  6.4)). Sixty-five patients (80.2 %) underwent Endoscopic procedure at some stage whereas sixteen patients had only followed up (19.8 %).

#### Endoscopy

Out of the 65 patients who underwent Endoscopy, 25(30.9%) had already undergone an Endoscopic procedure (Upper GI or Lower GI) at the time of presentation and further 40(49.3%) patients underwent Endoscopy during the course (Table -6). Forty-seven patients who underwent upper gastrointestinal (GI) Endoscopy one patient (2.1 %) had erosive esophagitis and 10 patients (21 %) had a hiatal hernia. Twenty-four patients (29.6%) have undergone lower GI endoscopy and there were Colorectal (n=1;4.1%) cancer, Chron's disease (n=1;4.1%) and Diverticula (n=1;4.1%) among them.

#### **Imaging**

Besides 42 patients underwent imaging (Ultrasound Scan 41, and Computerized Tomography (CT) scan (n=01) of the abdomen. There were four patients with Gall stones and one patient with 'Fatty Liver' among them.

#### Other assessment

All five patients with the sensation of a lump in the throat have been referred by the ENT surgeons since they found no abnormality. Six patients with heartburn or epigastric pain were assessed by the Cardiologist to exclude ischaemic heart disease though none of them had abnormal findings. No abnormality was found among the 3 female patients who presented with abdominal pain (other sites) and were assessed by the Gynaecologist. Out of the two patients seen by the Psychiatrist, one patient was diagnosed with Depression.

#### Organic illnesses

During follow up (Table -5) two patients were diagnosed with organic illnesses. Both presented with a history of epigastric pain of 03 months duration. However, they later underwent lower GI endoscopy since there was a history of

Table 1. Demographic criteria of the study population

Age	Mean	SD
	45.2	13.2
Gender	Male – 47	FM - 56
	(45.6%)	(54.3%)
	FM:M	1.1:1
Total	103	

**Table 2.** Presenting symptoms and duration

Symptom	Number of patients	Mean duration (SD)
Abdominal pain (other sites)	38	37.9 (62.4)
Epigastric pain	22	49.5 (64.9)
Abdominal distension	21	19.5 (26.4)
Change of bowel habits	09	43.9 (56.2)
Lump in the throat	05	9.8 (7.6)
Belching	04	79.2 (64.1)
Heart burn	03	6.6 (7.6)
Nausea	01	03

**Table 3.** Prevalence of functional gastrointestinal disorders

Diagnosis	Total	%
Functional bloating	40	48.7
Unspecified Excessive Belching	20	24.3
Unspecified FBD <sup>a</sup>	34	39.6
IBS- C	1	1.2
IBS- D	1	1.2
IBS- M	1	1.2
IBS- O	1	1.2
Functional Diarrhoea	1	1.2
Functional Heart Burn	7	8.4
Functional Globus	5	6
FAPS <sup>b</sup>	3	3.6
Functional Chest pain	1	1.2
Functional Dysphagia	1	1.2
EPS <sup>c</sup>	1	1.2
Idiopathic Nausea	4	4.8
Functional vomiting	1	1.2
Cyclical Vomiting	1	1.2
PPDSd	5	6
Functional Rumination	1	1.2

a- Functional bowel disorder; b- Functional abdominal pain syndrome;

Table 4. Overlap symptoms

Number of symptoms in a cluster	Number of clusters	Number of patients (%)
2	12	21(25.6%)
3	7	11(13.4%)
4	1	1 (1.2%)

Table 5. Follow up of patients

Results	Number	%
Cured with treatment	14	17.2 %
Initially responded but experienced recurrent of symptoms	47	58 %
Experienced different symptoms	03	3.7 %
No response to treatment	14	17.2 %
Diagnosed with organic illness	03	3.7 %

change of bowel habits on systemic review. One of them (a 48-year-old male) was diagnosed with carcinoma of the sigmoid colon while the other patient (a 32-year-old female) was diagnosed with Crohn's disease.

Other findings such as Gall stones, 'Fatty Liver", Hiatal hernia and diverticular were regarded as incidental findings since they do not bare clinical relevance to the patients' symptoms.

#### Discussion

#### **Demography**

The age and sex distribution of our study group showed a similar trend when compared with other studies [5, 6]. Mean age of our study group was also comparable (45 to 38 years) to the other similar studies [4, 6. 7]. However, differences were observed in the prevalence and the spectrum of the FGID in our patients. Population based studies on the entire spectrum of the FGID reveal that the prevalence of FGID varies, ranging from 61% to 36% among the general population [4].

Other population-based studies have reported a lower incidence of FGID (26.2 %) than this [8] suggesting a wide variation of FGID among deferent populations. Still fewer studies have been conducted in a tertiary care setting. One such study examined the prevalence of FGID among the patients attending the primary clinics and tertiary care hospitals in Korea [9] and FGID was diagnosed in 49.7% patients. In this study, functional dyspepsia (46.0%) and irritable bowel syndrome (40.2%) were the commonest FGIDs. A similar study examined the prevalence of FGID among patients referred to a Gastroenterology clinic in the UK and found 34.9% of patients as having an FGID [10]. However, this study is retrospective in nature and being criticized for not using specific diagnostic criteria such as Rome criteria.

c- Epigastric pain syndrome; d- Postprandial distress

Several other studies have reported FGID in more than 40% of all new referrals to general gastroenterological outpatient clinics [11, 12]. Our study was conducted in a Gastrointestinal surgery clinic of a tertiary care hospital and the prevalence of FGID was 12.3% among them. Low incidence among our patients could have been due to multiple factors including a lower incidence of FGID in our population, small number of cases in this study or because our study is from a GI surgical clinic. Besides, since the diagnosis of FGID also depends on other factors including clinical suspicion [13] we may have underdiagnosed them in our patients.

#### **Spectrum**

Though IBS and FD are the two most frequently studied FGIDs and presumed to be the commonest in the general population, published data investigating the entire spectrum of the FGIDs suggests that deferent groups of the population may have deferent leading FGIDs. In a study carried out among military personal in Korea, Nausea and vomiting disorders (6.93%) and functional abdominal bloating (6.39%) were the two leading FGIDs9. Population based study analysing the spectrum of the FGID among Taiwanese population [5] revealed that the Unspecified FBD was the most prevalent (8.9%) followed by FD (5.3%). In Australia, Functional Heartburn (10.4%), IBS (8.9%) and functional incontinence (7.6%) were the commonest symptoms in a population-based study [6]. Similarly, the most prevalent FGID among tertiary referrals in South China were FD (54.6%), IBS (40.7%) and unspecified functional bowel disorder (13.9%)4. The two commonest FGIDs in our patients were Functional bloating (48.7%) and Unspecified FBD (39.6%). Therefore, it appears as if there is a wide variation in the spectrum of the FGID among the deferent population. Unlike the population-based studies, those conducted in referral centres record higher percentages probably due to the small number of patients.

#### Symptom overlap

Symptom overlap seems to be a common phenomenon across most of the published studies. Chinese study4 reported overlapping symptoms among (50.3%) of patients. In this study, functional bloating had no overlap. In comparison, 40.2% of our patients reported symptom overlap and Functional bloating was the commonest overlapping FGID. In the same study, 37.4% had two coexisting FGID, 8.9% had three coexisting FGID and 4.0% had more than three coexisting FGID. In our study 25.6% had two, 13.4% had three and 1.2% had four overlapping FGID.

#### **Economic aspect**

The economic impact of FGID could be considerable given the high prevalence of the condition. This will create increased budgetary constraints, especially within the healthcare system in a developing country like us. Unfortunately, no such cost analysis has been done on the entire spectrum of the FGID according to our knowledge. Most of the cost analysis has been done on IBS and FD. A Danish study compared the diagnosis of IBS by exclusion with a positive clinical diagnosis using Rome criteria in a primary care setting. The total cost of diagnosing IBS with the minimum number of investigations was \$913.59 compared to \$50.11 for clinical diagnosis supported few diagnostic investigations such as full blood count and inflammatory markers [14]. This study concluded that diagnosing IBS adhering to clinical findings with a normal full blood count and inflammatory markers in the absence of alarm features could significantly reduce the cost without significant detriment to the patient. Several other studies also have confirmed the non-inferiority of the positive diagnostic approach in IBS [15]. The study conducted among patients with dyspepsia in Brazil concluded that diagnosis by exclusion may not be suitable for developing countries with scarce resources. They also concluded that empirical treatment for patients without alarm signs especially those who are below the cancer age group may be the best approach for managing undiagnosed dyspepsia [16]. In this study, FD was diagnosed using Rome III criteria [17].

In our study, having studied the entire spectrum of the FGID we were able to manage almost one fifth (19.8%) of the patient without investigations using a treat and test strategy. This is a considerable saving to a health care system in a developing country like us. However, like in Korean study [10] 24 hours, oesophageal pH monitoring was not routinely performed to diagnose functional heartburn in this study.

#### Organic diseases and alarm symptoms

It is well known that organic disease can co-exist with FGID [18]. In contrast to diagnosis by exclusion, diagnosis of FIGD based on symptoms needs alarm symptoms to exclude patients with possible organic illnesses. Several studies have addressed the validity of alarm symptoms in excluding organic disease among patients with symptoms of FGID. The focus of these studies has mainly been either IBS, dyspepsia or both [2, 19, 20]. Though most of them have shown that the alarm futures are useful in excluding the organic causes [21, 22] contradictory results also could be found in the literature [23]. Very few studies have reported organic diseases in a study like this. A study from Australia reported six patients with organic disease in a similar algorithm-based study among 110 (5.4%) patients. Among them were two patients with malignancy. Others were diagnosed with inflammatory bowel disease (n=2) and one patient each with pancreatic insufficiency, reflux esophagitis and dietary iron deficiency [7]. Among the 103 patients in our study group, 03 patients were found to have organic causes (3.7%). Two patients who were diagnosed with colon cancer and ulcerative colitis. Both presented with epigastric pain which could have been investigated with Gastroscopy. In both instances, colonoscopy was undertaken since they reported a change of bowel habits at the subsequent visits. This highlights the importance of following up patients if empirical treatment (algorithmic approach) is used in the initial management of FGID especially in tertiary care hospitals.

#### Symptom evolution

At the end of the follow-up period, 17.2% of patients did not have symptoms and 58% of patients experienced recurrent symptoms. Long term studies on FGID reveal that the persistent symptoms may either change or fluctuate in severity and the patients rarely become symptom-free [18, 24]. A study among children found complete improvement in 60.1%, no improvement in 10.1% and recurrence in 35.7% of the patients whereas 11.6 5% of patients reported new symptoms [25]. In our study, 3.7% of the patients reported deferent symptoms during the follow up. In a prospective cohort study conducted in the USA, approximately 20% had the same symptoms, 40% had no symptoms, and 40% had different symptoms after 12-year follow-up [18]. It is difficult to ascertain whether wide variation in symptom free and symptom recurrence among the deferent population is due to the disease characteristics or due to variation in treatment approach among these studies.

#### Conclusion

There is a variable but significant number of patients with Functional gastrointestinal disorders among deferent referral centres. Making a positive diagnosis using Rome III criteria can avoid unnecessary investigations and reduce the usage of health care resources. The predominant type of the FGID and overlap may vary among deferent patient populations. Given the low reliability of alarm symptoms in excluding organic diseases, close follow up is necessary to avoid false negatives if empirical treatment (algorithmic approach) is used in the initial management of FGID.

All authors disclose no conflict of interest. The study was conducted in accordance with the ethical standards of the relevant institutional or national ethics committee and the Helsinki Declaration of 1975, as revised in 2000.

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## SCIENTIFIC ARTICLE

### Knowledge and practices regarding standard precautions among supportive staff in the National Hospital of Sri Lanka

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Keywords: Standard precautions; hospital acquired infections; health care workers; knowledge; practices

#### Abstract

#### Introduction

Adherence to standard precautions significantly reduces the transmission of hospital-acquired infections. We intended to assess the knowledge and practices regarding standard precautions among supportive staff members in the National Hospital of Sri Lanka (NHSL).

#### Methods

A descriptive cross-sectional study was conducted among supportive staff members at NHSL. They were selected using stratified one-stage cluster sampling and their knowledge and practices regarding standard precautions were assessed using an interviewer-administrated questionnaire.

#### Results

Of 108 participants, 69 (63.9%) were aged 20-40 years. Onehundred and five (97.2%) were educated up to Ordinary Level and 48 (44.4%) had working experience of more than six years. Twenty-six had at least one needle-stick injury during their career. Six (5.6%) have not been vaccinated for Hepatitis B since their recruitment. Mean knowledge and practice scores were 66.3±12.5% and 70.0±7.7% respectively. There were no differences in knowledge scores based on the level of education (t=1.19, p=0.24) and the total years of service (t=-0.44, p=0.66). Similarly, there were no differences in practising proper precautions based on their educational level (t=0.25, p=0.80) or the duration of service (t=0.87, p=0.39). However, the knowledge score positively correlated with the good practice score (r=0.197, p=0.04).

#### **Conclusions**

The supportive staff members with good knowledge were more adherent to the correct practice. Neither the level of education nor the experience was associated with their knowledge or good practices. Provided the potential risk of

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transmission of blood-borne infections, Hepatitis B vaccination and post-vaccination antibody testing could be made mandatory before starting their carrier.

#### Introduction

Hospital Acquired Infections (HAI), a.k.a. Healthcare Associated Infections are a major public health burden and it is estimated to account for the annual expenditure of \$ 6.5 billion in the USA [1] while contributing to significant morbidity and mortality [2, 3]. One of the most cost-effective strategies to prevent HAIs is adhering to a set of guidelines referred to as standard precautions which minimize the spread of infective organisms from one person to another [4].

The World Health Organization defines the standard precautions as infection control safety measures to minimize the transmission of infectious microorganisms from known and unknown sources [5]. Studies have shown that the adherence to these guidelines by the health care workers is not optimum [6, 7], thus increasing the transmission of diseases at health care settings, both to the patients and the healthcare workers [8]. The supportive healthcare staff a.k.a. hospital attendants play a major role in transporting blood and body fluids, maintaining the hygiene of patients and ensuring the cleanliness of the ward. Nonetheless, the role of the supportive healthcare staff in adhering to standard precautions are explored sparsely in the literature, especially in the developing countries like Sri Lanka where patient load per health care worker is comparatively high [9]. Therefore, the objective of this study was to assess knowledge, practices and associated factors for the adherence to the standard precautions among supportive staff in the National Hospital of Sri Lanka (NHSL).

#### Methods

A descriptive cross-sectional study was conducted among the supportive healthcare workers (attendants) of the NHSL from February to May 2019. Those who have at least six months of work experience in the patient handling units of the hospital were recruited for the study. A stratified one-stage cluster sampling method was used to obtain a representative sample from the entire hospital. The supportive staff of the NHSL is categorized into 13 sections for administrative purposes. Usually, more than 100 support staff members are working

under each section. Of them, two sections (kitchen and officers' sections) are not involved in patient handling, thus were excluded from the study. Of the remaining 11 strata, 27 clusters were randomly identified based on the wards/units where they work, and the final sample size was 108. The details of sampling and the sizes of clusters in each stratum are summarized in the Electronic Supplementary Material 1.

An interviewer-administered questionnaire was used for the data collection. The questionnaire was designed to collect sociodemographic data, knowledge and practices on standard precautions on day-to-day patient care. The knowledge was assessed using true/false and single-best-response type questions and was weighted according to the importance of the precaution or the technique predetermined by experts. The practices were measured on 10-point Likert scales.

Cumulative scores were subsequently computed for both knowledge and practices, and the total scores thus computed were 100 marks each for knowledge and practice. Betweengroup comparisons of continuous data were conducted using t-tests while associations between two continuous variables were explored using Pearson's correlation coefficient test. All the statistical analyses were conducted using Statistical Package for Social Sciences (SPSS) version 26 and GraphPad Prism version 8.4.2 at a significance level of 0.05. The study protocol was approved by the Ethics Review Committees of the Faculty of Medicine, University of Colombo (CSRP/19/018) and the National Hospital of Sri Lanka (ETH/COM/2018/13).

#### Results

Of 108 eligible supportive staff members invited for the study, the positive response rate was 100%. The sociodemographic characteristics of the study sample are summarized in Figure 1.

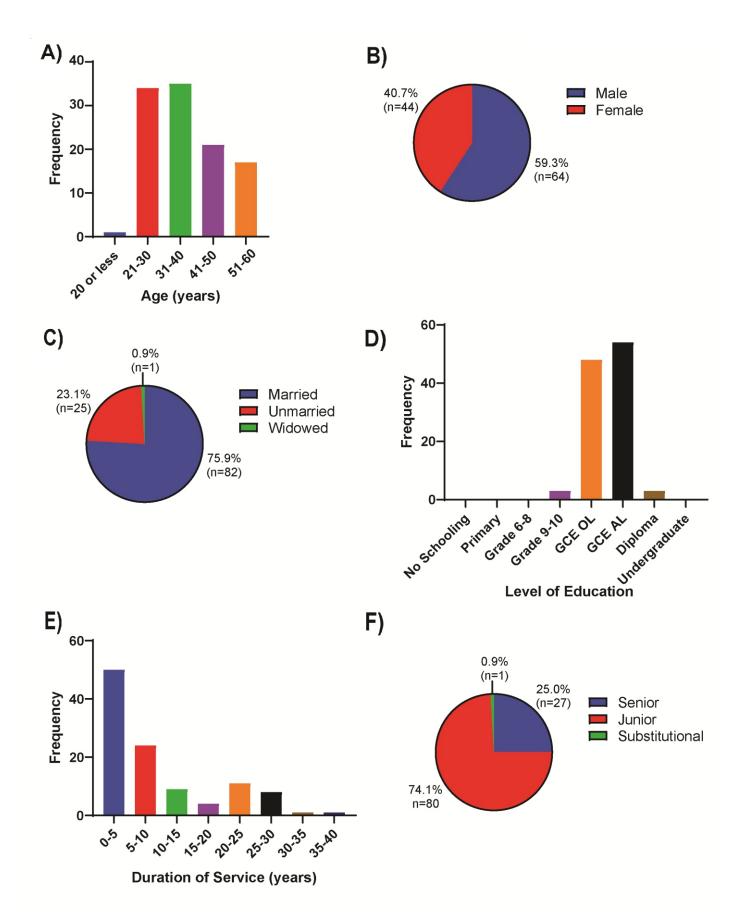
Out of seven questions regarding basic knowledge on standard precautions, most of the participants (88.9%, n=96) answered correctly to the question regarding the importance of handwashing after touching blood or body fluid, even if gloves were worn. Only 35.2% (n=38) answered correctly to the question that all patients should be considered as infected with Human Immunodeficiency Virus (HIV) unless proven otherwise, which had the worst proportion of correct responses among the questions. Fifty-seven participants (52.8%) correctly stated that the base of the thumb was the most vulnerable site of germ accumulation in hand. The necessity of handwashing before touching the patients, when touching one patient after touching another, before handling invasive devices and when changing the procedures of the same patient if there is contamination with body fluids, was known by 97 (89.8%), 104 (96.3%), 85 (78.7%) and 67

(62.0%) participants respectively. Majority of participants (64.8%, n=70) did not know that they must wash their eyes for at least 15 minutes in case of an eye splash with body fluids. However, the colour code of disposal of contaminated material was correctly answered by the majority (96.3%, n=104).

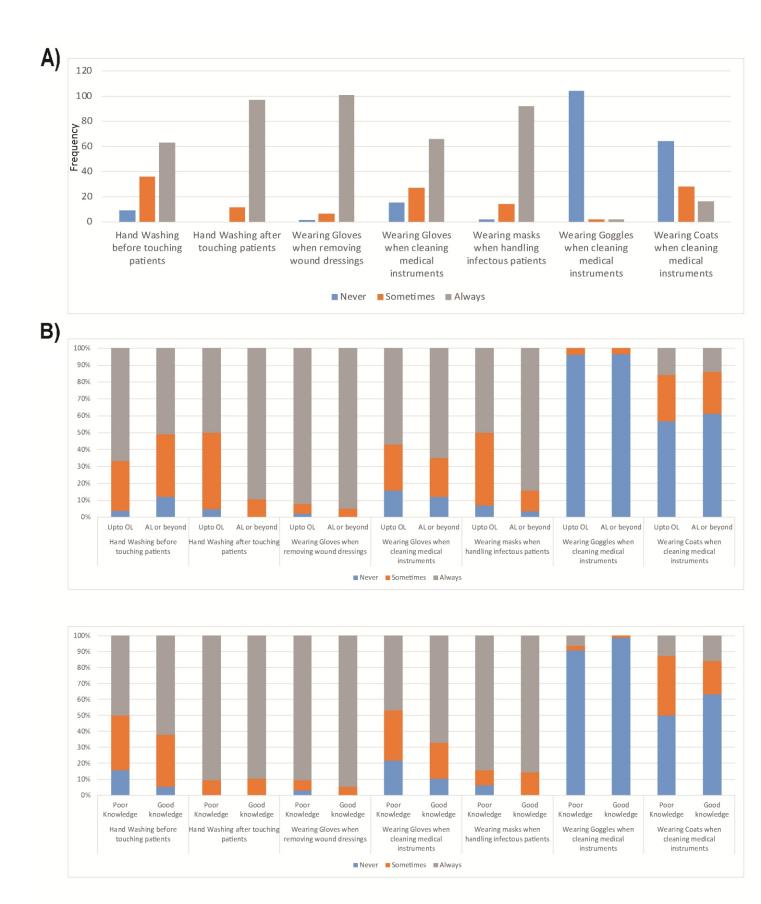
Distribution of practices regarding standard precautions on different health care practices of the supportive staff is shown in Figure 2. Interestingly, only 58.3% (n=63) of the staff members routinely practised washing hands before touching patients. Most of the participants washed their hands only for 10 to 20 seconds (31.5%, n=34) while only nine (8.3%) spent more than forty seconds for hand washing. Most of them (n=93, 86.1%) preferred soap and water when washing hands. Sixty-three participants (61.7%) declared that they routinely recapped the contaminated needles and 26 participants (24.1%) had experienced needlestick injuries in their carrier. Of those who had needle stick injuries, twenty (76.9%) had sought further medical management after the incident while three participants (11.5%) had ignored the incident. Six (5.6%) participants had never received the hepatitis B vaccination since recruitment. Only 98 participants (90.7%) had received a formal learning session on standard precautions during their carrier. Mean knowledge and practice scores were  $66.3\pm12.5\%$  and  $70.0\pm7.7\%$ respectively. There were no significant differences in knowledge scores based on the level of education (i.e. below and above advanced level) (t=1.19, p=0.24) and the total years of service (i.e. below and above six years) (t=0.44, p=0.66). Similarly, there were no difference in practising proper precautions based on their educational level (t=0.25, p=0.80) or the duration of service (t=0.87, p=0.39). However, the knowledge score positively correlated with the good practice score (r=0.197, p=0.04).

#### Discussion

In our study, we identified several knowledge gaps among the supportive healthcare staff members. Over 10% of the study sample was unaware of the fact that handwashing needs to be practised before and after touching a patient, while more than one-third of the sample was ignorant of the importance of handwashing in between procedures conducted on the same patient, particularly if there is contamination with the body fluids of the patient. Regardless of the knowledge of proper handwashing practices, the proportion of those who practised handwashing before touching a patient was 58%. Intriguingly, this figure highlights the importance of implementing regulations and conducting routine audits to ensure the adherence to the standard precautions, since only providing with knowledge might not be adequate to motivate the healthcare workers to practice them like in the previous reports [6].



**Figure 1.** Sociodemographic characteristics of the study sample | A. Distribution of the age B. Distribution of the sex C. Distribution of the marital status D. Distribution of the highest completed educational level E. Distribution of the total duration of service as a supportive healthcare worker F. Distribution of the designation. Abbreviations: GCE - General Certificate of Education; O/L - Ordinary Level; A/L - Advanced Level



**Figure 2.** Distribution of practices regarding standard precautions of different health care practices of supportive staff | A. A composite bar chart shows the standard precautions practiced by the participants. Since questions on practices are answered on 10-point Likert scale, the three categories are determined as follows: 1 = never, 2-9 = sometimes, 10 = always B. Percentage component bar charts illustrate the practices according to the highest completed level of education (top) and the level of knowledge (bottom). The level of knowledge is categorized into two groups; poor knowledge and good knowledge; by splitting the knowledge score about the median. Abbreviations: GCE - General Certificate of Education; O/L - Ordinary Level; A/L - Advanced Level

Body fluid splashes on eyes not only cause blindness but also act as a source for the transmission of infections [10, 11]. According to a prospective national study conducted in France, healthcare workers were frequently affected by eye splashes with blood or body fluids, of which 39% cases were preventable if proper standard precautions were followed [12]. The most effective first aid measures to be taken irrespective of the splash is to wash eyes with running water for at least 15 minutes [13]. Nonetheless, this correct first aid measures for eye splashes with body fluids was not known by approximately two-thirds of the supportive healthcare workers, whose knowledge was comparatively poor than the first-year medical students [14] in a Sri Lankan Medical Faculty.

Even though venepuncture is routinely conducted by the nurses, the supportive healthcare workers are also exposed to contaminated syringes and needles in routine ward and theatre work. Regrettably, recapping of the used needles was practised by 61.7% of the study sample, which is higher than the reported proportions of recapping practised by the nurses in several previous studies [15, 16].

Inadequacy of the knowledge that all the patients should be considered as infected with HIV unless proven otherwise may be one of the reasons for practising routine recapping of the used needles and the inadequate use of gloves by the supportive healthcare workers, which the authors have observed in the state sector hospitals. Moreover, poor knowledge may have contributed to ignoring needle stick injuries by some of the staff members. This needs the urgent attention of the medical administrators and strategies such as periodic awareness programmes and post-exposure prophylaxis protocols need to be implemented. The importance of such periodic training programmes is further highlighted by the fact that approximately 10% of our study sample being never taught regarding standard precautions during their career and six participants had not being vaccinated for Hepatitis B since recruitment.

We found that those who had good knowledge scores adhered to the standard precautions well, however, their education level or the experience did not significantly associate with good practice. Similar to our study, the education level had no association with the adherence to the standard precautions among radiographers in a tertiary care hospital of Sri Lanka [17]. However, a Sri Lankan study conducted among the nursing staff at the same setting concluded that the junior nurses were more compliant on the standard precautions than the senior nursing staff, probably since the former have updated their knowledge recently [18].

Hence, we recommend organizing awareness programmes targeting supportive staff, both new recruits and experienced staff members, which might be helpful in reducing hospital-acquired infections in the long run.

#### Limitations

In this study, we assessed the practices by questioning the individuals rather than directly observing. Furthermore, since we used interviewer-administered questionnaires, the responses towards practices might have been biased since participants may not have disclosed their bad practices to the interviewers. The sample size of 108 was employed based on the availability of logistics for the study rather than using an objective calculation.

#### **Conclusions**

There were several gaps regarding the indications for handwashing, first aid measures in case of an eye splash and recapping of the contaminated needles among the supportive healthcare workers in our study sample. The supportive staff members with a good knowledge of standard precautions were more adherent to the correct practice. Neither the level of education nor the experience associated with their knowledge or good practices. Moreover, provided the potential risk of transmission of blood-borne infections, Hepatitis B vaccination and post-vaccination antibody testing could be made mandatory before starting their carrier.

# Acknowledgement

This research was carried out as a requirement of the Community Stream undergraduate academic programme of the Faculty of Medicine, University of Colombo, Sri Lanka.

All authors disclose no conflict of interest. The study was conducted in accordance with the ethical standards of the relevant institutional or national ethics committee and the Helsinki Declaration of 1975, as revised in 2000.

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# SCIENTIFIC ARTICLE

# Prevalence and severity of non-alcoholic fatty liver disease in patients with gall stone disease

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**Keywords:** Non-alcoholic steatohepatitis; NASH; NAFLD; hepatic steatosis; fatty liver; metabolic syndrome

#### Abstract

#### Introduction

Metabolic syndrome independently has a significant alliance with both non-alcoholic fatty liver disease (NAFLD) and gall stone disease (GSD). NAFLD can present variably in different individuals from simple steatosis to non-alcoholic steatohepatitis (NASH). For establishing a valid prognosis, it is essential to differentiate appropriately between the presence and absence of NASH. Hence, the present study aimed to assess the prevalence and severity of NAFLD in GSD by using Fibroscan with Controlled Attenuation Parameter (CAP).

#### Methods

A hundred patients of GSD who were being evaluated for cholecystectomy and were negative for HBV and HCV infection, with no history of alcohol intake or documented liver cirrhosis were evaluated prospectively. Diagnosis and severity of NAFLD were assessed by CAP. Necroinflammation was assessed by levels of transaminases; hepatic fibrosis and cirrhosis were measured on Fibroscan.

#### Results

Of 100 patients, NAFLD prevalence was 77% on CAP. On fibro scan, 17 had mild fibrosis, 8 had significant fibrosis and 1 had evidence of cirrhosis. Significant necro-inflammation was present in 16 patients. Body mass index > 25kg/m2 and central abdominal obesity was a strong predictor of steatosis in GSD with NAFLD (p 0.041, 0.029 respectively). Central abdominal obesity and low levels of high-density lipoprotein were a strong predictor of fibrosis in NAFLD (p 0.040, 0.037 respectively).

# Conclusions

A higher prevalence of NAFLD (77%) was observed in patients with GSD which might have bearing on the surgical

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management. The observations of the study recommend that health awareness and lifestyle modifications should be advised to patients with GSD as they may be having concomitant NAFLD which may in due course of time evolve into cirrhosis if ignored

#### Introduction

Gallstone disease (GSD) is a common condition worldwide with variable prevalence based on geographical location and ethnicity. The reported overall prevalence of GSD in the general population is 3.29% to 15% (10-15% in the West, 3-15% in Asia and <5% in Africa) [1]. Prevalence of GSD in India is 4.3% and is the highest in Northern India [1]. Factors which are found responsible for gallstone formation are: female gender, obesity, hypertriglyceridemia, diabetes mellitus, insulin resistance and metabolic syndrome (MS) [2].

Non Alcoholic Fatty Liver Disease (NAFLD) has become the most common liver disease the world over and is considered as the hepatic manifestation of MS. Prevalence of NAFLD is variable among different countries and different regions, and is higher in the West [3]. Insulin resistance is one of the important attributes for hepatic steatosis. Incidence of obesity, diabetes, insulin resistance, hypertension and other metabolic risk factors is increasing among Indians. The reported prevalence of NAFLD in India varies between 9-53% in general population [4-6]. Asian-Indians are more at risk to have NAFLD because of a higher incidence of insulin resistance even at lower BMI [7]. The prevalence of NAFLD among physically active but economically deprived rural adults of Sri Lanka is 18% which also strengthens the existing evidence that Asians have a susceptibility of visceral fat accumulation [8].

NAFLD can present variably in different individuals, at times as a simple case of steatosis to even as a complex condition of non-alcoholic steatohepatitis (NASH) or cirrhosis. As NASH is the leading indication for liver transplantation at present, therefore for deciding on the modality of treatment it is essential to differentiate appropriately between the presence and absence of NASH. NAFLD is a multisystem disease where morbidity and mortality are not only attributed to hepatic involvement but also the involvement of cardiovascular and renal systems, or extrahepatic malignancy.

Fatty liver is usually diagnosed using routine scanning procedures such as ultrasonography (USG), computed tomography (CT), magnetic resonance imaging (MRI) and magnetic resonance spectroscopy (MRS). However, these investigations are limited in their ability to differentiate between the presence and absence of NASH due to their inability to detect the degree of inflammation and fibrosis [9]. The accepted gold standard for diagnosing fibrosis and severity of liver damage is a liver biopsy. However, liver biopsy is an invasive procedure and is associated with procedure-related morbidity (1-3%) and mortality (0.01%) [10]. An excellent non-invasive modality with high sensitivity for detection of hepatic fibrosis is Transient elastography (Fibroscan) which measures liver stiffness (LSM) [11]. Controlled attenuation parameter (CAP) is an attachment with Fibroscan and is a good modality for measuring hepatic steatosis [12].

NAFLD and GSD are prevalent problems worldwide and they share common risk factors like obesity, hypertriglyceridemia, type 2 diabetes mellitus, insulin resistance and presence of the metabolic syndrome. Presence of NAFLD especially with significant fibrosis may have bearing on the surgical management of patients with GSD. Hence the present study aimed to non-invasively assess the prevalence and severity of NAFLD in patients with gall stone disease.

#### Methods

A hundred patients with GSD diagnosed on ultrasound (US) abdomen who were being evaluated for cholecystectomy were assessed prospectively for the presence and severity of NAFLD. Patients of GSD with no history of alcohol intake or intake less than 20 g/day were included. Patients with other causes of hepatic steatosis and raised transaminases (presence of hepatitis B and C infection, taking steatogenic drugs, autoimmune hepatitis, Wilson's disease etc) were excluded from the study. All patients were evaluated for the presence of MS as per the adult treatment panel III (ATP III) criteria with modified waist for the Indians [13]. Patients who were also grouped into: a) Normal weight (BMI <23 kg/m2); b) Overweight (BMI 23-25 kg/m2); c) Obese (BMI >25kg/m2) as per the Indian cut-offs [13]. Patients who have known hypertensives and taking treatment or with systolic blood pressure (SBP) > 130mmHg and diastolic blood pressure (DBP) > 85 mmHg were labelled as hypertensive. After overnight fast, blood was collected for blood glucose (FBS), serum total cholesterol (TC), serum high-density lipoprotein (HDL), serum low-density lipoprotein (LDL), serum triglyceride (TG) and liver function analysis. Serum values for FBS <100mg%, TC <200mg/dl TG < 150mg/dl, HDL >40mg/dl in males and > 50mg/dl in females, LDL <130 mg/dl were considered normal. Patients having three or more than three of the following components were labelled as

having MS: 1) waist circumference: men  $\geq$ 90 cm, women  $\geq$ 80 cm; 2) serum triglycerides  $\geq$ 150 mg/dL; 3) serum HDL cholesterol: men <40 mg/dL, women <50 mg/dL; 4) blood pressure: SBP  $\geq$  130 or DBP  $\geq$  85 mm Hg or use of medication for hypertension, 5) fasting glucose:  $\geq$  100 mg/dL or use of medication for hyperglycaemia.

US abdomen was performed for screening fatty liver and fatty liver was categorized as mild, moderate or severe steatosis. The severity of hepatic steatosis was assessed with CAP and categorized into S1 (215-251 db/m), S2 (252-296 db/m), and S3 (>296 db/m). The severity of necro-inflammation was assessed using ALT levels and divided into mild necroinflammation (ALT 40-60 IU/l) and significant necroinflammation (ALT >60 IU/l). Hepatic fibrosis was assessed non-invasively in all patients with the help of transient elastography (TE; Fibroscan). TE was carried out preoperatively in the department of Hepatology following manufacturer's instructions. The patient was made to lie down in dorsal decubitus position with maximum abduction of the arm. Liver stiffness measurement (LSM) was performed through intercostal space. The successful acquisitions were performed on each patient and minimum 10 readings were taken. The success rate was calculated as the number of successful measurements made divided by the total number of measurements. The result was expressed as the median (M) and interquartile range (IQR) in kPa (in kilopascals) and ranged from 1.5 kPa to 75 kPa. The severity of LSM was categorised as mild fibrosis (LSM 5-7.9 kPa), significant fibrosis (LSM 8-12.5 kPa) and as cirrhosis with LSM >12.5 kPa[11].

#### Statistical analysis

Statistical analysis was carried out using IBM Statistical Packages for the Social Sciences (SPSS) version 22. The categorical variables were described as a proportion. Continuous variables reported in descriptive statistics. To look for the difference in the association among variables between groups was tested by parametric test (Chi-square test, Fisher's exact test, Mann-Whitney test) and non-parametric test (student t-test). Performances of CAP and liver stiffness to assess hepatic steatosis and hepatic fibrosis were determined using Received Operating Characteristics (ROC) curve analysis. All statistical tests were performed at a significance level of alpha=0.05.

# **Results**

Of 100 GSD patients, there were 76 females and 24 males with a mean age of  $44.2\pm12.7$  years. Majority of patients (n = 48) were in 3rd and 4th decade of life; 20 patients were between 21 and 30 years, 19 were between 50-60 years, 12 were between 61-70 years and only one patient was > 70 years of age.

**Table 1.** CAP, LSM and ALT in assessing severity of steatosis, fibrosis, and necro inflammation in NAFLD

CAP	S1	(mild)	28
(Steatosis)	S2	(moderate)	24
	S3	(severe)	25
LSM	Mild	(5-7.9kpa)	17
(Fibrosis)	Significant	(8-11.9kpa)	80
	Cirrhosis	( >12kpa)	01
ALT	Mild	(40-60u/l)	10
(Necro-inflammation)	Significant	(>60u/l	16

(CAP- Controlled Attenuation Parameter, LSM- Liver Stiffness Measurement, ALT-Alanine Amino Transferase)

**Table 2.** Comparison of demographic features, anthropometry and MS components in patients of GSD with NAFLD

	GSD (		
	NAFLD	NO NAFLD	
	(n= 77)	(n=23)	
AGE (years)	44 ±12.8	43.7±12.7	0.815
BMI			
Normal weight [<23kg/m2] Overweight [23-24.9kg/m2]	26±4.6	24.5±4.3	0.041
Obese [>25kg/m2]			
Waist circumference Male [> 90CM] Female [> 80CM]	96.8±10.5	91.3±10.3	0.029
SBP [>130 mm hg]	127±15.2	123±7.4	0.253
DBP [ >85mm hg ]	77.8±10	77.9±8	0.977
FBS [> 100 mg/dl]	92.3±9.1	94.7±11.3	0.303
Cholesterol [>150mg/dl]	171.2±44.1	167.2±36.7	0.692
Triglycerides [>150 mg/dl]	153.2±84	26.59±56.6	0.086
HDL Male [<40 mg/dl] Female [<50mg/dl]	44.9±8.6	46.0±9.2	0.639

(SBP- systolic blood pressure, DBP-diastolic blood pressure, FBS-fasting blood sugar, HDL- high density lipoprotein)

**Table 3.** Comparison of demographic features, anthropometry, MS components in patients of GSD with NASH

	GSD(n=		
	NASH	NO NASH	
	(n=9)	(n=91)	
AGE (years)	49.2±10.5	43.8±12.9	0.227
BMI Normal weight [<23kg/m2] Overweight [23-24.9kg/m2] Obese [>25kg/m2]	27.9±9	26±4.6	0.308
Waist circumference Male [> 90CM] Female [> 80CM]	102.5±8.7	94.9±9	0.040
SBP [>130 mm hg]	131.5±15.7	126.3±14.5	0.313
DBP [>85mm hg]	78.8±9.2	77.6±10.08	0.748
FBS [> 100 mg/dl]	95.3±8.9	77.6±10.08	0.442
Cholesterol [>150mg/dl]	184±46	168±41.9	0.282
Triglycerides [>150 mg/dl]	190±71.8	142±79	0.089
HDL Male [<40 mg/di] Female [<50mg/di]	39.4±9.6	45.7±8.4	0.037

(SBP- systolic blood pressure, DBP-diastolic blood pressure, FBS-fasting blood sugar, HDL- high density lipoprotein)

# Association of BMI, Waist Circumference and Metabolic Syndrome components with GSD

Of 76 females in this study, 46 (60.5%) were obese, 13 (17.1%) were overweight and 17 (22.4%) had BMI <23kg/m2. Of 24 males, 11 (46.9%) were obese, nine (37.5%) were overweight and four (16.7%) had BMI <23kg/m2; with no significant difference between females and males, p=0.11). Abdominal obesity was significantly more common in females [68 (89.4%)] in comparison to males [17 (70.8%)] (p=0.008).

Forty-nine out of 100 patients with GSD had evidence of MS with higher prevalence in females [42 (55.3%)] in comparison to males [7 (29.2%)] (p=0.026). Of various components of MS, increased waist circumference was present in 85% (mean 95.59±10.68 cm); hypertension in 44% (mean SBP 126±14.6 mmHg and mean DBP 77±9.9 mmHg), type 2 diabetes mellitus in 22% (mean FBS 92.04±12.7 mg%), hypertriglyceridemia in 39% (mean 147±79.3 mg%) and low HDL in 61% of patients (mean 45.2±8.7 mg%).

Of 100 patients, at least one MS component was present in all but one patient (99%). Twelve patients had the presence of 1 component, 38 patients had 2 components, 33 patients had 3 components, 13 patients had 4 components and 3 patients had all 5 components of MS.

# GSD and NAFLD

Prevalence of NAFLD was 31% on USG and it was 77% based on CAP in 100 GSD patients. On USG abdomen, 24 (77.42%) had mild steatosis, 7 (22.58%) had moderate steatosis and none of the patients had severe steatosis. On CAP, 28 had mild steatosis (S1), 24 had moderate steatosis (S2) and 25 had severe steatosis (S3). CAP is an objective assessment, subsequent analysis and correlations of hepatic steatosis with various parameters were done based on CAP assessment rather than on ultrasound [12].

Of 61 females of NAFLD; 40 (65.6%) were obese, 10 (16.4%) were overweight and 11 had BMI < 23 (18%). Of 16 male patients with NAFLD; 6 (37.5%) were obese, 8 (50%) were overweight and 2 had BMI <23 kg/m2. There was a statistically significant difference in the incidence of obesity between male and female patients with NAFLD (p 0.018). Prevalence of increased waist circumference in males was 87.5% (n=14) and in females was 91.8% (n=56) (p 0.594).

# Severity of steatosis, fibrosis and necro inflammation in NAFLD patients

Of 77 NAFLD patients, 25 had severe steatosis based on CAP; 8 patients had significant fibrosis and 1 patient had cirrhosis based on LSM (Table 1). Necro-inflammation was diagnosed based upon serum ALT levels; 10 patients had mild necro-inflammation and 16 patients had significant necro-inflammation (Table 1).

# Prevalence of metabolic syndrome components in NAFLD

Prevalence of MS in NAFLD was 54.5% (n 42). MS was present in 6 (37.5%) of 16 males and 36 (51%) of 61 females with NAFLD (p 0.124). Increased waist circumference was present in 90.9% (n 70, mean  $96.86\pm10.5$  cm); hypertension in 49.4% (n 38, mean SBP  $123\pm12.3$  mm Hg and DBP 77.9 $\pm10$  mmHg); DM in 18.2% (n 14, mean FBS  $92.3\pm9.1$  mg%), hypertriglyceridemia in 44.15% (n 34, mean  $153.2\pm84.2$  mg%) and low HDL in 63.6% (n 49, mean  $44.97\pm8.6$  mg%).

# Comparison of metabolic syndrome components in patients of GSD with or without NAFLD and with and without significant fibrosis

Comparison of demographic profile, anthropometry and metabolic syndrome components showed that BMI and waist circumference were only two factors which reached a significant level in patients of GSD who were having NAFLD when compared to patients of GSD without NAFLD (Table 2). Nine patients had evidence of significant fibrosis (LSM>8 kpa). Patients with significant fibrosis had higher waist circumference (102.5±8.7vs 94.9±9, p 0.040) and lower HDL (39.4±9.6vs45.7±8.4, p 0.037) in comparison to those without significant fibrosis (Table 3).

# Discussion

Prevalence of NAFLD has increased with the improvement of living standards and lifestyle changes in the population. Incidence of NAFLD varies among different countries affecting up to one-fourth of the population in Asian countries and reported incidence from USA and Europe varies from 25% to 46% [3,14,15]. This variation in the reported incidence of NAFLD in different countries and different regions can also be attributed to awareness to look for its presence and also that which modality has been used for detection. USG and MRS have commonly used tools for detection of NAFLD worldwide. In this study prevalence of NAFLD was 31% when USG was used for assessment; but when the same study population was assessed by CAP, 77% of patients had NAFLD.

There is limited available literature reporting the true prevalence of NAFLD in India. The reported prevalence of NAFLD from West Bengal is 9% while it is 32% from south India with a higher prevalence of 53% in north India [4-6]. In the majority of these patients, NAFLD was detected incidentally on imaging which was performed for some other ailment in a patient. These patients were asymptomatic with normal liver functions. In the present study, 77% of patients of GSD had evidence of NAFLD based upon CAP. This high prevalence of NAFLD could be attributed to the presence of MS which was present in 49% of the study population, and 99% of these had the presence of at least one MS component.

Association between GSD and NAFLD is of considerable importance as both share common risk factors like DM, hypertension, dyslipidaemia, and increased waist circumference. All of these are also the components of MS. Hence, GSD, NAFLD and MS are related to each other. There is now evidence supporting that NAFLD may be the hepatic manifestation of MS [16]. Prevalence of MS in patients with NAFLD in this study was 54.5%. Majority of patients with NAFLD were in 3rd and 4th decade of life. Incidence of hypertension was more in this study when it was compared with the reported prevalence of hypertension in NAFLD patients from India [17,18]. Incidence of DM, hypertriglyceridemia and abnormal HDL levels were similar to the earlier reported high prevalence of abnormal TG and HDL in patients with NAFLD [17,18]. Comparison of demographic profile, anthropometry and MS components demonstrated that BMI and waist circumference were only two factors which reached a significant level in this study when patients with NAFLD were compared to patients without NAFLD.

Patients with NAFLD may progress to NASH, fibrosis or cirrhosis. The reported prevalence of advanced fibrosis was 17.5% by transient elastography in a multi-ethnic population-based study from Malaysia [19]. While the prevalence of advanced liver fibrosis by MRS and transient elastography in a population-based study from Hong Kong was only 3.7% [20]. In this study, 8 patients had significant fibrosis and 1 patient had cirrhosis based on LSM value. This comparatively high prevalence of fibrosis in our study may be secondary to the selected cut-off value of 8 kPa by LSM for the diagnosis of hepatic fibrosis. When these patients of NAFLD with or without significant fibrosis were compared, only waist circumference and HDL levels were significantly different between these two groups.

Limitation of this study was that details about the socioeconomic status and dietary habits were not obtained.

## Conclusion

The prevalence of NAFLD and hepatic fibrosis was significantly high in this study which indirectly gives the information about the disease burden which patients of GSD are harbouring while they were still asymptomatic for NAFLD. This may have surgical implications regarding their fitness for surgery and the use of various hepatotoxic drugs and anaesthetic agents. This study also showed the possible association between GSD, NAFLD and MS indicating a common pathophysiological mechanism. Therefore, we recommend health education which includes dietary advice and lifestyle modification in patients of GSD requiring cholecystectomy. The CAP and LSM are reliable non-invasive method in the evaluation of significant hepatic steatosis and advanced fibrosis.

All authors disclose no conflict of interest. The study was conducted in accordance with the ethical standards of the relevant institutional or national ethics committee and the Helsinki Declaration of 1975, as revised in 2000.

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Abbreviations

ALT : Alanine Aminotransferase

BMI : Body Mass Index

CAP : Controlled Attenuation Parameter

CT : Computed Tomography

DBP : Diastolic Blood Pressure

DM : Diabetes Mellitus

FBS : Fasting Blood Glucose

GSD : Gall Stone Disease

HDL : Serum High Density Lipoprotein

IQR : Interquartile range

LDL : Serum Low Density Lipoprotein

LSM : Liver Stiffness Measurement

M : Median

NAFLD : Non-Alcoholic Fatty Liver Disease

MRS : Magnetic Resonance Spectroscopy

MS : Metabolic Syndrome

NASH : Non-Alcoholic Steatohepatitis

OPD : Outpatient Department

ROC : Received Operating characteristics

SBP : Systolic Blood Pressure

TC : Serum Total Cholesterol

TE : Transient Elastography

TG: Serum Triglyceride

USG : Ultrasonography

# SCIENTIFIC ARTICLE

# The yield of routine histopathology in fistula-in-ano

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**Keywords:** fistula-in-ano; histopathology; tuberculosis; Crohn's disease

#### Abstract

# Introduction

Fistulae-in-ano with a specific aetiology such as TB and Crohn's are usually complex and challenging to treat. This study was aimed to determine the yield of routine histological analysis in fistula-in-ano, in detecting specific aetiology.

#### Methods

A descriptive study was conducted at the Professorial Surgical Unit, National Hospital of Sri Lanka, Colombo from 2001-2016. Histopathology reports of all patients without a histological diagnosis and who underwent surgery for fistulae-in-ano were analysed.

# Results

A total of 215 patients [median age:40 years (range:14-73), males=179(82.8%)] were analysed. The majority (75%, n=161) were simple fistulae. Histological evaluation revealed inflamed granulation tissue in 94.9% (n=204) of patients. Five (2.3%) patients had conclusive evidence of Crohn's disease and three (1.4%) had tuberculosis. One patient (0.5%) had evidence of adenocarcinoma with mucinous differentiation. Significant proportion of fistula with underlying specific aetiology were complex fistulae (82% vs. 22%, p<0.001) and associated with abscess/collections (45.5% vs. 11.8%, p<0.001). Age, type of fistula, level of internal opening, recurrence and presence of haemorrhoids were comparable in those with and without a specific aetiology.

# Conclusions

Complex fistula and the presence of abscess/ collection were associated with a specific aetiology. Routine histopathological analysis in patients presenting with fistula in-ano should be performed as a clinical prediction based on the nature of fistula may not be always accurate.

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#### Introduction

Fistula-in-ano is a benign anal condition which has been described in the literature for over 2500 years [1]. It is commonly encountered in colorectal surgical practice with a reported incidence of 8.6 per 100 000 population [2]. The majority are simple fistulae which can be delineated fairly accurately and treated easily without significantly affecting the quality of life [3,4]. However, complex fistulae are challenging to treat and can have frequent recurrences requiring multiple surgeries [5].

Repeated surgical interventions can increase the risk of anal sphincter injury, which is often irreversible and can result in anal incontinence [6]. Some of these complex fistulae may have a specific cause which may be successfully managed medically such as tuberculosis (TB), Crohn's disease or actinomycosis. Diagnosis of these aetiological factors is aided by histopathological analyses. Studies that have analysed the histopathology of perianal fistula specimens to find a specific aetiology are few [7-10]. However, previous studies have not analysed the associated factors of specific aetiology in fistula-in-ano.

Therefore, this study was aimed to determine the yield of routine histopathology in identifying a specific aetiology in patients undergoing surgical treatment for fistula-in-ano. Furthermore, the associated factors were also determined.

# Methods

A retrospective analysis of the histopathology reports of the patients who underwent surgery for fistulae-in-ano without a diagnosis for the fistulae, over 6 years (from 2011-2016) at the Professorial Surgical Unit at the National Hospital of Sri Lanka was done. All examinations and investigations were carried out by a senior consultant colorectal surgeon. Data including demographic parameters, type of fistulae, number and type of procedures, the complexity of the fistula were prospectively entered into a computerised database.

Fistulae with multiple external openings, high transphincteric, suprasphincteric and extrasphincteric fistulae and/or with high blind extensions or horseshoe tracts and/or were anterior in a female patient were defined as complex fistulae [11,12]. The anatomy and complexity of the fistulae were

assessed by endoanal ultrasonography and examination under anaesthesia. During examination under anaesthesia, a segment or the entire tract of the fistulae were sent for histological evaluation to look for a specific aetiology.

Data were analysed using SPSS version 20. Data were expressed using the odds ratio (OR), frequency and percentages where relevant. Pearson Chi-square test was used to determine associations. Statistical significance was determined at an alpha of 0.05. Ethical clearance was obtained from the Ethics Review Committee of the National Hospital of Sri Lanka.

#### **Results**

A total of 215 patients underwent surgical treatment for fistula-in-ano during the study period. Histopathological analyses were carried out for all fistulae. The median age of the participants was 40 years (range, 14–73). Of the participants 82.8% (n=179) were males and 17.2% (n=36) were females. Around 75% (n=161) were simple fistulae and 25% (n=54) were complex fistulae. Most were transphincteric fistulae (60.5%, n=130) followed by intersphincteric fistulae (23.7%, n=51). Other types were superficial (n=28, 13%), suprasphincteric (n=5, 2.3%) and extrasphincteric fistulae (n=1,0.5%).

The majority of the histopathological analyses showed only the presence of inflamed granulation tissue and did not reveal any evidence of a specific aetiology (n=204, 94.9%).

Two (0.9%) patients had inflamed granulation tissue containing non-caseating granulomata on histology. Further analysis with stains for acid-fast bacilli was negative and no conclusive evidence of Crohn's disease was seen. Five (2.3%) patients had conclusive changes of Crohn's disease on histology. Three (1.4%) had granulomatous changes and stains for acid-fast bacilli was conclusive of TB. One patient (0.5%) had evidence of adenocarcinoma with mucinous differentiation.

The associated factors of a specific aetiology have been summarised in table 1. All patients with specific aetiology were males. A significantly higher proportion of those having a specific aetiology were complex fistulae (82% vs.18%, Odds ratio: 15 (95% Confidence interval (CI): 3.3-76), p<0.001). Furthermore, significantly higher proportion had associated abscess/collections (45.5% vs. 12%, OR: 6.3 (95%CI: 1.8-22), p=0.001). Although a higher proportion of fistulae with specific aetiology were transphincteric fistulae (82% vs. 59%), the association was not statistically significant (p=0.217). The level of the internal opening was comparable between the two groups (Table 1).

Four out of five (80%) Crohn's disease patients presented with a complex fistula of which, two were non-recurrent. The remaining patient presented with a simple fistula which was non-recurrent and did not have any associated symptoms to suggest Crohn's disease. Three out of four patients with complex fistulae had altered bowel habits and abdominal pain at the time of presentation. However, the remaining patient with complex fistula had no other symptoms except for perianal discharge. Transphincteric fistulae were seen in 4 patients and one had an intersphincteric fistula. The internal opening was found below the dentate line in 4 patients and above the dentate line in 1 patient.

The two patients who were found to have a non-caseating granuloma had complex transphincteric fistulae with internal openings at the level of the dentate line with associated abscesses. All patients (n=3) with TB had evidence of caseation in the granulomas and were positive for acid-fast bacilli. All presented with recurrent fistulae and of them, two patients had an associated abscess. However, they did not have other systemic symptoms of TB. Two were transphincteric fistulae with an internal opening below and at the level of the dentate line while one patient had a suprasphincteric fistula with the internal opening in the rectum.

The patient who was diagnosed to have a malignancy was a 57-year-old male who presented with a long-standing transphincteric complex fistula with multiple tracts with the internal opening at the level of the dentate line. Furthermore, there was an induration in association with the fistula on rectal examination. Further investigation with imaging and endoscopy revealed that the adenocarcinoma developed in the longstanding fistula tract itself and was not part of a bowel malignancy.

# Discussion

In this retrospective analysis of 215 patients who underwent evaluation for fistula-in-ano, eleven patients (5%) had histopathological evidence of a specific aetiology. Complex fistula and the presence of an abscess/ collection were found to be associated with a specific aetiology. Other factors such as type of fistula, level of internal opening, recurrence and presence of haemorrhoids were not associated with the diagnosis of a specific aetiology.

Fistula-in-ano is a common cause of perineal sepsis which can be very challenging to treat. Management of fistula-in-ano is complex and includes control of infection, assessment of the anatomy of the fistula tract by examination under anaesthesia and imaging followed by the definitive treatment [13]. Most fistulae-in-ano are idiopathic or cryptoglandular in origin

Table 1. Associated factors of specific cause in anal fistula

		Present		Absent		Odds ratio	P value
		N	%	N	%	(95% CI)	
Age (Median/range)		34(20-60)		40(14-73)		-	0.201
Sex	Male	11	100%	168	82.4%	-	0.121
	Female	0	0%	36	17.6%		
Complexity	Complex	9	81.8%	45	22.1%	15 (3.3-76)	<0.001
	Simple	2	18.2%	159	77.9%		
	Superficial	0	0.0%	28	13.7%		
	Intersphincteric	1	9.1%	50	24.5%	-	
Type of fistula tract	Transphincteric	9	81.8%	121	59.3%	]-	0.217
,	Suprasphincteric	1	9.1%	4	2.0%	-	
	Extrasphincteric	0	0.0%	1	.5%	-	
	Below the dentate line	6	54.5%	109	53.4%		
Level of internal	At the dentate line	3	27.3%	79	38.7%	-	
opening	Above the dentate line	1	9.1%	11	5.4%	]-	0.408
,	Rectum	1	9.1%	3	1.5%	-	
.	Could not be located	0	0.0%	2	1.0%	-	
Abscess/Collections	Yes	5	45.5%	24	11.8%	6.3(1.8-22)	0.001
	No	6	54.5%	180	88.2%	0.3(1.8-22)	0.001
Haemorrhoids	Yes	1	9.1%	23	11.3%	0.78 (0.09-6.4)	0.823
	No	10	90.9%	181	88.7%	0.76 (0.05-0.4)	0.023

 $\textbf{Table 2.} \ \ \textbf{Summary of previous studies comparing histological findings of anal fistula}$ 

Author	Year	Country	Sample	Study type	ТВ	Crohn's	Malignancy	Others
Sainio	1983	Finland	458	Population based study	1 (0.2%)	6 (1.30%)	None	UC: 7(1.5%)
Shukla	1988	India	122	Retrospective	19 (15.6%)	None	None	None
Stupart	2009	South Africa	96	Prospective	7 (7.3%)	None	None	None
Wijekoon	2010	Sri Lanka	84	Retrospective	2 (2.4%)	1 (1.2%)	None	None
Present	study	Sri Lanka	215	Retrospective	3 (1.4%)	5 (2.3%)	1(0.5%)	NCG: 2 (0.9%)

which is usually simple, uncomplicated and responds well to treatment. Surgical treatment is the treatment of choice for idiopathic fistulae. However, surgery carries a risk of injury to the anal sphincter complex and can result in complications such as anal incontinence which can be extremely disturbing to the patient [14,15].

However, fistulae occurring secondary to a specific cause is known to occur infrequently, which can be managed pharmacologically. These usually present as complex fistulae-in-ano which are often difficult to manage. Some of the known specific causes are tuberculosis, Crohn's disease, actinomycosis, chlamydia and malignancies [16]. The incidence of TB and acquired immunodeficiency syndrome (AIDS) are on the rise especially in developing countries [17]. Therefore, excluding the possible specific cause is necessary to decide on the definitive treatment. Previous studies that have analysed the histopathological findings have been summarized in table 2 [7-10].

## Prevalence of TB in fistula-in-ano

In a study from Sri Lanka involving 84 patients, TB was confirmed in two (2.4%) patients.

Both patients were suspected to have a specific cause clinically as they presented with complex fistulae with poor response to the surgical treatment [10]. In a prospective study of 96 patients from South Africa, 7 (7.3%) were found to have tuberculosis. Of those, none had systemic manifestations of TB and only one had some evidence of TB in the chest radiograph. [9]. Sainio et al conducted a study in Helsinki and noted that 0.2% of all fistulae are tuberculous in origin [8].

However, in that population-based study, those with the previous history of TB were not excluded from the analysis. In a study by Shukla et al from India, 122 cases of fistulae inano were analysed and a considerable proportion (15.6%) were diagnosed as tuberculosis [7]. Anorectal TB is usually associated with pulmonary TB but the occurrence of anorectal TB without pulmonary involvement in also reported in the literature [18,19]. In our study 3 patients (1.4%) were found to have anorectal TB. Of which 2 were complex fistulae and all three were recurrent fistulae. Furthermore, they did not have any other systemic features of TB and thus histology was useful to clinch the diagnosis.

#### Prevalence of Crohn's disease in fistula-in-ano

An anorectal fistula is a known manifestation of Crohn's disease and it usually occurs with other classical symptoms of Crohn's disease. The presentation of perianal Crohn's disease is variable as some (5%) may even develop anal fistulae before other manifestations of Crohn's disease [19-21]. Although Crohn's disease was previously regarded as a

disease of the Western world, it is increasingly being reported in South Asia [22]. In a study by Sainio et al involving 458 patients with anal fistulae, 1.3% were secondary to Crohn's disease [8]. Interestingly, a higher proportion (1.5%) were associated with ulcerative colitis. In our study, there were no anal fistulae associated with ulcerative colitis, although an increased incidence of ulcerative colitis is noted in the South Asian region [23].

However, the study conducted by Sainio et al was a population-based study, therefore it is possible that those with previous confirmed ulcerative colitis were also included in the analysis [8]. In a similar study from Sri Lanka including 84 patients, one patient (1.2%) was diagnosed with Crohn's disease [10]. In the present study, 5 patients (2.3%) were found to have Crohn's disease of which, four patients (80%) presented with complex fistulae. However, the remaining patient presented with a non-recurrent simple fistula without any associated symptoms to suspect the diagnosis of Crohn's disease. This finding is clinically significant as it is evident that non-recurrent simple fistulae can also have a specific aetiology. Interestingly, two out of five patients did not have any other associated symptoms to suggest a possibility of Crohn's disease at the time of presentation. However, they later manifested other symptoms of Crohn's disease. Therefore, histological evaluation in these patients was helpful to diagnose Crohn's disease early.

Malignancy associated with a recurrent anal fistula is a rare entity and it is reported to occur in long-standing fistulae [24]. In our study, one patient was found to have adenocarcinoma with mucinous differentiation. The patient was a 57-year-old male with a history of long-standing fistula for four years. There was an induration in association with the fistula on rectal examination and thus, the history was suggestive. Other studies summarised in table 2 did not find an associated malignant histological finding.

Although a few studies have analysed the histological findings in fistula-in-ano (table 2), the associated factors of fistulae with a specific aetiology were not previously studied. In this study, we have shown that in a few patients, histology was useful in detecting the specific aetiology in the absence of clinical features. This was not reported in previous studies.

Being a retrospective analysis is a limitation. However, we found that in certain cases it was difficult to predict those with a possible underlying disease clinically. Thus, the routine histopathological analysis was useful to detect specific aetiology early. However, the usefulness and cost-effectiveness can only be confirmed by large prospective studies.

# **Conclusions**

In our study, the prevalence of Crohn's disease, TB and malignancy were 2.3% (n=5), 1.4% (n=3) and 0.5% (n=1) respectively. Complex fistula and the presence of an abscess/collection were the only associated factors of a specific aetiology. Other factors such as type of fistula, level of internal opening and presence of haemorrhoids were not associated with a specific aetiology.

Routine histopathological analysis in patients presenting with fistula in-ano may be useful to detect any specific aetiology early which will be helpful in the management of these patients.

# Ethics approval and consent to participate

Ethical approval was obtained from the Ethics Review Committee of the National Hospital of Sri Lanka. Consent is not aplicable as it was a retrospective analysis.

All authors disclose no conflict of interest. The study was conducted in accordance with the ethical standards of the relevant institutional or national ethics committee and the Helsinki Declaration of 1975, as revised in 2000.

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# SCIENTIFIC ARTICLE

# The workload, outcome and waiting time of cardiothoracic operations: a single unit study in Sri Lanka

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**Keywords:** Cardiothoracic; waiting time; workload; CABG; outcome

#### **Abstract**

#### Introduction

Heart disease is the commonest cause of death worldwide. Its surgical treatment is expensive, and resources are limited. Although there is general concern regarding the work of cardiothoracic units in Sri Lanka, there is very little scientific data regarding it. Our objective was to establish the workload, outcome and waiting time of cardiothoracic operations in a single unit in Sri Lanka.

## Methods

Prospectively entered data from the clinic register and operation logbooks from August 2010 to March 2020 were reviewed retrospectively and collected on data extraction sheets. The data was entered onto a Microsoft EXCEL database and analyzed using SPSS [Statistical Package for Social Sciences].

#### Results

In 1100 patients, 759 [69%] were males and 341[31%], females; The mean age was 50.8 years [1 day-77 years]. Coronary artery bypass grafting [CABG] was the commonest operation [573;52.1%].

Others were thoracic operations [207;18.8%], valve operations [160;14.5%], congenital operations [89;7.8%], Extracorporeal Membrane Oxygenation/ECMO [29;2.6%], cardiothoracic trauma [20;1.8%], cardiac tumours [14;1.3%] and aortic operations [6;0.5%]. Urgency categories were elective [855;77.7%], urgent [179;16.3%], emergency [36;3.3%] and salvage [30;2.7%]. The mortality rate for elective surgery was 3.3% and that of CABG, 2.4%. The recent death rate while waiting is 5.7%. The present waiting time for elective operations is 9.4 months and is increasing.

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#### Conclusions

Coronary, thoracic and valvular operations are the commonest operations in this unit. The outcomes of surgery are within accepted international standards. The waiting time is long. This study provides a baseline for future research and audit to prioritize capacity building.

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## Introduction

Heart disease especially ischaemic heart disease [IHD] is the commonest cause of death worldwide [1]. According to the World Health Organization [WHO], cardiovascular diseases caused 17.9 million deaths globally in 2016 [2]. Given that resources to treat heart disease - especially with operative procedures such as Coronary Artery Bypass Grafting [CABG] are not unlimited - the workload, outcome and state of the waiting lists for cardiothoracic operations are of concern to both the public and medical professionals all over the world [3]. In Sri Lanka too, the escalating number of patients in waiting lists across the cardiothoracic units in the country is a hot topic of discussion in clinical circles as well as the media [4, 5]. Yet, very little scientific data is available regarding the actual state of cardiothoracic surgery in Sri Lanka.

In most developed countries, it is mandatory to submit comprehensive data regarding cardiac operations on standard data extraction forms [6]. These help to assess not only the volume but also the patient-specific risk factors and the risk-adjusted morbidity and mortality. Studies show that benchmarking a unit's results against that of a National registry will improve the outcome and organization of a unit [6]. Some units in Sri Lanka do periodically assess their outcome in terms of quantity [i.e. number of operations] and quality [i.e. morbidity and mortality]. However, there is no common data collection system or a registry for cardiac surgeons to submit such data to, and therefore no means of benchmarking their results against a national registry.

The average cost for a cardiac operation such as a CABG in the private sector is SLR 800 000 – 1000 000. Given the life-saving and pain-relieving nature of such operations, the demand for an early date for heart surgery is obvious. The usual procedure in most institutions is to wait-list patients during the first clinic visit. There is a tendency for patients to register in waiting lists in multiple institutions, in a desperate

attempt to have the operation done at the earliest opportunity, thus distorting any general count that could have gauged the size of the problem nationally. If the chance of an early operation appears bleak, those who can afford may get it done in the private sector or abroad. Some may die while waiting. Others simply change their mind and—for better or for worse—opt for non-surgical management. If these events have not been tracked, any figures, merely giving the numbers of those who have been registered, will overestimate the actual number on the waiting list.

We present the workload, outcome and waiting time for surgery of a single surgeon-led cardiothoracic unit in Sri Lanka.

#### Methods

Ethical clearance was obtained from the local ethical review committee and permission was obtained from the head of the institution to do this study. No identification details were exposed to anyone other than the investigators.

We retrospectively reviewed the prospectively entered data from August 2010 to March 2020. Information was extracted from the clinic registers, ward admission books, operation logbooks and the audit data of the morbidity and mortality records. All patients who underwent a major surgical procedure by the cardiothoracic surgical team of this unit were included. A single patient was entered only once, even if repeated procedures were done. Minor procedures such as thoracostomies were excluded. Data was gathered on data extraction sheets by the investigators and entered onto a Microsoft EXCEL database. Analysis of waiting time was done using SPSS [Statistical Package for Social Sciences] version 25.

### Results

During the period of study, 1100 patients had undergone cardiothoracic operations. Their mean age was 50.8 years [range 1 day to 77 years]. There were 759 [69%] males and 341 [31%] females. Coronary artery bypass grafting [CABG] was the commonest operation [573; 52.1%] followed by thoracic operations [207;18.8%].

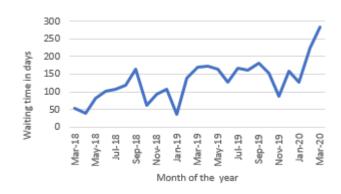
The others included valve operations [160; 14.5%], congenital operations [89; 7.8%], Extracorporeal Membrane Oxygenation/ ECMO [29; 2.6%], cardiothoracic trauma [20;1.8%], cardiac tumours [14;1.3%] and aortic operations [6; 0.5%]. The operations were largely elective [855; 77.7%] while the other categories were urgent [179;16.3%], emergency [36; 3.3%] and salvage [30;2.7%]. The overall mortality, including emergency and salvage procedures, was 5.6% [62/1100] and with the exclusion of salvage and emergency procedures, it was 3.5% [36/1034]. The mortality

rate of elective operations was 3.3% [27/855]. The index operation, CABG, had a mortality rate of 2.4% [13/531].

There were 94 referrals from many parts of Sri Lanka for ECMO and 32 were performed; the commonest reasons [21%] for not doing ECMO was difficulty in transferring the patient to our centre. All ECMO procedures have been either salvage or emergency procedures on six neonates, five children and 21 adults who have collectively been supported for a total of 5493 ECMO hours. The commonest indication [87.5%] for ECMO was severe respiratory failure; 2/32 [6.25%] were post cardiotomy ECMO. While the overall ECMO survival was 46.9%, some groups have shown better survival: leptospirosis with pulmonary haemorrhage has had 70% [7/10] survival, and neonatal meconium aspiration has had 100% (3/3) survival—all with no neurological or other sequelae.

Over the last two years, the median waiting time for urgent operations was 37 days and for elective operations, 96.5 days. While there was no change in the trend in waiting times of urgent operations, that of elective operations has increased. The average number of days the patients operated at the beginning of 2020 had waited were: 127 in January, 224 in February and 283 in March [Fig 1]. During these three months, although 35 patients had been scheduled for elective surgery, due to 12 urgent operations, only 14/35 [40%] of elective operations could be done as scheduled. Thus 17/35 [48.6%] were postponed. Furthermore, 2/35 [5.7%] died while waiting for surgery, 1/35 [2.9%] opted for non-surgical management and 1/35 [2.9%] were lost to follow up.

In the year 2019, although 120 theatre session were available, only 84 sessions [70%] were utilized. The reasons for non-utilization were theatre repairs [12; 33.3%], academic sessions [11; 30.6%] public holidays [7; 19.4%] and miscellaneous reasons 6[16.7%]. Although two other fully equipped theatres are available to run parallel sessions, 89/120 [74.1%] sessions did not utilize the second theatre due



**Figure 1.** Trends in the average waiting time for an elective cardiothoracic operation

to lack of doctors. The third theatre is not utilized due to the lack of a third consultant.

#### Discussion

There are 23 cardiothoracic and thoracic surgeons for the almost 22 million population of Sri Lanka. They are distributed in 17 institutions: i.e. eight government hospitals, one semi-government hospital and eight private hospitals. Hosain et al compared the patterns of cardiac surgery in Southern Asia in 2016 and found that 5500 cardiac operations had been done in Sri Lanka, amounting to 265 operations/million population [7].

In comparison to a country such as the USA doing 2160 /million, this may appear inadequate [7]. Nevertheless, Sri Lanka was still the highest performer in Southern Asia, when compared with her neighbours: India [113.3/million], Pakistan 108.8/million, Nepal 69.2/million and Bangladesh 68.6/million population. Bhutan and Maldives had no cardiothoracic programs and had been sending their patients abroad for cardiac operations at the time [7].

International studies have shown that cardiothoracic centres with higher volumes show lower mortality [8]. Centres performing <125 CABG /year are generally considered as low volume centres [8]. A study done in 2017 involving five countries showed the overall mortality rate for CABG to be 3%. [Denmark 2.8, England 2.2, Portugal 2.3, Slovenia 3.5 and Spain 4.9%] [8]. Accordingly, our unit which has performed 73.5/CABG /year over the last couple of years would be considered a low volume centre. Still, our unit's mortality rates for CABG is 2.4 % and is well within acceptable international standards.

A recent study from Ireland quoted 32 days as their waiting time for an urgent cardiac operation [9]. Our average waiting time has been only slightly higher [37 days] with minimal change over the years as the very nature of the disease severity requires urgent attention. It is the elective group that appears to be the problem in the region: In 2005, Thailand reported 27.9 weeks of waiting for paediatric cardiac surgery [10]. In 2009 the National Hospital of Sri Lanka [NHSL] reported 10 months as their average waiting time [11]. Our waiting time in 2020 is 37.5 weeks.

A waiting time of 6-8 weeks has been considered acceptable for elective cardiothoracic operations internationally [12]. Accordingly, the waiting times in the region, including our centre, appear to be unacceptably long.

Prolonged waiting has adverse effects. Teo et al. have shown that it is associated with increased anxiety [13]. Sampalis et al. reported a significant decrease in physical and social functioning for patients waiting for more than 3 months for

CABG [14]. Underwood et al. have shown a positive correlation between waiting for time and anxiety, depression and social morbidity— irrespective of the severity of their clinical symptoms [15]. A Canadian study in 2018 found that 0.8% of patients died while waiting for cardiac surgery [16]. In our unit, it is much higher, with currently 5.7% dying while waiting, which underscores the seriousness of the problem.

According to a recent systematic review of strategies to reduce waiting time, the need to use multidimensional strategies that are tailored to the requirements and opportunities presented in each unit was emphasized [6]. The reasons for the delay cited in the study from NHSL was the lack of ICU beds [11]. On the other hand, our study found the lack of doctors to be the main obstacle. Cardiothoracic and ECMO procedures can be technically complex and energyintensive, and even experienced doctors take time to acquire familiarity with them. Unfortunately, by the time doctors acquire some competence with these procedures, most are due for transfers. Thus, although waiting list initiatives to encourage more operating are in place, lack of experienced junior doctors makes it difficult to utilize such initiative schemes to run parallel theatres safely. Some countries have successfully overcome similar problems by utilizing nurse practitioners as physician assistants, who among other duties, also perform vein harvesting and surgical first assisting [17].

Provision of long-term junior staff in adequate numbers, encouraging more cardiothoracic residents, an in-service training /diploma in cardiothoracic surgery for doctors and creating physician assistant posts are all potential strategies that could utilize theatre time more effectively. In our unit, we have periodically increased our output by inviting an overseas consultant cardiothoracic surgeon to help us utilize the second operating theatre by running parallel theatre sessions that are staggered safely.

Our third theatre could be utilized if newly qualified cardiothoracic surgeons are appointed to the unit. This would be more sensible than allocating them to peripheral stations that do not have cardiothoracic theatres. This study has provided some insight into the data needed by clinicians and administrators to formulate local and national strategies. After implementing these changes, it will be important to reassess their success and to close the audit loop. Waiting time is likely to increase with the COVID 19 pandemic, as surgeons have been forced to drastically reduce operating worldwide.

This is a retrospective study and has several limitations. The records had minimal data on the severity of the disease/ Euro score that could have given the interpretation of outcomes more meaning [18]. Furthermore, the morbidity data during

the waiting and after surgery were not robust enough to be used and had to be ignored. Further prospective studies could address these issues.

#### **Conclusions**

This study has established, for the first time, important data about the present state of cardiothoracic surgery in a single unit in Sri Lanka: Coronary [52.1%], thoracic [18.8%] and valvular operations [14.5%] are the commonest operations. The outcomes of surgery are within accepted international standards with a 2.4% mortality rate for isolated CABG operations. The current waiting time for an elective cardiothoracic operation is 9.4 months and is likely to increase. Currently, 5.7% patients die while waiting for their heart operation This study provides a baseline for future research and audit which are essential to generate reliable and accurate data on an important national problem which requires long term solutions.

All authors disclose no conflict of interest. The study was conducted in accordance with the ethical standards of the relevant institutional or national ethics committee and the Helsinki Declaration of 1975, as revised in 2000.

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# SCIENTIFIC ARTICLE

# Short-term outcome of acute appendicitis at a rural surgical facility in Sri Lanka; a disease beyond benign simplicity

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**Keywords:** Acute appendicitis; appendicectomy; alvarado score

#### **Abstract**

#### Introduction

Acute appendicitis is the commonest intra-abdominal emergency requiring surgical intervention. The preferred treatment is appendicectomy with variable access techniques, but some patients with uncomplicated appendicitis respond well to antibiotics. Despite the benign nature of the disease, complications are not uncommon in appendicitis and after appendicectomy.

## Methods

Outcome data of all cases diagnosed as acute appendicitis at District General Hospital, Mannar were prospectively collected from August 2016 to April 2017. Association between the age and duration of symptoms with the operative findings and postoperative complications were evaluated. Clavien-Dindo classification was used to grade the complications. Cases were reviewed at one month and one year.

#### Results

Out of 96 cases (Mean age 25.5 years, Range 7-64) diagnosed with acute appendicitis 43 were males. Eighty-three patients underwent surgery (Open appendicectomy–48, Laparoscopic appendicectomy–30, Appendicular abscess drainage-3, Midline laparotomy-2). Seventy-three (76%) and twenty-three (24%) cases presented with less than two and more than three days of symptoms respectively. Fifty (60.3%), twenty-eight (33.7%) and five (6%) cases had uncomplicated appendicitis, complicated appendicitis and macroscopically normal appendix as operative findings. Mean age of 30.9 years in the cases with complicated appendicitis was significantly higher than the cases with uncomplicated appendicitis (23.7 years) or ones with normal-looking appendix (22.8 years) (p=0.007 and p=0.004, post-hoc ANOVA). Mean duration of symptoms of 2.5 days noted in

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the cases with complicated appendicitis was significantly higher than the ones in the other groups (1.75 and 1.65 days) (p < 0.001 and p < 0.001 post-hoc ANOVA). Eighteen (21.7%), five (6%) and one (1.2%) cases had grade 1-2, grade 3-4 and grade 5 complications on Clavien-Dindo classification respectively. Mean age of 46.8 years in the cases with grade 3-5 complications was significantly higher than 24.4 years in the cases with no complications or 22 years in the ones with lesser complications (p=0.001 and p < 0.001 post-hoc ANOVA). Mean duration of symptoms of cases with grade 3-5 complications (3.25 days) was higher than the rest. Sixteen of 28 (57.14%) with complicated appendicitis developed postoperative complications.

#### **Conclusions**

Within the study cohort, advanced age and prolonged symptoms were risk factors for complicated appendicitis. Advanced age was associated with severity but not the occurrence of postoperative complications in acute appendicitis. Delayed presentation and complicated appendicitis lead to post-operative complications.

#### Introduction

Acute appendicitis is the commonest intra-abdominal inflammatory disease requiring surgical intervention worldwide [1, 2]. It is also the most frequent surgical emergency in childhood [2]. Appendicitis is widely seen between the ages of 10 to 20 years but there is no age exemption [1, 2]. Lifetime risk ranges from 7 to 14% across both genders and females tend to have a slightly higher risk range [3]. In 1886, Dr Reginald Fitz emphasized that the vermiform appendix as the commonest culprit for the inflammation of the right iliac fossa [1, 4].

Since then several postulations have been made on the pathophysiology of acute appendicitis. Out of which the most popular theory being the luminal obstruction with a faecolith followed by distension of the appendix leading to bacterial overgrowth, raised intraluminal pressure with tissue compromise and gangrenous perforation as the result [1, 3]. Even 125 years after the first documented diagnosis of appendicitis, the exact pathophysiology of this common disease is still unclear as solid supporting evidence is lacking for the theory of fecolith obstruction leading to luminal

hypertension [3]. Appendicectomy remains the foremost mode of treatment in acute appendicitis [1, 3]. Variable access techniques have been utilized by surgeons over the years, ranging from the midline or paramedian laparotomies used in the nineteenth century, famous right iliac fossa muscle splitting incision of McBurney preferred laparoscopic minimal access techniques of the late twentieth century to natural orifice transluminal surgery (NOTES) and endoluminal surgery in the twenty-first century [1, 4, 5]. Some patients with acute appendicitis respond well to antibiotics, a modality that has been successfully practised in naval and military medicine due to lack of access to the surgical facility [6]. There have been several trials to assess the efficacy of antibiotic therapy alone or antibiotic first policy in appendicitis with varied conclusions [1, 3, 7, 8,].

Several governing bodies in general or gastrointestinal surgery and emergency medicine still recommend appendicectomy as the treatment of choice for acute appendicitis and states antibiotic first policy 'may be effective with the potential risk of reoccurrence' [3]. Despite all the advances in medical knowledge and surgical technology of the twenty-first century, there were 54000 deaths caused by appendicitis around the globe in 2016 as estimated by the World Health Organization and almost two-thirds of such fatalities occurred in low-income countries in Africa and South-east Asia [9]. Most of these deaths happen due to complications of the disease with intra-abdominal sepsis. Although appendicectomy is considered a relatively safe procedure, surgery for uncomplicated appendicitis still carries a mortality rate of 0.8 per 1000 procedures [2].

Sri Lanka is a third world developing country in South Asia with a gross domestic product per capita of \$4073 in 2017 and utilizes less than 3% of gross domestic product for the health expenditure [10, 11]. However, the country has a well-established state-driven free health care system with average health indices comparable to the developed world despite the limited health care budget. Mannar is one of the least developed districts of the country with a population of 106000. District General Hospital, Mannar is manned by two general surgeons with continuous specialists' cover despite limited resources and manpower.

The institution has limited critical care support and lacks a facility for computed tomography and specialist anaesthesiology and radiology cover over weekends. In such a background, this study attempts to audit the outcome of the cases with acute appendicitis managed at the index low resourced institution and to identify the risk factors for complicated disease and post-operative complications.

#### Methods

Outcome data of all cases diagnosed as Acute Appendicitis managed at District General Hospital, Mannar were prospectively collected for eight months between August 2016 and April 2017. The ultimate working diagnosis was made by one of the Consultant Surgeons upon clinical findings and basic haematology, biochemistry and urinalysis; occasionally supported by abdominal ultrasonography. Alvarado score was used as an aid for decision making [12]. Management decision on surgery or antibiotic therapy (Co-Amoxiclav or Cefuroxime with Metronidazole) was taken by the surgeon upon the clinical picture without randomization. For the cases commenced on the trial of antibiotic therapy, failure to experience a reasonable clinical response at 48 hours was considered as an indication for operative management.

Access mode of surgery was decided by the same surgeon accordingly without randomization, to best suit the clinical scenario. Association between the age of the patients and the duration of symptoms with the operative findings and postoperative complications were correlated. Operative findings were classified as uncomplicated appendicitis, complicated appendicitis and negative appendicitis. Complicated appendicitis was defined as the presence of perforation, gangrenous appendix, and phlegmon or periappendiceal abscess formation.

Histopathological correlation was performed in all specimens and emphasis was made to confirm or exclude microscopic appendicitis in the cases with negative appendicitis. Clavien-Dindo classification was used to grade the complications. All patients were reviewed at one month and ones with complications or concerns according to the clinical needs subsequently. At one year from the index admission, cases were reviewed again or contacted over the phone to assess the outcome based on a structured questionnaire. Parametric tests were used for statistical evaluation when data followed a normal distribution.

#### Results

Ninety-six (49 males; age range 5-64 years, mean 20.8) patients were diagnosed as having acute appendicitis. Mean Alvarado score for cases diagnosed as having acute appendicitis was 7.2 (Range 5-10). Thirteen (6 males; age range 5-32 years, mean 16.4) were successfully managed with antibiotic therapy. Twelve out of them were adjudged as having uncomplicated appendicitis and the other had an appendicular mass confirmed by ultrasonography. Eighty-three patients (43 males; age range 7-64 years, mean 25.5) underwent surgery which included three cases of

unsuccessful antibiotic treatment. Mean age of cases successfully managed with antibiotics was significantly low (p=0.002 Pooled t-test). Mean Alvarado score of the cases successfully managed with antibiotics was 5.9 and ones who had surgery as 7.4, and these values were statistically significant (p=0.003 Pooled t-test). Within surgical group sixty-three (75.9%) cases presented within two days from onset of symptoms and rest presented with a delay of more than three days (Range 12 hours to 5 days). Among the 13 cases successfully managed with antibiotics ten presented within two days and the other three presented after five days from onset of symptoms (Range 6 hours to 7 days).

Attempted treatment with local remedies or other traditional medical modalities and socioeconomic reasons were the key reasons for delayed presentation. Surgical procedures performed included 48 Open appendicectomies with right iliac fossa incision, 30 Laparoscopic appendicectomies, three Open appendicular abscess drainages with lateral incisions and two Midline laparotomies. One laparotomy ended up with a Right hemicolectomy and during the other large peri appendiceal abscess was drained in addition to appendicectomy. On perioperative macroscopic appearance, 50 (60.3%) had uncomplicated appendicitis and 28 (33.7%) had complicated appendicitis. Five (6%) cases underwent appendicectomy despite the gross appearance of the appendix is normal as no other structural cause was apparent to describe the symptoms.

Mean age of 30.9 years in the cases with complicated appendicitis was significantly higher than in the cases with uncomplicated appendicitis (23.7 years) or ones with normal-looking appendix (22.8 years) (p=0.007 and p=0.004 post-hoc ANOVA). Mean duration of symptoms of 2.5 days noted in the cases with complicated appendicitis was significantly higher than the ones in the other two groups mentioned above (1.75 and 1.65 days) (p < 0.001 and p < 0.001 post-hoc ANOVA).

All three cases who had surgery due to a lack of response to antibiotic therapy had uncomplicated appendicitis. Eighteen (21.7%) cases had Clavien-Dindo classification grade 1-2 complications and five (6%) had grade 3-4 complications. There was one (1.2%) mortality of a 64-year-old patient with ASA grade 3 presenting with five days of symptoms. Following laparotomy to drain a large peri appendiceal abscess patient went into multi-organ failure. The mean age of the cases ending up with postoperative complications was 24.7 years and of the others was 21.8 years. Mean age comparison between the two groups, cases with and without postoperative complications was not significant (p=0.25 Pooled t-test). Mean age of the cases with grade 3-5 complications was 46.8 years.

This was significantly higher than the mean age of 24.4 years in the cases without complications or mean age of 22 years in the ones with lesser complications (p=0.001 and p < 0.001 post-hoc ANOVA). All five cases with apparently normal appendices had an uncomplicated recovery. Mean duration of symptoms was 1.9 days in the cases with no post-operative complications and 2.2 days for the ones with grade 1-2 complications. Mean duration of symptoms in cases with Clavien-Dindo grade 3-5 complications was 3.25 days and that was higher compared to the rest. Sixteen out of 28 patients with complicated appendicitis developed post-operative complications compared to 7 out of 50 cases with uncomplicated appendicitis.

All 78 cases with macroscopic appendicitis had histological confirmation of the disease. Out of the five negative appendicectomies two had transmural neutrophil infiltration confirming microscopic disease and the other three showed lymphoid aggregations. None of the specimens contained incidental neoplasia. All who underwent surgery except for the case of mortality were reviewed at one month, and 75 were available for the follow up at one year. Two cases had woundrelated concerns in one month. Seventy-five cases reviewed at one year included both and none had persistent surgical concerns. Nine out of 13 cases managed with antibiotics were contacted at one year. One of them had undergone laparoscopic appendicectomy during that time due to a subsequent acute attack. Another one has had a hospital admission for non-specific right iliac fossa symptoms and the rest were symptom-free.

### **Discussion and conclusions**

Diagnosis of acute appendicitis may not be straight forward at times due to atypical presentation. Despite all technological advancements, clinical history and examination findings play a major role in the diagnosis [2]. There is no unique biomarker to confirm the diagnosis of appendicitis, but elevated white blood cell count with a left shift is the most used laboratory marker aided by elevated C- Reactive Protein levels [3]. Confirming appendicitis remains a challenge and scoring systems have been developed to aid identify the probability of having the disease. Alvarado score has been a useful adjunct for this matter since the description in 1986 [3, 12]. Computed tomography and Magnetic Resonance Imaging have the highest specificity and sensitivity of the imaging modalities when compared with ultrasonography [3].

However, in settings with limited supporting facilities surgeons may still have to proceed solely upon clinical judgment on acute appendicitis. This audit shows that the clinical diagnosis of acute appendicitis can be made with reasonable accuracy with acceptable negative appendicectomy rates.

Despite the developing trends to use antibiotics to treat uncomplicated acute appendicitis, both surgeons were keen on appendicectomy in most of the cases. A minority of cases with very early symptoms and another with mass formation were successfully managed without surgery. The mean age and Alvarado score of cases successfully managed with antibiotics were low. This fact suggests that the surgeons would feel safer to manage younger patients with 'less severe' clinical features of appendicitis with antibiotics, probably due to lesser possibility of missing a sinister pathology even without definitive imaging. Lack of imaging for confirmatory diagnosis of appendicitis may be considered as a limitation in the study.

Advanced age and delayed presentation with prolonged symptoms were risk factors for complicated appendicitis within the study cohort. Although it is not considered as a direct indicator of the severity of the disease, the Alvarado score as a predictor of the complicated nature of appendicitis during this study. Increased age was not associated with the occurrence of postoperative complications in acute appendicitis but was associated with the severity of the complications.

Delayed presentation and complicated appendicitis were risk factors for postoperative complications. Delay in seeking proper allopathic medical/surgical assistance by patients has always been a concern especially in developing countries and causative socioeconomic and cultural reasons are beyond a clinical discussion. Clinicians may not have direct control over these identified risk factors for complicated appendicitis or post-operative complications after appendicectomy. However, surgeons, especially in limited-resource setting, must be vigilant when dealing with cases of suspected appendicitis in older patients with comorbidities and ones presenting late to anticipate complicated disease and greater post-operative concerns. Such anticipation would help the surgeon to predict the 'uneasy' outcomes of common benign disease at presentation and allow space for detailed communication with the patient and family to minimize subsequent hardships.

# Presentation

This study was presented at the Annual Scientific Session of the College of Surgeons of Sri Lanka and joint academic meeting with Royal College of Surgeons of Edinburgh in August 2017 at Kandy and won the award for the best outstation paper.

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All authors disclose no conflict of interest. The study was conducted in accordance with the ethical standards of the relevant institutional or national ethics committee and the Helsinki Declaration of 1975, as revised in 2000.

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# REVIEW ARTICLE

# Critical care management in burns: A review of current evidence and guidelines -Part 1

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Keywords: Burns; severe burns; critical care; burns resuscitation; fluid resuscitation; review

#### **Abstract**

Recent literature on the management of critically ill patients have altered the beliefs and clinical behaviours, questioning many dogmas that were practiced without much evidence. The critical care in a severely burn-injured patient requires special attention in resuscitation, haemodynamic monitoring, management of complications, organ support and determinants of outcome. The goal of resuscitation is to maintain intravascular volume and tone while correcting the reversible changes in altered physiology, aided by early debridement of burned tissue and elimination of the source of physiological derangement. Practitioners should target resuscitation based on goal-directed therapy using noninvasive markers of cardiac output. The management requires the input of a multi-disciplinary team to achieve critical care and early surgical intervention and management of complications and organ support.

Introduction

Recent literature on the management of critically ill patients have altered the beliefs and clinical behaviours, questioning many dogmas that were practiced without much evidence [1]. Furthermore, the fundamental understanding of critical care in terms of fluid management, haemodynamic monitoring, management of acute respiratory distress syndrome (ARDS), organ support and nutrition support are changing [1]. The goal of resuscitation is to maintain intravascular volume and tone while correcting the reversible changes in altered physiology, aided by early debridement of burned tissue and elimination of the source of physiological derangement. The definition of severe burns is based on the surface area (20% excluding superficial burns), presence of inhalational or electrical injury, patients' age and comorbidities [2]. The critical period in severe burns is usually transient, lasting for few days. However, may include intermittent episodes of deterioration based on burn related complications. This

narrative review focuses on the contemporary literature, on the critical care of severe burns once the patient has been stabilised after the initial injury. The review consists of two parts and the first part focusses on fluid resuscitation, goaldirected fluid therapy, haemodynamic monitoring and coagulopathy in severe burns. The second part describes aspects such as thromboprophylaxis, role of suppressing hypermetabolism, glycaemic control, nutritional support, sepsis and infection control, management of inhalational injuries, surgical debridement, pain management and palliative care in severe burns.

#### Methods

We performed a literature search on PubMed and Google Scholar, and looked for published original articles, review articles and guidelines on critical care management in burns, up to November 2019. Our search was limited to articles in English. Correspondence, dissertations and unpublished materials were not considered. The information were summarised and presented qualitatively (narratively) under subheadings.

#### **Contents:**

Fluid resuscitation in severe burns

Goal-directed fluid therapy and Haemodynamic monitoring

Evidence on choice of fluid for resuscitation

Management of coagulopathy in severe burns

Thromboprophylaxis in burns

The role of suppressing hypermetabolism in severe burns

Glycaemic control in severe burns

Nutritional support in severe burns

Sepsis and infection control in burns

Management of inhalational injuries and acute respiratory distress syndrome (ARDS)

Early surgical debridement and soft tissue cover

Pain management in severe burns

Palliative care in severe burns

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## Fluid resuscitation in severe burns

The patients with severe burns receive a large volume of fluid in the first 24 hours compared with any other trauma patients due to the pathophysiological processes involved. The initial burn shock results due to a combination of hypovolaemic shock and cell shock. In addition to the local increase in vascular permeability in affected tissue, the inflammatory mediators such as Nuclear factor κB, tumor necrosis factor (TNF- $\alpha$ ) and other cytokines released by burned tissue causes sequestration of leucocytes and other inflammatory cells. These cells act as a major source of proinflammatory mediators and initiate a major systemic inflammatory response syndrome, increasing the vascular permeability in both the affected and healthy tissue throughout the body [3]. The cascade of events leads to increased fluid shift from the intravascular compartment to the interstitial space causing oedema, haemoconcentration and hypovolaemia. In addition, the cytokine storm produced by the inflammatory response results in decreased vascular resistance due to vasodilation and decreased cardiac contractility, contributing to shock. Furthermore, the severity of the inhalation injury also impacts the fluid requirements and the prognosis.

The Parkland formula is widely used for initial fluid resuscitation in the burns patient. According to the American Burn Association guidelines the formula was revised to 2-4 ml of Ringer's lactate (RL) solution per kilogram of weight per percentage of burned body surface area in adults [4]. The primary objectives of fluid resuscitation are preserving and restoring tissue perfusion and preventing ischaemia. However, this is challenging due to the worsening oedema and transvascular displacement of fluids during resuscitation [5, 6]. Although the Parkland formula is utilised, the volume of fluid has to be adjusted according to the urinary output and other parameters leading to considerable variations in the fluid administered. A study by Ete et al has shown significant differences in the fluid administered based on urine output and the fluid calculated by Parkland formula [7]. The imprecise body surface area calculations and variations in fluid shift may contribute to this discrepancy. Suboptimal resuscitation leads to increase of burn depth and prolongs the shock period resulting in higher mortality [1, 6].

## Determining the initial amount of fluid therapy

As the volume of fluid during resuscitation is proportional to the extent of burns, the severe burns are the most challenging to treat [8]. In many units, severe burns is arbitrarily categorised as involvement of at least 20% of body surface area excluding superficial burns because, strict monitoring and intravenous fluid resuscitation is needed in such patients [9]. In severe burns, selecting the appropriate choice of fluid is essential in determining the outcome and incorrect

replacement may lead to a series of complications [8].

# Goal-directed fluid therapy and Haemodynamic monitoring

Goal-directed fluid therapy has become as essential concept in initial fluid resuscitation in severe burns and for critical care in general. Patients with severe burns require a large volume of fluid in resuscitation. This may not be well tolerated and may contribute to complications such as ileus, abdominal and extremity compartment syndromes, respiratory complications such as pulmonary oedema and adult respiratory distress syndrome (ARDS), and also generalized oedema [1]. Therefore, many studies have been conducted to identify feasible targets to guide fluid resuscitation. Furthermore, studies have shown that the vital signs and the urine output showed minimal variations after fluid resuscitation, however significant changes were noted in other parameters such as those measured by pulmonary artery catheterization (PAC). Therefore, vital signs alone was found to be inadequate to guide the adequacy of fluid resuscitation in critically ill patients [10].

Therefore, cardiac output has become an important parameter to guide volume resuscitation, however only less than 10% of specialised burns units utilise this parameter as PAC is required for its measurement [11]. Several studies have attempted to find non-invasive alternatives to PAC in fluid resuscitation based on goal directed therapy. However in the past, the applicability and validity of the novel alternatives in burn resuscitation have been questioned. Therefore, further studies were conducted for validation, identification of end points and the relevance in terms of improving outcomes [12]. Several techniques have been identified as useful or potentially useful monitoring parameters for guided fluid therapy in burns. Oesophageal echo-doppler monitoring was found to be a useful adjunct to clinical judgement in severe burns [13]. Transpulmonary thermodilution is one such noninvasive method that has been validated in burns [14]. Other methods include extra-vascular lung water, intrathoracic blood volume, pulse contour cardiac output (PiCCO), arterial waveform monitoring (LiDCO) devices and bioimpedance spectroscopy [1, 12, 15, 16] (Figure 1). However, certain studies have shown that use of arterial waveform monitoring devices such as LiDCO systems had lower fluid requirement than what was calculated by Parkland formula [12, 17]. Therefore, there is a discrepancy in the amount of volume between the Parkland formula and certain monitoring parameters (Figure 1) [12].

Although the majority of the studies showed the need of a more intensive initial fluid resuscitation compared to the Parkland formula to improve the pre-load factors such as cardiac index, venous oxygen saturation and oxygen delivery,

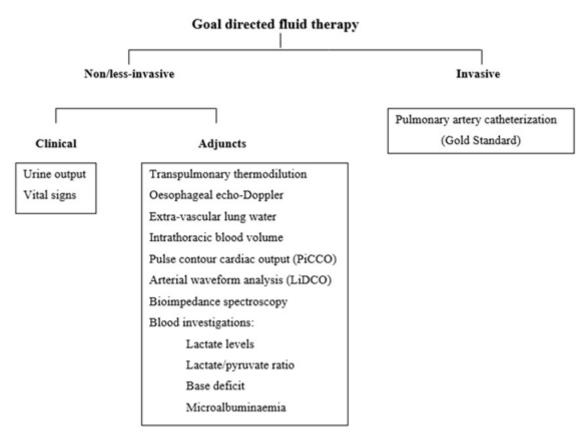


Figure 1. Goal directed fluid therapy in severe burns

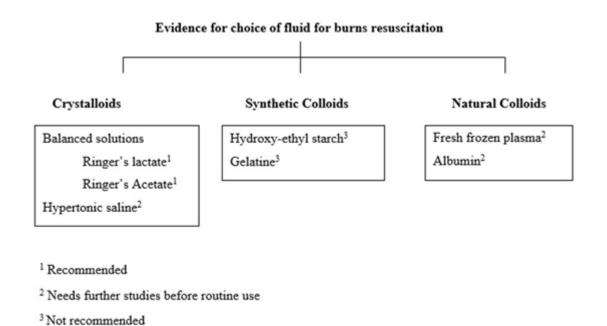


Figure 2. Evidence for choice of fluid in burns resuscitation

the achievement of normovolaemia was challenging [1, 12]. Therefore, normovolaemia may not be the main goal to achieve, and overzealous fluid resuscitation and trying to normalise the haemodynamic parameters should be avoided.

According to the recent systematic review on fluid resuscitation, the non-invasive alternatives to PAC have a reasonable role in initial fluid resuscitation in burns [12]. However, it is important to note that the studies included small sample sizes and based their conclusion on short-term haemodynamic parameters rather than long term outcome. To date, the impact of these monitoring parameters on patients' survival has not been determined. It is important to note that, most centres managing critically injured burn patients, especially in developing countries do not have these sophisticated resources to guide goal-directed fluid therapy techniques. Therefore, these centres reply on basic haemodynamic and biochemical parameters to guide fluid resuscitation.

Several metabolic factors have also been analysed in burn patients. Some variables such as lactate levels, the lactate/pyruvate ratio, the base deficit, and microalbuminuria were shown to be useful as prognostic markers and may be useful to guide initial resuscitation [12, 18]. However, the evidence to support routine use of these parameters is not available [18]. Therefore, fluid resuscitation in severe burns should ideally be performed as goal-directed therapy with thermodilution methods as they have been validated in burns and are less invasive than PAC [12].

# Evidence on choice of fluid for resuscitation

Crystalloids are the fluids of choice in initial burn resuscitation although, the volume retained in the intravascular compartment and the subsequent volume expansion is lower than colloids [8]. That is because the increased capillary permeability during the initial period will cause the colloids to pass through capillaries to the interstitial space and exert a deleterious oncotic effect and paradoxically reduce the intra-vascular fluid volume and worsen the oedema [19]. Despite the recent studies which claim that the increased vascular permeability is relatively short lasting (from 2-7 hours post-burn), the use of colloid in burns remains controversial [12].

According to the studies published on crystalloid-based fluid therapy in various types of critically ill patients, balanced solutions were superior to unbalanced crystalloids, due to the multiple adverse effects identified with saline solutions [20]. However, these studies include other critically ill patients and the studies on severe burns patients are limited and therefore, the question arises whether these can be extrapolated to burns patients. By definition, the Parkland formula is calculated for

Ringer's lactate (RL), and therefore has been the fluid of choice in burns [21]. The study by Oda et al compared RL with hypertonic lactated saline in severe burns and found that lactated saline group needed significantly lower amount of fluid and had lower peak abdominal and inspiratory pressures [22]. Furthermore, abdominal compartment syndrome was seen in 14% of patients in the hypertonic lactated saline group in comparison to 50% in the RL group [22]. Gille et al compared RL with Ringer's acetate and found Ringer's acetate to be superior in terms of lower organ failure assessment scores, requirement of smaller amount of colloids, packed cells and plasma infusion, shorter duration of hospital stay and mechanical ventilation. However, there was no difference in the volume of crystalloid infused and the mortality [23].

As balanced solutions have been proven to be superior for critically ill patients, Ringer's acetate seems most suitable for large replacement in burns patients based on the above study. However, further studies are needed to compare RL and Ringer's acetate in burns patients due to the methodological weaknesses in the available studies. Although hypertonic solutions may be useful in burn resuscitation, the analyses by the Cochrane systematic reviews, and USA guidelines have shown no clear benefit in terms of efficacy and therefore, further studies are required before routine use can be recommended [24].

Colloids are controversial in the management of burns especially after the recent warning regarding the use of Hydroxy-ethyl starch (HES) in critical ill patients including severe burns. Colloids contain macromolecules and possess a greater volume expanding effect than crystalloids [25]. They consist of either synthetic (HES and gelatine) or natural (plasma and albumin) components [25].

After the HES warning, the gelatins were the only available synthetic option for burns though the expansion capacity is inferior and short lasting (1 hour) [26]. However, there are no studies ensuring safety in burns patients and meta-analyses showed no advantages in using gelatin over crystalloids [26]. Therefore the use of gelatins in burns remains controversial and routine use is discouraged [26].

Several reviews have shown that HES use in critical care including burns had a higher risk of mortality and kidney injury as opposed to other resuscitation fluids [12]. However, due to the methodological concerns, a randomized trial comparing mixed resuscitation therapy (HES plus RL) and crystalloids alone (RL) was performed. In that study, no differences were found in the mortality, volume of fluid administered, or kidney injury between the groups [27].

Of the natural colloids, fresh frozen plasma has been used as

plasma expanders however, the risk of transmission of infections has discouraged its use in fluid resuscitation and it is mainly used when there is associated coagulopathy [28]. Also the activity based cost of fresh frozen plasma per each unit is around 410 USD in the United States [29] Although studies have shown benefits of using plasma in burns in terms of lesser resuscitation volume and lower abdominal compartment pressures, the sample size was very small. Therefore, larger studies are needed before considering routine use in burns patients [12, 28].

The use of albumin for fluid resuscitation in burns patients have been assessed by multiple studies and have shown conflicting results [12]. However, the recent meta-analysis of clinical trials in 2014, found that albumin was associated with a lower incidence of compartment syndrome and mortality [30]. Therefore, both albumin and plasma may be a suitable option for burn patients, however the lack of large scale clinical trials restrict their routine use [12] (figure 2).

## Management of coagulopathy in severe burns

Similar to major trauma, coagulopathy is also associated with severe burns. The coagulopathy interferes with proper surgical debridement and repeated surgical debridement causes more bleeding and worsening coagulopathy. The coagulopathy is a combination of procoagulation, antifibrinolysis and impaired activity of anticoagulation systems of the body [31]. This process is associated with

thromboembolic complications, multi organ failure and increase in morbidity. Moreover, coagulopathy was recently identified as an independent predictor of mortality within 28 days in patients with severe burns [32]. Pathophysiology of the coagulopathy includes dilution of factors by fluid resuscitation, hypothermia, endothelial injury, burn wound excision causing bleeding and activated systemic inflammatory response [33]. In burns, the evidence and recommendations for targets in management of coagulopathy are lacking. An international survey on coagulopathy in burn patents showed that although this entity is recognized, there is lack of specific treatment among physicians [34].

The management of coagulopathy includes, general measures for minimizing triggers and specific treatment depending on type of coagulopathy. Minimizing triggers includes, prevention of tissue hypoperfusion by goal directed fluid management, avoidance of hypothermia, and prevention of excessive blood loss during surgical treatment. Specific treatment and interventions may be directed towards anticoagulation or procoagulation depending on the type of coagulopathy. Treatment with antithrombin, activated protein C, and tissue factor pathway inhibitor have not shown any benefit[35]. Newer options like recombinant activated factor VIIa have been studied in reduction of perioperative bleeding in burn wound excision but the associated arterial thrombotic events hinder its use [36] (Figure 3).

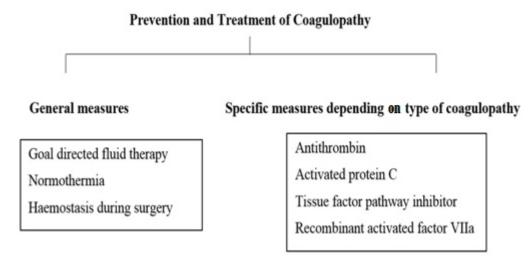


Figure 3. Prevention and treatment of coagulopathy in severe burns

All authors disclose no conflict of interest. The study was conducted in accordance with the ethical standards of the relevant institutional or national ethics committee and the Helsinki Declaration of 1975, as revised in 2000.

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# REVIEW ARTICLE

# Consensus on peri-operative surgical practice during the COVID-19 pandemic: an appraisal of the literature

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Keywords: Surgery; surgical practice; COVID-19; pandemic; SARS-CoV-2; review

#### Abstract

The coronavirus disease-2019 [COVID-19] pandemic is an ongoing pandemic caused by severe acute respiratory syndrome-coronavirus-2 [SARS-CoV-2]. Although COVID-19 pandemic is not a direct surgical problem, its impact on the surgical units has been substantial. Many operations have been cancelled or deferred due to the risk of disease spread and staff shortages. Operating theatres are identified as areas of the high risk of disease transmission due to aerosol generation during the surgical procedures and prolonged patient contact. Resource limitations, including lack of personal protective equipment [PPE] and limited availability of testing, continue to expose the surgical community to COVID-19. In this review, evidence and consensus guidelines on surgical practice during the COVID-19 pandemic are summarised and described. Immediate action is deemed essential to ensure the unhindered provision of surgical care while optimizing the use of limited resources and ensuring staff safety.

# Introduction and Background

In late December 2019 hospitals in Wuhan, China reported an outbreak of pneumonia of an unknown cause [1]. Later in January 2020, a novel coronavirus strain [SARS-CoV-2] was isolated from the suspected patients. Despite the early recognition and the public health measures, the infection spread rapidly across China and then the rest of the world. The World Health Organization [WHO] declared the outbreak as a Public Health Emergency of International Concern [PHEIC] on January 30th, 2020 [2].

Although COVID-19 is not a primary surgical problem, its impact on the surgical units has been considerable, which to some extent could be viewed as a mass casualty incident with a global impact. With human and financial resources overwhelmed, the rational use of available surgical resources

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has become a matter of utmost importance. The main threats of COVID-19 to the surgical community are related to; staff management, halting elective procedures, effective triaging of overwhelmed resources, practising precautions to combat the high risk of transmission and social distancing at the workplace.

The objective of this review is to summarize and describe the current evidence and consensus guidelines on surgical practice during the COVID-19 pandemic.

# Preoperative preparation and general precautions

Managing logistics to provide continuous optimum patient care should be the goal in all surgical centres. In scheduling patients for surgery, evaluating the individual patient's risks of infection versus consequences due to delay in the procedure should be considered. During the decision making, it is also important to consider the availability of resources such as personal protective equipment [PPE], staff and other medical and logistical concerns [3]. The Royal College of Surgeons of England recommends considering the logistical capacity determined by the theatre manager, the risk to patient outcomes due to the delay determined by a surgeon in the relevant speciality balanced with the capacity of the institution to manage an outbreak. This triage should be based on a real-time data-driven assessment [4].

Wearing adequate PPE should be considered in all situations involving patients confirmed or suspected to have COVID-19. The American College of Surgeons has published a set of guidelines on the use of PPE in the operating room [OR] in line with the Centres for Disease Control and Prevention [CDC] recommendations for the use of PPE for healthcare personnel [5, 6]. In addition to asymptomatic carriers of COVID-19, as the incubation period of the virus may be as long as 14 days, asymptomatic infected individuals also may pose a threat to health care personnel. It is recommended to wear N95 respirators in the OR since standard surgical facemasks are inadequate to protect against virus transmission from aerosol-generating procedures. Depending on the logistic constraints, institutions may implement policies on extended use or limited reuse of N95 respirators to ensure adequate supplies at times of peak demand. Such limitations may prioritize the personnel having the highest

risk of exposure as recommended by the CDC and the American Society of Anaesthesiologists [6, 7].

The Secretary-General of the WHO emphasized on the importance of testing during the pandemic where he said "You cannot fight a fire blindfolded. Our key message is test, test, test," [8]. Therefore, it is important to consider the preoperative testing of patients undergoing surgery. Priority needs to be given to patients having suspicious symptoms, evidence of respiratory illness, high risk due to contact history and in patients from areas of outbreaks. Although surgeons are encouraged to request testing in patients scheduled for surgery, this must be balanced with the capacity for COVID-19 testing and potential risk of COVID-19 in the community.

The available tests for COVID-19 include nucleic acid amplification tests for viral RNA using reverse transcription-polymerase chain reaction [RT-PCR] and serology for antibody detection which includes detection of IgM, IgA, IgG or total antibodies [9]. Studies have suggested that most COVID-19 patients seroconvert within seven to eleven days although, some may develop antibodies sooner. Antibody testing is used to identify individuals who were previously infected and recovered as well as individuals who may be immune to COVID-19 [9].

Hospital environment itself may spread the disease to patients awaiting surgery, who in turn may spread the disease among other patients and healthcare staff. This risk will be greater among patients with prolonged hospital stays due to potential cancellations leading to delays in surgery. Therefore, ideally, all patients should be screened with the gold standard test [RT-PCR] 24-hours before the procedure with or without an antibody test, followed by isolation until surgery [9]. If they test positive for PCR, public health protocols for COVID-19 should be followed and the surgery postponed in case of routine surgeries. If positive for only the antibodies, they will require further testing to confirm complete recovery from COVID-19. If negative for both the PCR and the antibody screen, still they may require weekly PCR during the hospital stay and be discharged after undergoing a PCR for confirmation [9]. However, such repeated investigations would be a major burden to many resource-limited settings in developing as well as developed countries during the height of the pandemic.

Forrester et al, have recommended assuming all patients undergoing emergency procedures to be infected and appropriate safety precautions be practised. All aerosolgenerating procedures of the upper aero-digestive tract as well as endoscopy, open or laparoscopic bowel surgery are included into the high-risk category, given that the virus may survive in the gastrointestinal tract [10, 11]. As aerosolization

of the virus may occur through exhaled gases, it is advised that even when a procedure is performed under deep sedation, to avoid the use of high flow oxygen and, if feasible the patient to wear a surgical face mask throughout the procedure [12]. When a patient is proven to be positive, after the approval of the surgical and the anaesthetic teams, the surgery could proceed with precautionary measures with all members of the teams wearing appropriate protective attire as recommended by the CDC. For patients who test negative by RT-PCR, the team members may use standard surgical attire [6, 10].

Practising social distancing and avoiding public gatherings at the workplace should also be practised as recommended by the CDC to contain the possible spread of the virus within the working environment [13]. Segregating staff between hospitals is an important measure which would also prevent cross-infection among hospitals. Resorting to webconferencing instead of large meetings is recommended and should be implemented. Recording attendance at small group staff meetings would further help contact tracing in the event of an outbreak [14]. Furthermore, it is important to develop a pandemic preparedness protocol in collaboration with surgeons and anaesthesiologists with the involvement of infection control experts which should be incorporated into the routine hospital management plan. Staff training should be considered an immediate priority with effective communication between the hospital's central command team and all surgical teams [15]. In addition to these, Brindle et al had suggested having a clear plan in place for essential surgeries, limiting staff to only the essential number, and having a dedicated operating area for suspected COVID-19 patients [16].

## Theatre setting during the COVID-19 pandemic

Due to the highly contagious nature of the virus and its spread through fomites, it is necessary to have designated ORs for COVID-19 patients undergoing surgery. Choosing an OR near the entrance of the theatre block would minimize the potential for contamination of other theatres [17]. Patient transport to the theatre block is recognized to be associated with a high risk of disease transmission. It is recommended to have a short pre-determined path for transport, avoiding any public areas and areas with non-infected patients as much as possible. The personnel transporting the patient should be equipped with adequate PPE and should have had training in handling high-risk patients. Furthermore, the patient should wear a facemask ideally an N-95 as a precaution. The environmental surfaces coming in contact should be immediately sanitized before and after patient transport. It is useful to have a dedicated team to handle sanitization. Having the same personnel handle a single patient will be beneficial in effectively managing resources. Furthermore, bringing nonessential items to the OR should be avoided. All disposable items should be discarded after a single case, traffic in and out of the theatre should be minimised, a dedicated recovery area should be allocated for suspected patients, or patients may be recovered within the OR itself [16]. Where possible, the duration of the case could be shortened to decrease staff exposure [16].

Standard ORs are designed to have a positive pressure environment. However, during the pandemic, it is ideal to have a negative pressure environment with a high [25 per hour] frequency of air changes which will minimize dissemination of the virus from the OR. Measures should be taken to limit the flow of contaminated air out of the OR through only one outlet. A designated workflow should also be established with coordination of the staff while allocating a separate anesthesiologist for the designated OR with the allocation of a separate area for donning and doffing of PPE as recommended by the CDC [18]. Furthermore, strict infection control practices and decontamination procedures including routine checks and cleaning of the anaesthetic machines and powered air-purifying respirator [PAPR] sets are necessary [14]. Where feasible, it is advised to discard the anaesthetic breathing circuit and the canister of soda lime to avoid potential cross-contamination [19]. High-efficiency particulate air filters [HEPA] should be used in the anaesthetic machine at the patient's end and between the anaesthetic machine and the expiratory limb of the circuit [14]. The surfaces of electronic appliances coming into frequent contact with staff can be covered with plastic wrap for the ease of decontamination [14].

Measures such as risk assessment and serology testing of members of the teams working in the OR should be done [20]. Additionally, surgical sections should be ideally divided into two categories, a dedicated section for positive patients which only needs minimum OR and surgical staff and another section dedicated for emergency surgery and urgent oncological surgery and depending on the risk assessment, for other routine surgeries in COVID-19 negative patients [21].

Environmental sanitization, proper waste disposal and linen management after every procedure should be carried out adequately. Maintaining hygiene should be the responsibility of all the individuals of the team. Single use contaminated material should be discarded, and reusable material should be decontaminated and disinfected conforming to the institutional protocols. Wearing full PPE is a must during sanitizing procedures. A dedicated area should be assigned for disposal of waste, and appropriate PPE should be worn in transporting and handling such waste. They should not be placed on floors but in dedicated containers and immediately sent for cleaning minimizing the time left outside the OR [17]. The cleaning of surgical equipment used in procedures of a

COVID-19 positive or suspected patient should be done separately from other surgical equipment [22].

# Elective surgery during the COVID-19 pandemic

Due to the impact of the pandemic on the health system, surgeons witnessed a dramatic change in their practice with decreasing elective surgeries at the outset. General surgeons seemed mostly affected by this due to the diverse procedures they perform. Many countries have imposed regulations limiting elective surgeries to make their acute care facilities function at maximum capacity [23, 24]. Despite the frequently changing guidelines, individual decisions should be taken considering the situation in the locality and consulting an expert panel not limited to surgeons but including nurses, resource managers, hospital administration and epidemiologists. Furthermore, it is important to identify the trajectory of the local COVID-19 disease in guiding these recommendations [25].

A joint guideline had been released with the collaboration of the American College of Surgeons, American Society of Anaesthesiologists, Association of Perioperative Registered Nurses, and the American Hospital Association on resuming elective surgery after the COVID-19 pandemic in the USA. The timing of reopening should be after a sustained reduction of the rate of detecting new COVID-19 cases with the hospitals are no longer using crisis standards of care. They also should have adequate staff, ICU beds, PPE, ventilators and other medical supplies. Patient and staff testing should be freely available and proper protocols should be in place for handling positive patients and staff. Prioritization of cases should be done with a scoring system with identification of essential health care staff for the procedures and their willingness to comply with the increased workload. Strategies should be in place for the phased opening of ORs after identifying the capacity goals. Further, the guidance recommends having institutional guidelines for the five phases of surgical care; preoperative, immediate preoperative, intraoperative, postoperative and postdischarge care planning ensuring the safety of patients and staff. It also emphasises on keeping records to reflect and reevaluate. It is further recommended to expect and be ready for a possible second wave of infection and has plans in hand for risk mitigation [26].

## **Emergency surgery during the COVID-19 pandemic**

Emergency surgical care during the pandemic could be unrelated or directly related to COVID-19. In one hand, emergency surgery may be needed in patients admitted with COVID-19, especially in the ICU they are prone to develop mesenteric ischemia, perforation of hollow viscera and acute limb ischemia [15]. On the other hand, there may be patients with acute surgical problems unrelated to COVID-19

requiring emergency surgery who have concurrent COVID-19 infection [15].

According to the guidelines by the American College of Surgeons, emergency surgical procedures should be undertaken if delaying would likely prolong hospital stay or cause potential harm to the patient. Furthermore, it states that certain surgical conditions may be managed non-operatively or if necessary, in an outpatient setting if possible. These include acute thrombosed haemorrhoids, superficial perianal abscesses, superficial and localised soft tissue infections, uncomplicated appendicitis and symptomatic cholelithiasis. It is advisable to opt for non-surgical interventions [i.e. radiological] in conditions such as acute pancreatitis complicated with necrosis while emergency surgery is mandated in conditions including bowel perforation, intestinal ischemia, and strangulated hernias [27].

Despite the threats posed by the pandemic, trauma patients will require urgent life-saving interventions. This pandemic has hindered the ability of trauma care centres to provide care for the critically injured. Guidelines have been issued on the management for trauma centres during the pandemic. The American College of Surgeons Committee on trauma had proposed a planning process which involves regional planning, hospital planning involving the considerations on ICU capacity and capabilities and training of staff ensuring the protection of both staff and patients.

Furthermore, they recommend strategies that should be implemented at the point of care. The trauma bay should determine a patient's COVID-19 status by an assessment of their symptoms and, droplet and contact precautions should be followed for all patients. The OR should work based on the hospital policy for COVID-19 patients preventing any delays. The hospital should be aware of its ICU capacity and the availability of ventilators. Proper management of limited resources such as blood products and PPE should be done, and hospital policies should be implemented in preserving these. Setting up restrictive transfusion strategies in the ICUs for blood products and encouraging blood donation in the community should be done to conserve and ensure the availability of blood [28].

# **Conclusions and Recommendations**

The COVID-19 pandemic had caused a paradigm shift in the health sector. It has made a dramatic impact on the professional commitments of surgeons in their diverse specialities. Preventing infection in a high-risk work setting and providing optimum care to the patients by managing limited available resources in the facility is challenging. To face this challenge, modifications in infrastructure, strict healthcare policy changes and solid infection control

strategies need to be implemented. This should be done with the involvement of multiple stakeholders including surgeons, anaesthetists, nurses and support staff. Aligning interests of all parties is essential in providing unhindered care at the patients' best interest minimising the risk of viral transmission to other patients and healthcare workers.

# **Conflicts of interest**

In compliance with the ICMJE uniform disclosure form, all authors declare the following: Payment/services info: All authors have declared that no financial support was received from any organization for the submitted work. Financial relationships: All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work.

#### Other relationships

All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

All authors disclose no conflict of interest. The study was conducted in accordance with the ethical standards of the relevant institutional or national ethics committee and the Helsinki Declaration of 1975, as revised in 2000.

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#### List of abbreviations

COVID-19 : Coronavirus disease-2019

SARS-CoV-2 : Severe acute respiratory syndrome-coronavirus-2

WHO : World Health Organization

PHEIC : Public Health Emergency of International Concern

CDC : Centres for Disease Control and Prevention

RT-PCR : Reverse Transcription -PCR Polymerase Chain Reaction

OR : Operating Room

HEPA : High-efficiency particulate air filters
PAPR : Powered Air Purifying Respirator
PPE : Personal Protective Equipment

ICU : Intensive Care Unit

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ANZHPBA: Australian and New Zealand Hepatic, Pancreatic

and Biliary Association

HIPPA : Health Insurance Portability and Accountability act NICE : National Institute for Health and Care Excellence

NHS : National Health Services

ESMO : European Society of Medical Oncology

SAGES : Society of American Gastrointestinal and

Endoscopic Surgeons

FFP3 : Filtering Face Piece-3
USA : United States of America

UK : United Kingdom

### REVIEW ARTICLE

### Surgical management of hepato-pancreato-biliary cancers in Covid-19 pandemic: perspective from the developing world

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Keywords: COVID-19; HPB malignancies; Pakistan

### **Abstract**

Coronavirus disease has dismantled the health care systems in the world and the situation is worse in the developing countries. One of the biggest challenges faced by clinicians in this situation is the optimal management of cancer patients. Hepato-pancreato-biliary [HPB] malignancies are the most aggressive cancers among other gastrointestinal cancers. Timely surgical intervention is the only cure for resectable tumours. However, resource limitations in hospitals, economic crisis and the lockdown in the current pandemic have forced clinicians to choose alternate non-surgical therapies to get temporary control of disease with the hope to provide definitive surgical management once the situation gets better. In this communication, we provide a summary of the management guidelines for HPB cancers and their application in the developing world.

### **Background**

The spread of coronavirus disease [COVID-19] is rapid without respecting any boundaries. The death toll has reached up to 738,000 worldwide and seems to be rising daily [1]. The numbers of infected and critically sick patients are also expected to rise, threatening the lives of many individuals. This pandemic has already dismantled the best health care systems in the world, and they are struggling to cope with the rising trends in the coming days. The current health situation has forced clinicians to make difficult triage decisions to provide optimal health care [2]. One of the biggest challenges faced by clinicians is the optimal management of cancer patients. Unlike other health conditions, cancer care is complex and costly; requiring a multidisciplinary approach. Elective cancer surgeries have been suspended in most of the countries in the developed world due to severe strain on the resources, including ventilators. There are reports that the operating theatres have been converted into intensive care units to accommodate the influx of sick patients infected with COVID-19 [3]. This could result in the progression of cancers

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with subsequent metastasis or obstruction in case of gastrointestinal cancers with an immediate threat to survival.

Hepato-pancreato-biliary [HPB] malignancies are the most aggressive cancers among other gastrointestinal cancers [4, 5]. Timely surgical intervention is the only cure for resectable tumours. However, this pandemic has challenged the provision of cancer care due to competing risks of death from cancer versus death from complications of a deadly virus. Patients with curable cancers may contract COVID-19 during treatment which might offset the advantage of cancer treatment. The study from China reported that cancer patients affected by COVID-19 were more likely to require ventilatory support, intensive care admission and the mortality rate was five times higher than their non-cancer counterparts. [6].

Also, inadequate supplies of personal protective equipment for surgeons and other healthcare providers in the operating room as well as the limited hospital capacity including ICU have contributed to the suspension of elective cancer procedures in both the developed and the developing world. In this communication, we have summarized the guidelines published for HPB cancers in this pandemic situation and their application in the local context of the developing world during this time of crisis.

### Recommendations for the treatment of Hepato-pancreatobiliary malignancies:

HPB malignancies have been notorious for high morbidity and mortality with prolonged hospitalization and readmissions following surgery. The adverse effects are secondary to the technical complexity of operations, cachexia, and malnutrition due to underlying malignancy and age-related comorbidities which may be associated with higher perioperative morbidity in COVID-19 positive asymptomatic patients.

Additionally, these operations have the potential to consume a significant amount of hospital resources. Considering their aggressiveness, managing them according to routine cancer guidelines may pose a huge burden on resources of the hospital in the times of COVID-19 pandemic. Oncology societies around the world have been efficient enough to alter cancer management during COVID-19 pandemic and have

published guidelines for the management of various cancers. This has helped the healthcare providers across the globe to practice oncology efficiently and with uniformity.

Society of surgical oncology [SSO] has referred HPB malignancies as biologically aggressive tumours and not just 'elective' operations. The decision on operating needs to be done according to the input from the multidisciplinary care providers, mode of presentation and biology of the disease, ICU/ventilator bed availability and utilization and the projected number of COVID-19 patients influx. During the acute phase I, when hospital resources including ICU and ventilator are not exhausted, all patients with upfront resectable pancreatic and biliary tumours, and patients who have completed neoadjuvant therapy including those with colorectal liver metastasis should be operated. Neoadjuvant therapy should be considered for newly diagnosed pancreatic adenocarcinoma and large intrahepatic cholangiocarcinoma requiring major liver resection. Similarly, ablation, regional therapy or neoadjuvant therapy should be the initial approach for hepatocellular carcinoma [HCC]. During phase II, when intensive care and operating room resources are restricted, only tumours with gastric outlet obstruction or bleeding which are not amenable to endoscopic intervention, symptomatic hormone-producing tumours like insulinomas and surgical complications not feasible to interventional approach should be operated. All other pancreaticobiliary cases should be offered neoadjuvant therapy and liver tumours should be treated with ablation and locoregional therapies. During phase III, when hospital resources are all directed to COVID-19 patients and intensive care beds and operating room resources are consumed bleeding tumours that cannot be managed with interventional therapy, acute tumour perforation and surgical complications not feasible to interventional approach should be operated [7].

American College of Surgeons has published detailed guidelines for elective cancer surgery during the acute and recovery phase of COVID-19 pandemic. During the phase I, pancreatic and ampullary surgeries should be performed in patients with limited comorbidities with expected short length of stay and utilization of fewer hospital resources. Patients with potentially curable pancreatic cancers with or without neoadjuvant therapy and patients with biliary and gastric obstruction should be operated. All other cases should be offered neoadjuvant therapy and interventional procedures. During phase II, all but emergent lifesaving HPB operations should be deferred due to limited operating room supplies, ICU, and ventilators. Only emergencies associated with these cancers should be palliated with nonsurgical methods. The endoscopic or percutaneous route should be used for biliary drainage in biliary sepsis, endoscopic enteral stenting for gastric outlet obstruction, and radiologic

management for bleeding tumours. All patients with potentially curable pancreatic, duodenal and ampullary cancers should be offered neoadjuvant treatment [8].

European Society of Medical Oncology has recommended surgery for patients with primary or post neoadjuvant resectable pancreatic cancers, and borderline cancers are not fit for neoadjuvant on high priority. For patients with bile duct obstruction in non-resectable or metastatic cancers, cholangitis and bilirubin levels more than 250 µmol, or nonresectable localized cancers allocated to neoadjuvant or palliative treatment should be decompressed endoscopically with biliary stents. High priority should be given to patients with postoperative complications like an anastomotic leak, bleeding and fistulae to offer surgical or image-guided procedures. For HCC, the liver transplant should only be offered to patients with a poor short-term prognosis, a high model for end-stage liver disease [MELD] score and HCC at the upper limit of Milan criteria on high priority. Similarly, surgical intervention with curative intent has been advised for patients with large curatively resectable HCC lesions [9].

Despite these consensus guidelines published by the experts given the current situation, management of HPB malignancies is not straight forward. From a clinical standpoint, aggressive tumour biology, the complexity of procedures with associated high morbidity and mortality, and added risk of becoming affected by a coronavirus and its complications challenge the caregivers to undertake these procedures. There are suggestions that opting non-surgical management like initiating or continuing neoadjuvant chemotherapy for curable cancers can increase the risk of COVID-19 and other infections due to immune suppression [3] with the added risk of disease progression. Another consideration in the management of such patients is the availability of local hospital resources for the evolving situation [10]. Cancer societies have modified their management guidelines regarding the available hospital resources in different phases of the pandemic.

### Perspective from Pakistan

Where COVID-19 has shaken the best health care systems in the world, the situation in developing countries is equally alarming. Unlike other developing countries, where a significant portion of gross domestic product [GDP] is allocated to maintain and improve healthcare, Pakistan only spends two percent of its GDP on health. Per statistics, one doctor is available to treat 1073 people, only one bed available per 1600 people, the number of registered nurses is only 90,000, and approximately 4000 ventilators are available for a population of 220 million [11]. The total number of confirmed COVID-19 positive cases are more than 284,000 till date [12] but the actual number of cases including

asymptomatic patients is still unknown due to lack of testing capacity, and only limited patients are being tested daily [13]. According to experts, the number is expected to peak in the next few months, which is going to increase pressure on an already overburdened health care system.

With relevance to HPB malignancies, only a few centres in the country offer integrated services to the entire population of 220 million, located in three major cities of Pakistan. Given current COVID-19 pandemic, the country has been in a state of partial lockdown for more than four weeks now and hospitals are already overburdened with the influx of COVID positive patients requiring intensive care. This has resulted in a temporary suspension of elective HPB surgeries to provide intensive care beds and ventilators to complicated COVID-19 positive patients [13]. Providing neoadjuvant chemotherapy for operable cancers for disease control to operate them later in such situations is not an easy task either. Lockdown has deprived poor patients of using public transport to reach hospitals, the economic crisis has affected poor patients who can no longer afford expensive chemotherapy and those who can get chemotherapy treatment are at risk of contracting COVID-19 due to immunosuppression.

With the increasing number of COVID-19 cases day by day, the stage of operable HPB malignancies are expected to progress or metastasize due to definitive treatment delays.

In the current situation, the management guidelines for HPB cancers have been modified and the priority is to save lives. Health care system around the world is forced to prioritize treatment and take difficult decisions. Management plans need to be tailored according to available resources by HPB units to deliver the best management to patients in the time of crisis. As the duration of the pandemic is unpredictable and the country is still in phase I of the pandemic, few HPB units in the country should be dedicated to providing definitive surgical treatment to selected patients with limited comorbidities and shorter expected length of hospital stay.

This is particularly applicable to young patients whose survival may be seriously compromised due to delays in the provision of definitive care. It is strongly suggested that the developing countries should focus on developing local guidelines considering the local health facilities and the impact of the pandemic on the health care system. There is a need to have a balanced approach in offering the surgical and non-surgical therapies to HPB cancer patients with involvement of multidisciplinary teams. Due to limited resources compromised by the corona pandemic, only a well thought out approach can help save precious lives in this difficult situation.

All authors disclose no conflict of interest. The study was conducted in accordance with the ethical standards of the relevant institutional or national ethics committee and the Helsinki Declaration of 1975, as revised in 2000.

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### REVIEW ARTICLE

### Minimal invasive surgery during COVID-19 pandemic: A review of current and emerging evidence

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Keywords: COVID-19; laparoscopy; surgical smoke; smoke evacuation; viral transmission

### **Summary**

The COVID-19 pandemic has necessitated restructuring of surgical care globally. Concerns were raised about the continued practice of minimally invasive surgery (MIS) during the pandemic due to risk of viral transmission especially from pneumoperitoneum. As the pandemic progressed, some of the initial recommendations to address this concern were revised and some centres have gradually resumed offering MIS for a select group of patients. This is a commentary on global recommendations and guidelines on laparoscopy since the beginning of the pandemic including eight published guidelines and six original articles. Currently, there is no convincing evidence to support increased risk of viral transmission during minimally invasive compared to open surgery. Laparoscopy is still considered a safe approach during the COVID-19 pandemic when undertaken by experienced surgeons. However, judicious case selection, modification to standard practices with additional safety precautions is universally recommended.

### **Background**

In December 2019, an outbreak of COVID-19, an acute severe respiratory syndrome was first reported in Wuhan, China. Subsequently, it was identified that COVID-19 was due to a novel corona virus named as SARS-CoV-2. On the 11th of March 2020, WHO declared a global pandemic when disease has spread to more than 210 countries and territories [1]. SARS-CoV-2 is a RNA virus, which ranges from 0.06 to 0.14 micron in size, and has been found within the cells lining the respiratory tract from nasopharynx downwards and gastrointestinal tract from mouth to anus. The virus has been found in nasal swabs, saliva, sputum, throat swabs, blood, bile, faeces with multiple modes of viral transmissions [2]. The exponential increase in the number of hospital admissions, particularly those requiring critical care supports including ventilator support required alterations in all aspects

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of medical care delivery. This change was pronounced in surgical care with abolition of all elective and non-urgent surgery initially guided by local hospital policies, mainly to protect and maintain capacity. The role of minimally invasive surgery (MIS) was questioned and the heightened risks of viral transmission during MIS were debated. Since then, the emerging guidelines and national/international policies have largely guided refinement of surgical provisions including the continued offering of MIS during the pandemic.

### **Evolving guidelines on MIS**

The initial response from the Royal College of surgeons (RCS) in United Kingdom was to delay all elective surgery including all non-urgent oncological resections. Further, it was advised against all MIS including laparoscopy, roboticassisted and trans-anal procedures [3]. As a result, most centres across the United Kingdom stopped offering both elective and emergency laparoscopic procedures including diagnostic laparoscopy and laparoscopic appendicectomy. But the updated RCS intercollegiate guidelines on 7th of April considered laparoscopy only in selected individuals where benefits outweigh the risks [4].

Society of American gastrointestinal and endoscopic surgeons (SAGES) and its European counterpart, European association of Endoscopic surgery (EAES) has jointly issued a revised guideline recognising the potential benefits of laparoscopy during the present pandemic [5].

The revised guidelines on safe surgery by the Royal Australasian College of surgeons on 9th of April also recognized no added risk of laparoscopy to the surgical team, however recommended the safe capture of surgical plume during all procedures [6].

Also, a recent U.S. joint professional society statement on minimally invasive gynaecology during the COVID-19 pandemic and the European joint society of gynaecology statements endorsed laparoscopy as a safe surgical approach in the present setting [7, 8].

### Benefits and risks of MIS during the COVID-19 pandemic

Laparoscopy offers faster recovery, reduced post-operative complications and shorter length of hospital stay. Consequently, MIS can potentially increase the hospital bed availability and reduce the risk of transmission of SARS-CoV-2 virus to the patient during the shorter hospital stay [9-12]. Practicing safe distancing among surgical team during operation is also more feasible with MIS rather than open surgery where members standing in proximity [10-11]. At present, there is insufficient evidence to prove MIS specific risk of COVID-19 exposure to the surgical team compared to open surgery [6, 9-12].

But prolong operating times, increase demand for surgical expertise, additional members of staff, complex equipment and increase intra-operative airway pressures exposing to more aerosols are some of the challenges for MIS during the pandemic [9-10]. Irrespective of open or MIS, the highest risk of aerosol generation and consequent viral transmission is during intubation and extubating of airways. Surgical plume generated by various energy devices carry a lesser risk of viral transmission [13]. However, CO2 insufflation which is a unique feature to laparoscopic and other MIS procedures, have been debated as an additional risk for generation and exposure to aerosols. This was largely based on isolation of other viruses such as human papilloma, Hepatitis-B and human immunodeficiency viral particles in surgical smoke and insufflate CO2 during previous studies [14-16]. Recent case reports on isolation of SARS-CoV-2 virus on peritoneal fluid is still to be widely established and multicentre studies are currently underway for more evidence [17].

The proponents of MIS argued that due to MIS being conducted in a self-contained field should in fact reduce any risks of spillage of both generated surgical smoke and contaminated body fluids rather than increase the risk of contamination. This thinking is reflected in the recent American (SAGES), Australasian (RACS) guidelines and consensus statement from association of laparoscopic surgeons of Great Britain and Ireland (ALSGBI) [5, 6, 12]. All advocates the routine use of a safe and effective smoke evacuation system to release the surgical plume during the procedure and to aid the controlled release of pneumoperitoneum at the end of procedure. Commercially available smoke evacuation systems with built in ultra-low particulate air (ULPA) filters can remove particles in air up to 0.1 microns. However, such systems are often in-built or single use, more expensive and not widely available in most settings [6, 10-12, 18].

### Future of MIS during COVID-19 era

Careful selection of patients who would benefit from a surgical interventions than non-operative alternatives, screening of all surgical patients pre-operatively for high risk exposure and symptoms of COVID-19, test to rule out COVID-19 infection high risk patients before any surgical

procedures, minimising theatre staff inside the operating room and the correct use of personal protective equipment (PPE) are some of the considerations that should be given for both open and laparoscopic surgery.

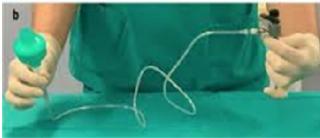
Management of pneumoperitoneum both during and after the procedure, aiming to minimise the risks of viral transmission by aerosol generation require attention to detail and modifications to existing practices. Optimising port incisions to avoid air leak, reducing the number of ports used, use of balloon ports to avoid accidental port displacement, avoiding port exchanges and ensuring function of the valves for reusable ports will all help to reduce inadvertent viral transmission risks. Operating with the lowest possible insufflation pressure with minimal instrument exchanges and judicious use of electrocautery demands a higher skill set, hence in general the most senior and experienced member of the team should provide MIS to increase safety. Controlled and systematic desufflation with suction evacuation of pneumoperitoneum at the end of procedure before conversion to open, removal of ports or specimen extraction reduces the potential risks of inadvertent viral transmission. This process can be mostly reliable with automated insufflation, filtration and air evacuation systems [18, 19]. However, these devices are costly, of single use and are not readily available in all settings, especially in developing countries.

Recently, Mintz et al. published a low-cost alternative for the commercially available smoke evacuation system to safely filter the air during MIS. This international group of surgeons representing the technology committee of the EAES used a heat and moist exchanging breathing filter removed from an ET tube or ventilators, an intravenous tubing set and two 2 connectors to develop the system [19]. The illustration is above with the permission from the authors of the original publication.

For best outcomes this should be connected to the largest port with insufflation inlet, shorter length of tube with tightly fitted connectors and should be used intermittently when smoke build during the use of energy devices and at the end of operation before removal of ports, extraction of specimen or conversion to open, whichever the step is earliest.

Integrating this system with direct, controlled suction of air into trocars and use of filtration face piece (FFP) masks during procedure can achieve comparable safety and efficacy to integrated surgical smoke evacuation systems which are expensive and not freely available. This could be an effective and easily adaptable alternative for surgical smoke and pneumoperitoneum evacuation in laparoscopic surgery during this challenging time in resource limited settings.





- (a) Breathing filter, ET tube connector (ETC), drain tube connector (DTC), IV tubing set and laparoscopic port (cannula) with insufflation inlet
- (b) System made with connecting screwed end of IV tub to insufflation inlet of the port and other end to the small side of ETC using DTC for tight fitting. Larger end of ETC is now fixed into ventilator filter

### Conclusion

With judicious case selection, modification to standard practices with additional safety precautions laparoscopy is still a safe approach during the COVID-19 pandemic.

All authors disclose no conflict of interest. The study was conducted in accordance with the ethical standards of the relevant institutional or national ethics committee and the Helsinki Declaration of 1975, as revised in 2000.

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### CASE REPORT

### Journey of Surgical Mask: from Bra to N 95 in COVID -19

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**Keywords:** Face mask; respirator; aerosol; pandemic; lockdown

### Abstract

The role of the surgical mask during COVID-19 pandemic is undoubtedly very vital in preventing infections. A review of the evolution of the face mask from the animal bladder of the past to the present N 95 is being done with an emphasis on the importance and problems currently faced by the surgical community due to constant wearing of N 95 mask in the hospital. Though N 95 mask is the ideal mask during Coronavirus pandemic, there are a few issues like carbon dioxide retention and headache which is hampering its prolonged use.

### Introduction

### "If I could choose, I would rather save 100 million lives than 100 million dollars " – Peter Tsai ( Brain behind N 95 surgical mask )

In the ongoing COVID-19 pandemic, Facemask is one of the most important parts of Personal Protection Equipment (PPE) for health care professionals in the hospitals and civilians conferring essential services during the ongoing Coronavirus pandemic. Gaius Plinius Secundus of Rome, 2000 years ago, conceptualized the first design of respirator to protect the Roman miners from the toxic dust of red lead oxide and involved using an animal bladder. It is also reported that Leonardo Da Vinci had suggested a respirator made of wet woven cloth to filter out a poison gas weapon he had invented. Thereafter a brief lull, it was in the year 1340 when 'Beak Mask' was used to keep away the stench during the time of Plague. Even today the iconic symbol of Black Death is the Beak Mask. According to the history of Medicine, the invention of the 'Beak doctor' costume is attributed to a French doctor Charles De Lorme, who served as chief physician of three French kings- Henri IV, Louis XIII and Louis XIV. He is credited with the design of the bird mask

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which was to be worn with a large waxen coat as a form of head to toe protection in the year 1619 ('medico della peste costume'). During the bubonic plague when visiting sick patients in quarantine, the special costume was designed for the doctors which included a beak filled with perfumes along with either sweet or strong smelling substances like lavender, along with gloves, boots, hat and official robe made of a particular type of leather made from the skins of goats, sheep, or seals, having irregular creases. (Levantine leather) [1]. It was probably the first step toward the modern-day PPE. Alexander Von Homboldt developed a mask with rubber in 1799 and John Stenhouse discovered that various form of Charcoal could capture and hold gas, thus pioneering activated charcoal filter. John Scott Haldane developed the first gas mask, that could protect against Chlorine gas attack during the war. In 1897, doctors started wearing the first surgical masks, a glorified version of handkerchiefs.

### The arrival of the modern mask

The cloth face mask was designed by Wu Lien-teh in 1910 when a contagious pneumonic plague was ravaging northeastern China. Wu Lien-the, a Cambridge scholar concluded that the disease is airborne and so he adopted the technique to wear mask using layers of cotton and gauze, a procedure he had seen in England. During Manchurian plague outbreak, Wu was able to conduct the epidemic's first postmortem (usually banned in China at that time) on a Japanese woman who had died of Plague and was able to identify the organism responsible, Yersinia pestis. Wu was able to convince the Russian as well as the Japanese authorities to strictly cremate the dead and also recommended cancelling trains, thereby isolating Manchuria and thereby preventing the spread of the disease.

He was able to initiate the concept of first-ever modern-day 'lockdown'. Having concluded with the autopsy that the Plague was spreading by air, Wu advocated the use of a surgical mask. One French doctor Dr Gerald Mesny dismissed his mask with this racist comment, "What can we expect from a China man?" Mesny went on to work without a mask, caught the plague and succumbed to the disease shortly after [2]. It is believed that the present N95 mask is a descendent of Wu's design.

### The arrival of N 95 mask

In 1961, 3M released bubble surgical mask, the design took inspiration from the moulded cup of a bra.

In 1992 Peter Tsai from Taiwan lead a team at the University of Tennessee and attempted to develop the electrostatic filtration technology. It was a successful research and led to the creation of N 95 face mask. Tsai used a method called corona electrostatic charging in producing the N 95 masks, whose filters help block and contain a minimum of 95 % of all particles. Tsai retired from the University of Tennessee in 2019. However, with the single-use N95 masks in short supply due to the COVID-19 coronavirus pandemic, he came out of retirement to study ways in which to disinfect the masks so that they could be safely reused. Maha Krishnamurty, Vice President of the University of Tennessee Research Foundation told Tsai once "You seem to be the man of the hour" and Tsai replied, "No, I am the man of the minute!"

While Tsai's friends have joked that he could be making a fortune, now that his expertise is in such high demand, he said that money has never been his primary motivation. He said "The front line hospital workers – they are heroes. I am just trying to help them wear the mask".

### The saga of N 95 mask

In 1972, the first single-use N 95 "dust" respirator was developed by 3M.

The 'N' in the respirator name denotes 'not resistant to oil' and '95' means the ability to remove 95% of submicron (0.3 microns) particle-like influenza virus, dust, pollen, haze and smoke. Initially, N 95 mask was used in the industrial sector in the 1950s to prevent getting black lung disease during coal mining. Its use as a mask in medicine was established during the 2009 H1N1 pandemic. Currently, N 95 mask is one of the main armamentariums of PPE for the health care workers working in this pandemic. It has been documented that the nanoparticles which mainly travel by Brownian motion, are effectively captured within the N95 filter via mechanical and electrostatic forces, even though viral particles are sometimes smaller than this. The outer side of the mask material is typically hydrophobic polypropylene.

The most useful aspect of the N95 mask is its. extended use. It can also be reused but re-processing of masks all invariably does affect the filtration capacity of the mask. N95 respirators can be decontaminated and re-used in times of shortage for up to three times by using Ultraviolet radiation (260-285 nm) and vaporized hydrogen peroxide, and up to two times by dry heat [3].

### Problems with N 95 mask

### "N 95 masks are a pain to wear" – Elon Musk (Tesla and Space X CEO)

In a controlled clinical study, it was seen that those who were wearing N 95 mask, their effect on pregnant healthcare workers lead to the impediment of the gaseous exchange and it led to an additional workload on the metabolic system [4]. Wearing N 95 mask for a long duration may induce physiological stress which can make regular tasks difficult and may cause a headache amongst health care providers, due to the respiratory microclimate change surrounding the mask [5]. It was seen that the nasal resistance was not recovered even after 1.5 hours removal of the facemask. As compared to the surgical facemask, N95 respirator does cause a higher post-wearing nasal resistance with different recovery routines. The use of N 95 respirator by professionals for more than 4 hours resulted in tiredness and fatigue, increased PaCO2 and decreased SpO2 with resultant overall discomfort. It is mandatory in the current scenario that the people with chronic obstructive respiratory disease, cardiac ailment, or any other chronic medical conditions that make breathing difficult should check with their physician before using an N95 mask.

### N 95 and Surgeons

Though not many studies are available in the journals regarding the difficulties the surgeons are facing while operating with N 95 mask along with PPE for long hours in the ongoing pandemic, the increased effort of breathing with discomfort and headache is being commonly reported. Moreover, spectacle glass misting up is also a vexing problem. The fogging effect of N95 mask is not only a tiring nuisance but even incapacitates the surgeon during surgery which can lead to a surgical error while surgery. It is recommended to wash the spectacle with soapy water before use when used with N 95 mask. Washing leaves behind a thin surfactant film that reduces the surface tension. As a result, the water molecules spread out evenly into a transparent layer, reducing the misting or fogging [6]. The surgeon must be cleanly shaven wherever the N 95 respirator comes in contact with the face as facial hair interferes with the seal of the N 95 to the face. According to the Leo Yee Sin, Executive Director, National Centre for Infectious Diseases Singapore "If you find the N95 mask easy to breathe in and comfortable, you are wearing it wrong and it is no use... you think you are protected, but you are not." This comment holds good each time one wears N 95 mask and has been felt by all medical professionals universally in this pandemic.

### Conclusion

Masks have evolved from being just a barrier to foul smell to filters of microscopic dust and pathogens. There are different materials of mask for different settings. In the operation theatre, where procedures are high aerosol-generating, surgical masks along with N95 mask is the present recommendation. Though highly effective, the use of the N95 mask along with suffocating PPE, makes the surgeon's life miserable in today's scenario. Not able to breathe with rising PaCo2 and decreasing SpO2 levels, with headaches can potentially lead to many cognitive errors in surgery. Advances in mask technology that would help the surgeon breathe better and restore the joy of operating are eagerly awaited.

All authors disclose no conflict of interest. The study was conducted in accordance with the ethical standards of the relevant institutional or national ethics committee and the Helsinki Declaration of 1975, as revised in 2000.

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### CASE REPORT

### Rapid development of recurrences after partial nephrectomy for papillary renal cell carcinoma initially presented as Wunderlich syndrome

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**Keywords:** : peri-renal haematoma; renal tumour; papillary renal cell carcinoma; Wunderlich syndrome

### Introduction

Renal cell carcinoma (RCC) represents 2-3% of all malignancies. It is the commonest solid lesion of the kidney and accounts for 90% of all kidney malignancies. Even though RCC classically presents as a triad of flank pain, haematuria and palpable mass, with the availability and common use of imaging techniques, more than 50% are diagnosed incidentally. Nephron sparing surgery in the form of partial nephrectomy is recommended for early renal tumours to avoid long term renal insufficiency. Rarely RCC presents as a spontaneous renal haematoma (SRH) in subcapsular or peri-renal spaces which are known as Wunderlich syndrome [1]. In such situations whether nephron-sparing surgery is an oncologically adequate option is unknown.

### **Case presentation**

A 40-year old man with sudden onset left loin pain was admitted to the emergency department. Severe, continuous and non-radiating pain was associated with vomiting and dizziness. There was no history of even trivial trauma. The patient was not known to have medical illnesses including diabetes mellitus, hypertension or hypercholesterolemia and family history was unremarkable. He was a cigarette smoker with 20 pack years. His BMI was 29.6kgm-2. Pulse rate was 88bpm and BP was 150/90 mmHg. Abdominal examination was normal except for left renal angle tenderness.

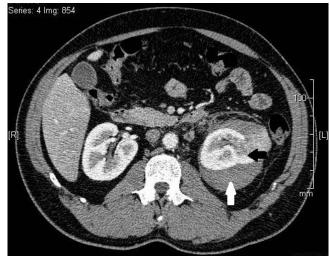
Haemoglobin level was 11.3 g/dl and serum creatinine were 95.3  $\mu$ mol/l. Abdominal ultrasonography revealed a mass in the left kidney with a peri-renal haematoma. A CT urogram confirmed the peri-renal haematoma. There was an underlying heterogeneous, exophytic mass measuring 4.8 cm with little contrast enhancement in the lower pole of the left kidney (Figure 1a). There was no fat in the mass to suggest an angiomyolipoma.

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**Figure 1a.** CT Urogram showing left renal mass (black arrow) and peri-nephric haematoma (white arrow)

**Figure 2a.** CT urogram showing the tumour recurrence in the remaining kidney (arrow)



Figure 1b. Histology of the tumour showing papillary type II renal cell carcinoma. (H&E x200)

**Figure 2b.** CT Urogram showing the recurrent tumour in the abdominal wall (arrow)

He was managed with analgesics, bed rest, intravenous fluids and closely monitored for early detection of haemodynamic instability. Size of the haematoma was assessed with regular ultrasound scans but was not progressing. As the CT scan was suspicious of malignancy and the RENAL nephrometry score

was 6, partial nephrectomy was planned. During the surgery tissue planes were not clear and the organized blood clot was evacuated exposing a solid exophytic mass of the underlying kidney. As planned, partial nephrectomy was performed.

Histopathological assessment of the tumour revealed a papillary type II renal cell carcinoma with a diameter of 4.5 cm extending up to the renal capsule without infiltration (Fuhrman grade 2, T1b stage) (Figure 1b). The closest resection margin was 4 mm from the tumour.

Seven months later the patient noticed a lump deep to the surgical scar. A CT Urogram showed a recurrent tumour in the remaining kidney as well as multiple metastatic deposits in the liver and subcutaneous tissues beneath the surgical scar (Figures 2a & 2b). He underwent completion nephrectomy and excision of subcutaneous nodules. The histopathology confirmed those to be recurrences of a papillary type II renal cell carcinoma. Thereafter he was treated with pazopanib orally. Eight months later he died of widespread metastases.

### **Discussion**

Spontaneous renal haematoma (SRH) was originally described by Bonet in 1700 and further explored by Wunderlich in 1856. It is a rare condition in which there is haemorrhage into the subscapular or peri-renal space in the absence of trauma [1,2]. Acute flank pain, internal bleeding and abdominal tenderness are described as the classic presentation of SRH (Lenk's triad). Nevertheless, abdominal pain, haematuria and hypovolaemic shock were observed more commonly [2].

According to a meta-analysis involving 165 patients with spontaneous peri-renal haemorrhage, 61% of SRH were caused by neoplastic lesions while the rest were vascular, infections and idiopathic in origin [3]. Benign and malignant neoplasms contributed equally, commonest being angiomyolipoma and RCC respectively. However, the prevalence of spontaneous renal haematoma as a complication of tumours low. It is around 1% in renal cell carcinoma and much higher in angiomyolipoma [3]. The extensive necrosis regularly found in papillary renal cell carcinoma can cause rupture of the tumour followed by haemorrhage [4]. It could be spontaneous or follow minimal trauma.

The rarity and nonspecific presentation of Wunderlich syndrome possess a challenge when arriving at a diagnosis. CT urogram is considered the gold standard for establishing the diagnosis, and often useful to elucidate the underlying aetiology. The main criterion for diagnosis is bleeding in the sub-capsular and peri-renal space [5]. However current studies have shown that the diagnostic accuracy of RCC by CT is reduced to 60% when presenting with haemorrhage

which is above 90% otherwise [5].

In general, papillary renal carcinoma has a better prognosis than clear cell variety and has a five-year cancer-specific survival rate of 80.5% though type II variety as in this patient has a poorer outcome than type I [6]. Despite that, the patient developed local recurrences and metastases within seven months. Therefore, in cases of peri-renal haematoma due to possible tumour rupture at the time of presentation, partial nephrectomy appears to be inadequate with the potential for tumour dissemination and seedling. Radical nephrectomy could be considered a more appropriate therapeutic option which may reduce the chances of local recurrences in such cases. In these cases, though there is no microscopic evidence of tumour infiltrating the renal capsule and invading the perirenal fat, staging the tumour as T1 may be an underestimation.

### Conclusion

In conclusion, though renal cell carcinoma can be diagnosed by CT urogram preoperatively with high accuracy, the sensitivity of the test falls to around 60%, in the presence of a peri-renal haematoma. Hence in cases of spontaneous perirenal haematoma, it is important to entertain the possibility of a malignant cause to avoid undue delay in treatment. In cases of peri-renal haematoma due to underlying malignancy, partial nephrectomy appears to be inadequate as it may predispose to tumour dissemination and local seedling.

All authors disclose no conflict of interest. The study was conducted in accordance with the ethical standards of the relevant institutional or national ethics committee and the Helsinki Declaration of 1975, as revised in 2000.

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### **Learning Points:**

- Underlying malignant pathology should be considered in a spontaneous renal haematoma.
- Radical surgery is recommended for RCC presented with peri-renal haematoma.

### CASE REPORT

### Granulomatous inflammation of gall bladder mimicking an impacted common bile duct stone

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**Keywords:** Granulomatous inflammation; tuberculosis; gall bladder; impacted CBD stone

### Introduction

Although intrabdominal tuberculosis is common in developing countries (reported incidence is 12%), it rarely involves the biliary system [1]. Clinical presentation is usually nonspecific [1-3]. Radiological findings of the gallbladder may raise the suspicion of malignancy [1]. Diagnosis is often made postoperatively on histopathology examination [4,5]. Herein, we present a case of a young male who presented with recurrent right upper abdominal pain, treated as a case of impacted CBD stone, was incidentally diagnosed as tubercular cholecystitis.

### **Case presentation**

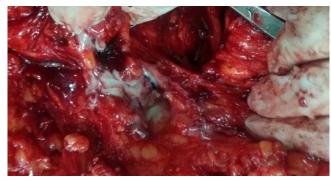
A 29 years old male (non-diabetic, non-smoker), was admitted for management of acute calculus cholecystitis at Rasheed Hospital, Lahore though A&H Laparoscopic Clinic, Lahore in July 2017. Mildly deranged liver enzymes and normal TLC (9.4 x 103  $\mu$ L) were recorded at time of admission. An edematous gall bladder with a wall thickness (up to 1cm), multiple heterogenic foci in the fundus of the gall bladder and normal-sized CBD were observed on ultrasonography. For further elaboration of heterogenic foci in the gall bladder, CT scan performed that reported a hypoechoic mass within the fundus of gall bladder surrounded by a rim of inflammatory exudate and a normal-sized CBD with small heterogenous shadows in its wall. The patient responded well to antibiotic therapy and discharged from hospital with a plan of interval cholecystectomy.

A preoperative ultrasound showed edematous thick wall (9mm) gall bladder containing debrinous fluid around a perforated area and single stone like a shadow (measuring 5mm) in CBD with proximal dilatation. Liver function tests were within the normal range. MRCP confirmed the gall bladder wall thickness of up to 8mm, multiple calculi in the gall bladder and 6mm sized CBD that had an impacted non

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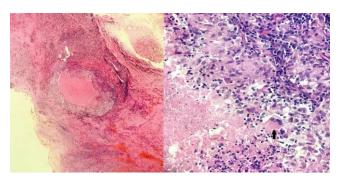
**Figure 1.** An operative view: Pus oozing out from thick walled shrunken gall bladder wall

obstructing shadow in its wall most likely a stone. Pancreatic parenchyma and the pancreatic duct were also normal. ERCP demonstrated normal CBD with no intraluminal pathology. An open cholecystectomy with CBD exploration was planned. Per-operatively, dense adhesions between the gall bladder and omentum were encountered. Meticulous dissection through adhesions explored a thickened, edematous gall bladder that oozing out the cheesy material and pus from its indurated areas while attempting to grasp the gall bladder with help of grasper (Figure 1).

Perforation at the fundus of the gall bladder was revealed. Due to dense adhesions, we could not negotiate the dissection of the calot's triangle. On opening the gall bladder, few calculi in the lumen and jam-packed stones in different compartments of gall bladder were noticed. Narrow gall bladder lumen was traced towards CBD. A sub centimetre sized tubercle was palpable on CBD near the cystic duct area which raised the suspicion of impacted stone.

A longitudinal incision was made over it aiming to extract the stone however, cheesy material oozed out. No intramural stone was found on CBD exploration. Per-operative cholangiogram excluded any stone presence and the dye was freely inflowing in the duodenum.

The procedure was completed with the placement of T-tube and subhepatic drain. Histopathology of resected specimen reported the presence of multiple scattered granulomas composed of a collection of epithelioid, histiocytes with admix lymphocytes and plasma cells. The granuloma



**Figure 2.**: A: Scanner view of gallbladder wall section with an ulcerated lining and a granuloma with central necrosis. (H&E stain, 4x magnification), B: High power field of granuloma showing epithelioid cells, necrosis and multinucleated giant cells (black arrow). (H&E stain, 40x magnification)

containing multiple Langerhans type giant cells containing multiple nuclei giving the horseshoe-shaped appearance, associated caseous necrosis was seen (Figure 2).

A tuberculin test was also found to be positive. The patient recovered completely without any significant complication. He showed improvement with the antituberculous treatment within 30 days interval. He gained weight up to 2Kg. The patient was followed up for 2 years. He remained symptoms free.

### Discussion

Gallbladder tuberculosis is more common in males (M: F; 2:1) with an age range of 30-50 years [1,2]. Hepatobiliary tuberculosis constitutes less than 1% of the total abdominal tuberculosis cases [3]. Low incidence of gallbladder tuberculosis is largely attributed to the high content of bile, alkaline pH and other inhibitory substances [4,5]. Tubercular infection may spread to gallbladder by peritoneal, lymphatic, hematogenous or ascending routes [5].

Most of the patients present with pain abdomen, anorexia and weight loss 1.5. Unusual presentation in the form of abdominal lump, perforation with abscess formation in anterior abdominal wall and port site sinus formation has also been described [2].

Radiological findings demonstrate cholelithiasis, wall thickening or intraluminal mass simulating gallbladder malignancy [6]. Laboratory findings include anaemia, raised ESR and positive tuberculin test. AFB examination of bile obtained from ERCP has extremely low sensitivity, however, increased adenosine deaminase (ADA) level favours tubercular aetiology. In our case, the clinical presentation was very misleading.

At initial presentation, both clinical and radiological findings were favouring acute cholecystitis. At 6-week interval, radiological findings still showed thick-walled gall bladder with an impacted CBD stone, which was further confirmed on MRCP and ERCP. But upon exploration, it was found to be a tuberculous lesion and histopathology confirmed the diagnosis. Theoretically, a preoperative diagnosis of tuberculosis may be established by brush cytology on ERCP, and PCR of bile for tuberculosis. However, it is not considered routinely. Reportedly, this is the first case of tuberculous lesion mimicking an impacted stone in CBD. Previously, some cases of tuberculosis of CBD causing stricture or obstruction has been reported [5].

This disease needs differentiation from acute and chronic cholecystitis including xanthogranulomatous cholecystitis, carcinoma and polypoidal lesions of gallbladder [4]. Regional lymphnodal enlargement is seen in both gallbladder tuberculosis and malignancy. Liver infiltration or metastasis is seen in gallbladder malignancy while lung lesions, omental or mesenteric thickening is frequent in tuberculosis. Treatment protocol like abdominal tuberculosis includes initial four drugs intensive phase for two months and two drugs for the continuation phase [5].

Ahmed HG et al, in a retrospective descriptive study, investigated the morphological pattern of tuberculous lymphadenitis and reported that the most major histological features were giant cell (88%), caseation (84%), epithelioid cells (80%), granuloma and caseation (68%), lymphocytes (31%), and histiocytes (4%) [6].

In this case, histopathology of diseased gall bladder showed mandatory histological features of tuberculosis to initiate anti-tuberculous treatment. The polymerase chain reaction is a reliable and rapid test for the detection of Mycobacterium tuberculosis (sensitivity 78.3%) [7]. However, we didn't perform PCR or AFB before the start of antituberculous drugs as we had histopathological confirmation of tuberculosis.

### Conclusion

Gallbladder tuberculosis being a very uncommon entity needs consideration in cases of cholecystitis and gallbladder mass, particularly in endemic areas. The high degree of clinical suspicion and mandatory histopathological examination is essential for diagnosis and management of gallbladder tuberculosis.

All authors disclose no conflict of interest. The study was conducted in accordance with the ethical standards of the relevant institutional or national ethics committee and the Helsinki Declaration of 1975, as revised in 2000.

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### **Learning Points:**

- Very rarely seen pathology, tuberculosis of hepatobililary tract, has no pathognomonic clinical or radiological features which
  makes it almost impossible to diagnose preoperatively.
- The only chance of establishing diagnosis is histopathological evidence which is mandatory in every hepatobiliary surgery.
- · Still there is paucity of data to establish any diagnostic or screening criteria even in endemic areas of the world.
- Adequate resection and routine anti tuberclous treatment regimens may provide cure without significant morbidity.

### CASE REPORT

### **Splenic injury following Colonoscopy**

Paheerathan N, Branavan S Teaching Hospital Batticaloa, Sri Lanka

**Keywords:** Colonoscopy; exploratory laparotomy; splenectomy

### Introduction

Colonoscopy is a procedure used as a diagnostic and therapeutic modality of colonic and rectal pathologies. Although colonoscopy is considered a safe procedure, it is associated with complications like intraluminal bleeding and perforation of the colon [1]. Splenic injury during colonoscopy is a rare and life-threatening complication.

### **Case presentation**

A 63 years old male presented with generalized abdominal pain and distention for two hours duration in the evening. On that same day morning, he underwent colonoscopy for constipation and per rectal bleeding for six years. He was discharged in the evening and readmitted. The colonoscopy finding was diverticulosis noted at descending colon with distended descending and sigmoid colon. He was discharged with syr. Lactulose and dietary advice.

He was a known patient with chronic obstructive pulmonary disease, hypertension and cerebrovascular accident, and was on Aspirin. He underwent cataract surgery in the past. He was allergic to penicillin and some foods. On examination, he was dyspnoeic and afebrile. The abdomen was not significantly distended, but there was generalized tenderness with guarding. His pulse rate was 90bpm, blood pressure was 100/60mmHg and oxygen saturation was 90% on pulse oximetry. Urgent ultrasound scan of the abdomen showed the moderate amount of free fluid in the abdominal cavity but erect chest Xray showed no gas under the diaphragm. Laboratory results were as follows: leukocyte count:  $22.68 \times 103/\mu L$ , haemoglobin: 9.6mg/dL and platelet:  $225 \times 103/\mu L$ .

He underwent exploratory laparotomy under general anaesthesia. There was hemoperitoneum with 1700ml of blood with clots and capsular tear of the spleen with bleeding was noted. Bruising along the ascending and descending

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colon and colonic diverticulosis were seen but no bowel perforation was identified. Splenectomy was done and haemostasis achieved. The patient was received three pints of blood and managed in an intensive care unit and uneventfully discharged.

### Discussion

Splenic injury during colonoscopy is a rare complication with an incidence of 0.00005–0.017% and a mortality rate of 5% [1]. Acute abdominal pain following colonoscopy is the most reliable symptom and requires further investigation and monitoring. Intra-abdominal bleeding causes persistent hemodynamic instability which mandates fluid resuscitation and operative intervention. The incidence of splenic injury during colonoscopy will probably high in the upcoming years due to the widespread use of the procedure [2].

The most possible mechanism for splenic injury even in the experienced hands is tension on the splenocolic ligament or pre-existing adhesions and existing splenic pathology may increase the risk [3]. Direct injury to spleen through the perforation of the colon is also possible. Prevention of these complications can be assisted by avoiding loop formation of scope, insufflation, and careful monitoring of a patient's response, especially under sedation during the procedure.

There is a high chance of splenic injury when patients under sedation during colonoscopy because patients cannot complain about pain and discomfort associated with overstretching of the colon and splenocolic ligament [3]. Some technical manoeuvres during colonoscopy may increase the risk of splenic injury such as the external pressure applied on the left hypochondrium, formation of an  $\alpha$ -loop and straightening of the sigmoid loop [4].

The severity of the injury can be identified by the symptoms and signs at the time of admission. On admission, our patient doesn't have features of shock probably due to arrest of bleeding and the compensatory mechanisms.

Gas under the diaphragm on a plain erect chest X-ray can diagnose a perforation of the colon. Ultrasonography and contrast-enhanced computed tomography are both reliable investigations to diagnose intra-abdominal free fluid. The

gold standard imaging is contrast-enhanced computed tomography because it can also detect injuries to other organs, and it gives the grading of splenic injuries [5].

Treatment options include observation in a high dependency unit, selective arterial embolization of splenic vessels, or emergency splenectomy; these options depend on the haemodynamic status of the patient, the type of blood loss (venous vs. arterial), and the availability to perform selective arterial embolization. Evidence shows, splenectomy is the treatment of choice for haemodynamically unstable patients and it is the most used option in 56.1% [1, 5] followed by conservative treatment in 27.3% [1] and embolization in 4.5% [1]. Conservative treatment with close monitoring is an option for haemodynamically stable patients [2].

### Conclusion

Splenic injury following colonoscopy is a rare complication and can be minimized by various techniques. Suspect splenic injury and other complications when a patient with acute abdominal pain and shock after colonoscopy. According to the current literature, splenectomy for haemodynamically unstable patients while conservative management is a safe option for stable patients.

All authors disclose no conflict of interest. The study was conducted in accordance with the ethical standards of the relevant institutional or national ethics committee and the Helsinki Declaration of 1975, as revised in 2000.

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### **Learning Points:**

- Splenic injury without colonic perforation following colonoscopy is a rare complication.
- Acute abdominal pain with haemodymanic instability following colonoscopy requires further investigation.
- Contrast enhanced computed tomography is the gold standard radiological examination.
- Splenectomy is the treatment of choice for haemodynamically unstable patients.

### CASE REPORT

### High grade foamy gland prostatic adenocarcinoma, a rare pathological variant treated with radical prostatectomy

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**Keywords:** : Prostatic adenocarcinoma; small acinar adenocarcinoma; foamy gland carcinoma; Gleason score; International Society of Urological Pathology grade; prostatic specific antigen; estrogen receptors

### Introduction

Prostatic adenocarcinoma is one of the commonest internal malignancies among men and its incidence is increasing with age [1]. Foamy gland carcinoma is one of the variants usually seen in combination with small acinar or usual adenocarcinoma and the pure form is rare (0.2-2%) [1, 2]. It is usually assigned as a low-grade tumour; the most common Gleason score being 7, although some authors have described it as 6 [1, 2]. We describe a rare high-grade, pure foamy gland adenocarcinoma occurring in a relatively young patient.

### **Case Presentation**

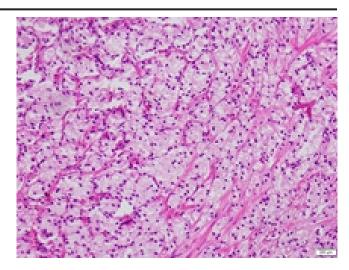
A 49-year old male presented with acute urinary retention. He had a preceding history of poor flow of urine for 1-year duration associated with frequency, nocturia and nocturnal enuresis. He was catheterised by the general surgical team and was referred to the urology unit for further care. Digital rectal examination revealed a clinically malignant, hard irregular prostate with obliterated medium groove. His initial serum creatinine was 254  $\mu$ mol/L which gradually declined to 124  $\mu$ mol/L after catheterization. His other basic biochemistry and complete blood count were unremarkable. Ultrasonography showed normal kidneys without any hydronephrosis or hydroureter. The bladder wall thickness was 6mm. The prostate size was 39 cm3. The prostate-specific antigen level was 1.5 ng/ml.

Cystoscopic examination showed enlarged lateral prostatic lobes which were almost meeting in the midline. The bladder was trabeculated with a high neck. He underwent transurethral resection of the prostate. Microscopic examination revealed prostatic tissue containing a small acinar type prostatic carcinoma predominantly composed of poorly formed and fused nests of tumour cells with foamy

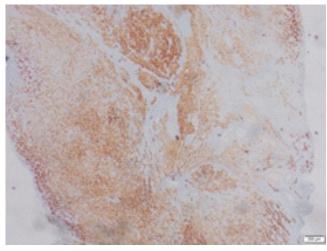
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**Figure 1.** H and E stain with 100X magnifications showing prostatic tissue containing a small acinar type prostatic carcinoma predominantly composed of poorly formed and fused nests of tumour cells with foamy cytoplasm with enlarged nuclei and prominent nucleoli (Gleason score 5).



**Figure 2.** H and E stain with 40X magnifications showing diffuse, moderate-strong cytoplasmic positivity for PSA

cytoplasm(Gleason score 5)(figure 1). The nuclei were enlarged and round with prominent nucleoli. Necrosis was not seen. There was focal perineural invasion (figure S1). Lymphovascular invasion and prostatic intraepithelial neoplasia were absent. Thus the histological findings were in

favour of high-grade foamy gland (pure) prostatic adenocarcinoma- with more than 80% tumour burden. The Gleason score was 5+4 and International Society of Urological Pathology group(ISUP) grade was 5.

The tumour cells showed diffuse, moderate-strong cytoplasmic positivity for Prostate-specific antigen (PSA) immunostaining (figure 2). Estrogen receptor (ER) immunostaining was negative in tumour cells, however, some stromal cells showed positive nuclear staining.

Computed tomography of the abdomen and magnetic resonance imaging (MRI) of the pelvis was performed and there was no evidence of local invasion or distant metastasis. Therefore, following a multidisciplinary team discussion a radical prostatectomy was performed. Exploration revealed bilateral pelvic lymphadenopathy and hard prostate. Therefore, bilateral lymphadenectomy was performed with radical prostatectomy.

Histology revealed a tumour burden of 47%. Gleason sum score was 5+4 and ISUP grade was 5. Established extraprostatic extension with circumferential involvement of anterior surface close to bladder neck with seminal vesicle invasion was seen (figure 2). There was no lymphovascular invasion or high grade prostatic intraepithelial neoplasia. Four of nine right pelvic nodes contained metastatic deposits and all four left pelvic lymph nodes were negative. Pathological stage was pT3bN1.

He underwent hormonal therapy with a course of Goserelin and Bicalutamide. He was asymptomatic without any evidence of recurrence at 12 months after surgery.

### Discussion

Foamy gland carcinoma is characterized by abundant foamy cytoplasm and often pyknotic nuclei [1, 2]. The nucleoli are usually inconspicuous and the cytological atypia is minimal [1, 2].

Zhao et al have reported a series of 55 patients with similar histological morphology, in which enlarged nuclei and prominent nucleoli were reported in approximately 80% and 70%, respectively [2]. The commonest morphological patterns were cribriform (73%) and poorly defined (fused) glands (55%). Less common patterns were cords single cells/cords and solid sheets [2].

Certain variants of high-grade foamy gland adenocarcinoma of the prostate were found to be difficult to diagnose as scanty amounts of bland foamy glands were seen scattered within a dense sclerosed desmoplastic stroma [2]. Diagnostic awareness of the existence of this variant is important for accurate diagnosis of prostatic cancer [1, 3]. The clinical behaviour of this variant is usually aggressive despite the benign histologic appearance, although Hudson et al. has reported 100 cases of foamy gland adenocarcinoma without a significant difference in prognosis compared with usual acinar adenocarcinoma [3].

Koca et al have studied 56 cases of foamy gland adenocarcinoma of the prostate based on core needle prostate biopsies. They found that these foamy gland adenocarcinomas had similar features to conventional prostatic adenocarcinoma (acinar type) in relation to clinical features such as age, biochemical features such as prostate-specific antigen titres and histological characteristics such as the presence of high grade prostatic intraepithelial neoplasia and Gleason's score [4]. The prostate-specific antigen serves as a useful immunohistochemical marker for prostatic epithelium with a great degree of specificity and sensitivity [1, 2]. It is useful in confirming a difficult diagnosis such as foamy gland carcinoma, although it does not distinguish benign and malignant processes in prostate [1].

It is demonstrated that estrogens are required for prostate development and carcinogenesis [5]. The ER- $\beta$  immunostaining gives a strong nuclear positivity in low-grade prostatic adenocarcinoma and it was negative in some high-grade carcinomas [5]. ER- $\alpha$  expression in stroma could play protective roles to reduce prostatic cancer development by decreasing androgen production [5]. Selective estrogen receptor modulators may potentially be used in combination with current therapies in the treatment of prostatic carcinoma [5].

It is important to highlight that in the presence of a normal serum PSA value (<4 ng/mL) only a digital rectal examination by an experienced finger could clinch an accurate clinical diagnosis. A clinically benign prostate on digital rectal examination, in this case, would have led to pharmacological treatment precluding a tissue diagnosis.

### Conclusion

Awareness of the occurrence of rare high-grade type foamy gland carcinoma will help to prevent misdiagnosis of this entity as a non-prostatic malignancy, such as urothelial carcinoma or metastatic deposits, especially when PSA is low. Furthermore, it is important to highlight that in the presence of a normal serum PSA value, only a digital rectal examination by an experienced finger could clinch an accurate clinical diagnosis. Stromal ER could play a protective role to reduce invasion of prostatic carcinoma and selective ER modulators may be used to treat prostatic carcinoma.

All authors disclose no conflict of interest. The study was conducted in accordance with the ethical standards of the relevant institutional or national ethics committee and the Helsinki Declaration of 1975, as revised in 2000.

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### Abbreviations

ISUP : International Society of Urological Pathology

PSA : Prostate specific antigen

ER : Estrogen receptor

MRI : Magnetic resonance imagine

### **Learning Points:**

- High-grade, pure foamy gland adenocarcinoma can rarely occur in young patients
- · Clinicians should be aware of this rare variety to prevent misdiagnosis of this entity as a non-prostatic malignancy
- Digital rectal examination by an experienced finger is needed to clinch an accurate clinical diagnosis in the absence of elevated PSA levels.

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