



# The Galle Medical Journal

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# The Galle Medical Journal

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## Editorial

### The GMJ: Transcending boundaries

The *Galle Medical Journal (GMJ)* is the official journal of the Galle Medical Association. The contents of the *GMJ* are relevant to the entire medical community transcending boundaries of Galle and the Southern Province of Sri Lanka. The leading articles, reviews, original articles, case reports etc. are of relevance to the medical fraternity all over Sri Lanka and abroad. We are striving to be a medical journal with a broad base of relevance and representation with its editorial offices based in Galle. It is your journal wherever you are-in Sri Lanka or any other country. We welcome national and international submissions. They need to conform to highest degree of ethical and research standards and will be subjected to stringent peer and editorial review prior to publication.

There is an evolving tendency to slavishly depend on laboratory reports and the expanding repertoire of imaging modalities. There are situations when clinicians at different levels, not following basic tenets of clinical medicine – the elucidation of symptoms and elicitation of clinical signs and their meaningful analysis. Ariyananda in his review surveys the place of the art of history taking and physical examination in “modern medicine.” Can the tools of modernity replace the basic history taking and physical examination? We need to recognise the value of effective communication, empathy and the “human touch” as vital attributes of the art of medicine.

Functional abdominal pain disorders form a key area in paediatric practice. Karunanayake focuses on this problem in his paper based on the Galle Medical Association Oration delivered in 2018.

**Satish K Goonesinghe**

**Eisha I Waidyarathne**

*Editors in Chief/ GMJ*


# Seroconversion following Hepatitis B immunization in National Immunization Programme in a selected Medical Officer of Health area in Galle District

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## ABSTRACT

**Introduction:** Hepatitis B immunization was introduced into the National Immunization Programme (NIP) of Sri Lanka in three phases in 2003. The study evaluates the protective efficacy of 2, 4, 6 month schedule of hepatitis B vaccination in the NIP in Sri Lanka.

**Methods:** A cross sectional study carried out among 154 infants (completed 9 months of age) attending the NIP in the Bope Poddala Medical Officer of Health (MOH) area in Galle District in 2008. Hepatitis B surface antibody (HBsAb) titres were tested using a quantitative enzyme immunoassay test. Forty-two infants detected with low titres of antibodies were given a booster dose of hepatitis B vaccine and HBsAb titer was retested 2 - 4 weeks later.

**Results:** The overall protection (HBsAb titre >10 mIU/mL) after 3 doses of vaccine was 94.2% with a geometric mean titre of 233.37 mIU/mL. There were 5.8% infants with HBsAb titres <10 mIU/mL and 30.5% with HBsAb titres between 10 to 100 mIU/mL. Sex, birth weight, body mass index and weight for height were not significantly associated with HBsAb levels. None of the infants had potential risk factors for acquiring hepatitis B virus infection. Only 26 out of 42 re-vaccinated infants returned for repeat testing of antibody levels where all had demonstrated a protective level.

**Conclusions:** The majority of infants seroconverted following three doses of Hepatitis B vaccine in NIP in Sri Lanka and the rest picked up the antibody levels following a booster dose.

**Key words:** *Hepatitis B vaccine, hepatitis B surface antibodies, seroconversion, infants, Sri Lanka*

## Introduction

Hepatitis B virus (HBV) infection is a serious global health problem. In 2015 the global prevalence of HBV infection in the general population was estimated at 3.5% with about 257 million persons living with chronic HBV infection and 887,220 deaths. The world can be divided into three endemic areas according to the prevalence of Hepatitis B surface antigen (HBsAg) namely high ( > 8%), intermediate (2% - 8%) and low (< 2%) endemic areas. Prevalence varies considerably among the

WHO Regions, with the highest in the African and Western Pacific Regions (1).

Viral hepatitis is a notifiable disease in Sri Lanka. In the year 2015, the average admission to government hospitals due to viral hepatitis was 12.9 per 100,000 population with the case fatality rate of 0.2 and mainly affecting the age group 25 - 50 years (2). The commonest type of viral hepatitis reported in the country was hepatitis A. Sri Lanka has an intermediate prevalence for HBV infection with a prevalence of HBsAg positivity not more

than 2.5% in different selected communities, although it is located in the high endemic region (3). However, a large number of clinically defined hepatitis cases remain unreported as most of them do not seek hospital admission or go to the private sector or visit other allopathic and ayurvedic practitioners.

Safe and effective vaccines against HBV infection have been available since 1982 (4). Routine immunization of infants against hepatitis B was recommended by the World Health organization (WHO) in 1991. This has dramatically decreased the incidence of HBV infection among infants, children and adolescents in many countries (5).

There are two immunization strategies for hepatitis B; routine infant immunization and selective immunization of risk groups. Routine infant immunization is found to be the most cost effective strategy in the prevention of hepatitis B infections even for a country having low endemicity as it prevents HBV infection in all age groups.

Hepatitis B vaccine was introduced into the National Immunization Programme (NIP) of Sri Lanka since 2003 in three phases to all infants at the completion of 2, 4, and 6 months of age (6). Initially a liquid monovalent vaccine used in the NIP which was later replaced the liquid pentavalent vaccine (DTP - HepB+Hib) with the introduction of Hib vaccine into the NIP (5).

The effective level of immunity in a vaccine recipient will be 10 mIU/ml which is recommended to test 4 - 6 weeks after the last dose of vaccine. Some vaccine recipients with antibody levels <10 mIU/ml will develop an adequate level of immunity following an additional booster dose. Primary non-responders, who will not develop protective levels of antibodies even after two courses of vaccines should be informed of their immune status and counselled on how to avoid exposure (7).

The study was conducted to assess the protective efficacy of 2, 4, 6 - month schedule of hepatitis B vaccination in the NIP in a selected population in Sri Lanka. Study determines the percentage of seroconversion following primary vaccination and identifies factors associated with low titres of antibodies following seroconversion. It also evaluates the effect of a booster dose among infants with inadequate level of seroconversion.

## Methods

The study was conducted in the Bope Poddala Medical Officer of Health (MOH) area in Galle District, Sri Lanka from 01/01/2008 to 18/04/2008. It is a semi-urban MOH area and considered as the field training area attached to the Faculty of Medicine, University of Ruhuna. The field staff members continuously have access to training and are able to update their knowledge, more than in the other MOH areas. This ensures minimal vaccine failures due to factors like maintenance of cold chain, injection technique and dose / volume of vaccine.

A descriptive cross sectional study was first carried out among infants (having completed 9 months of age) attending the NIP to detect HBsAb titres. The second stage of the study was an interventional study, where infants detected with low titres of HBsAb in the first stage, were given a booster dose of hepatitis B vaccine and retested for antibodies 2 - 4 weeks later.

The sample size was calculated using formula [ $n = Z_{1-\alpha/2}^2 P(1-P)/d^2$ ] for the descriptive study (8). For this study the proportion ( $P$ ) of the population estimated to have seroconverted was taken as 90% by estimating that there will be more than 90% will be seroconverted following 3 doses of Hepatitis B vaccine given in infancy (9, 10). P value of 5% and absolute precision ( $d$ ) of 0.05 considered. The final sample size was calculated as 152 with 10% correction.

All children attending the immunization clinics in the Bope-Poddala MOH area were screened by the principal investigator. Infants who have completed 9 months and who have received all 3 doses of hepatitis B vaccine provided by the NIP and whose parents have consented were enrolled to the study. Exclusion criteria were any infant who has been given a Hepatitis B vaccine not provided by the NIP, immunized for Hepatitis B at any place other than Bope-Poddala MOH area or having an acute infection at the time of visit.

Data collected using an interviewer administered questionnaire with extraction of certain information from Child Health Development Record and measuring the current weight and length of the infants. Two milliliter of venous blood obtained from the infant by a paediatric nursing officer and tested at the Faculty of Medicine, University of

Ruhuna, to check the HBsAb titre. All negative samples and those who were having a HBsAb titre of < 100 mIU/ml were repeated and confirmed.

The HBsAb titre was checked using an Enzyme-Linked Immunosorbent Assay (ELISA) test - "Monolisa Anti-HBs PLUS" of Bio-Rad, France. The analytical sensitivity was lower than 2 mIU/ml according to the National Committee for Clinical Laboratory Standards procedure. The specificity is 99.4% (98.8% - 99.8% with 95% confidence interval) and the sensitivity is 99.2% (98.1% - 99.7% with 95% confidence interval (10).

Optical density (OD) values were recorded on calibrated standards with known HBsAb titres of 10 mIU/ml (C1), 100 mIU/ml (C2), 400 mIU/ml (C3) and 1000 mIU/ml (C4) and a negative control (CO) using different filters at 450 / 620-700 nm and 405 / 620-700 nm. The assay is validated with following parameters specified by the manufacturer before obtaining test results. The measured OD values of CO must be > 0.000 and 0.070 OD units, C2 must be 0.400 OD units, C1 must be 0.050 and 0.200, and each absorbance value of C1 must be greater than or equal to 1.5 times the OD of the absorbance value of the CO. The mean absorbance of the C1 is calculated and taken as the cut off value for the assay. The A450 of CO, C1, C2 and C3 were graphed versus their assigned concentrations, using a polynomial (quadratic) regression to interpret samples with measured absorbance values less than OD of C3. A second graph plotted point to point, using A405 of C3 and C4 calibrators against their assigned concentrations to interpret samples with measured absorbance values greater than OD of C3. Samples with anti-HBs titers greater than 1000 mIU/ml were diluted and re-assayed (11).

The data was analyzed using the Epi Info (TM) 3.4.3 database and statistics software for public health professionals (10/25/2007) from the Centers for Disease Control and Prevention (CDC). Using WHO Anthro V2.0.2 software, WHO growth standards were applied to assess the growth and nutrition of the infants.

Ethical clearance for this study was obtained from the Ethical Review Committee of the Faculty of Medicine, University of Ruhuna and the permission obtained from the Regional Director of Health Services, Galle District to carry out the study.

Medical Officer attached to the Bope-poddala MOH who is in charge of the immunization clinic were informed of the study.

## Results

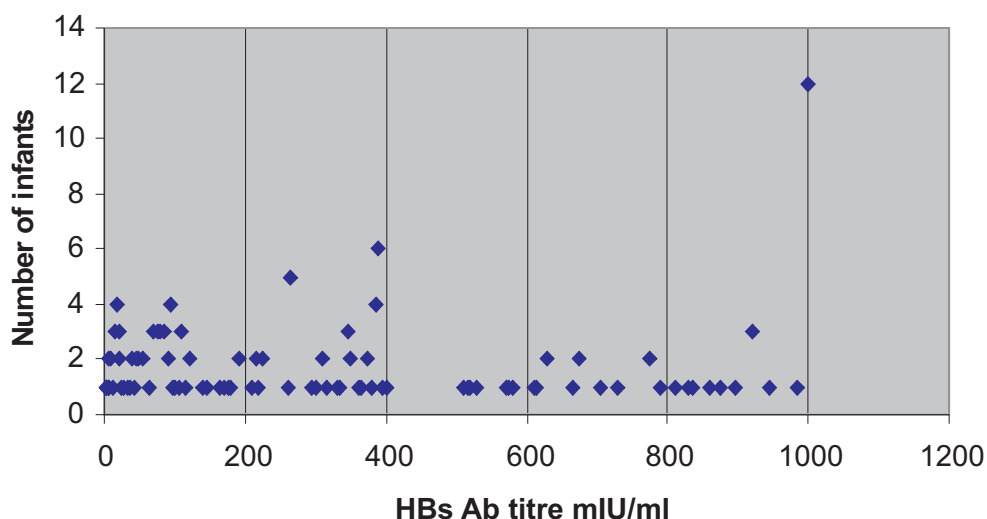
The study was carried out in the Bope-Poddala MOH area in Galle district, Sri Lanka where all the Hepatitis B vaccine doses to the selected infants have been administered from this MOH area. The vaccine used during this period was a recombinant DNA hepatitis B vaccine as a multi dose (10 dose) vial manufactured in the Serum Institute of India. Batch No. B 2069218. Although the calculated sample size was 152, 154 were included in the study, because all eligible children from the last clinic session who were willing to participate were taken into the study under ethical grounds. The majority had reported no complications following routine vaccination except for fever for 1-2 days recorded in 18% of vaccinees.

The distribution of HBsAb titre is shown in figure 1 and it is categorized in table 1. The WHO recommended level of protection or the positive cutoff value of HBsAb titre is 10 mIU/ml. Infants in the study sample who had protective levels of hepatitis B surface antibody titre following primary vaccination were 94.2% (145/154) with a geometric mean titre of HBsAb 233.37 mIU/ml.

## Factors associated with an inadequate level of seroconversion following Hepatitis B immunization in infants

The statistical relationship of probable factors affecting seroconversion with the titre of HBsAb of infants was tested (Table 2). The percentage of non-responders was inadequate to apply statistical tests. Therefore, the non-responders and hypo-responders were taken as one group - "Inadequate" (HBsAb titres <100 mIU/ml) and the rest as "Adequate" (HBsAb titres ≥ 100 mIU/ml) for statistical analysis.

The weight (range - 5.0 - 10.5 kg, mean=7.95Kg, SD=0.98) and the length (range - 62 - 80 cm, mean=71cm, SD=3.12) of infants at the time of the study adhered to the Gaussian distribution. The nutritional status of infants at the time of the study was assessed by the Body Mass Index (BMI), the Gomez classification and the Waterlow



**Figure 01:** Distribution of HBsAb levels among the sample of infants

**Table 1:** Category of seroconversion among the sample of infants

Category	Ab titre (mIU/ml)	Number	Percentage
Non-responders	< 10	9	5.8%
Hypo-responders	10 - 100	47	30.5%
Responders	> 100	98	63.7%

### Risk factors and the level of seroconversion

None of the mothers were diagnosed to be having hepatitis B or had an icteric illness before pregnancy. Only three mothers were given blood or blood products before delivery and one mother had a complicated pregnancy due to pregnancy induced hypertension. All infants born to these mothers had HBsAb titres of more than 945 mIU/ml. None of the infants were given blood or blood products or became icteric after birth. Only two infants had a stay in Premature Baby Unit having HBsAb titres of 950 mIU/ml and 20 mIU/ml. Since the numbers were few in each category, statistical testing could not be applied.

### The effect of the booster dose of the hepatitis B vaccine among infants having an inadequate level of seroconversion

Fifty-six infants (9 non-responders and 47 hypo-responders) selected from the first stage of the study were offered a booster dose of hepatitis B vaccine. However, only 42 parents of infants (9 non-responders and 33 hypo-responders) voluntarily consented for participation. Of them only 26 infants (3 non-responders and 23 hypo-responders) were brought for repeat testing of HBsAb levels.

Figure 2 shows the change in the distribution of HBsAb levels following the booster dose of hepatitis B vaccine. Among those who came for retesting of HBsAb titer; all the non-responders had HBsAb titre of >10 mIU/ml with a geometric mean HBsAb titre of 699.55 mIU/ml. All hypo-responders had a HBsAb titres of > 100 mIU/ml with a geometric mean HBsAb titre of 909.97 mIU/ml.

**Table 2:** Relationship of probable factors affecting seroconversion with the titre of HBsAb of infants

Characteristic	Level of seroconversion		Total No (%)	<i>p</i> value
	Inadequate < 100 mIU/ml No (%)	Adequate ≥ 100mIU/ml No (%)		
<b>Gender</b>				
Male infants	29 (49.0%)	50 (51.0%)	79 (100.0%)	0.929
Female infants	27 (51.0%)	48 (49.0%)	75 (100.0%)	
<b>Maturity of infants at birth</b>				
Preterm	9 (75.5%)	24 (24.5%)	33 (100.0%)	0.221
Term	47 (24.5%)	74 (75.5%)	121 (100.0%)	
<b>Birth weight</b>				
Normal	47 (38.2%)	76 (61.8%)	123 (100.0%)	0.342
Low	9 (29.0%)	22 (71.0%)	31 (100.0%)	
<b>Mode of delivery</b>				
Vaginal	42 (39.6%)	64 (60.4%)	106 (100.0%)	0.212
Other (LSCS & assisted)	14 (29.2%)	34 (70.8%)	48 (100.0%)	
<b>Place of delivery</b>				
Government hospital	53 (35.6%)	96 (64.4%)	149 (100.0%)	-
Private hospital	3 (60.0%)	2 (40.0%)	5 (100.0%)	
<b>Place of vaccination</b>				
All 3 doses given at the same vaccination center in the MOH area	48 (35.8%)	86 (64.2%)	134 (100.0%)	0.717
One or more doses of vaccine given in a different vaccination centre within the same MOH area	8 (40.0%)	12 (60.0%)	20 (100.0%)	
<b>Body mass index (BMI)</b>				
< 18.0	45 (10.2%)	88 (89.8%)	133 (100.0%)	0.101
≥ 18.0	11 (89.8%)	10 (10.2%)	21 (100.0%)	
<b>Gomez classification</b>				
Normal and Grade 1 malnutrition	7 (94.9%)	5 (5.1%)	12 (100.0%)	0.099
Grade 2 and Grade 3 malnutrition	49 (5.1%)	93 (94.9%)	142 (100.0%)	
<b>Waterlow classification</b>				
Normal & Acute malnutrition	5 (38.5%)	8 (61.5%)	13 (100.0%)	0.871
Chronic malnutrition & Acute on chronic malnutrition	51 (36.2%)	90 (63.8%)	141 (100.0%)	
<b>Mothers employment status</b>				
Housewives	46 (33.1%)	93 (66.9%)	139 (100.0%)	0.010
Employed	10 (66.7%)	5 (33.3%)	15 (100.0%)	
<b>Mothers education level</b>				
Less than Grade 10	16 (45.0%)	22 (55.0%)	40 (100.0%)	0.187
Equal or greater than Grade 10	38 (33.3%)	76 (66.7%)	114 (100.0%)	
<b>Number of children in the family</b>				
< 4	49 (36.0%)	87 (64.0%)	136 (100.0%)	0.813
≥ 4	7 (38.9%)	11 (61.1%)	18 (100.0%)	





and a minimal number of primary non responders in a community with a low prevalence of HBV infection and mother to child transmission. But still a routine booster dose to all the infants in the NIP might be beneficial to safely justify that all of them have achieved 100% seroconversion.

### Conclusions and Recommendations

The majority (94.2%) of infants seroconverted following three doses of Hepatitis B vaccine in NIP in Sri Lanka. Therefore, checking the hepatitis B antibody level at the end of the primary course of vaccination, in a routine immunization program of infants is not indicated.

Protective anti-HBs titres were demonstrated by giving a booster dose to infants with inadequate level of seroconversion, depicting a good memory following the primary vaccination and thus a booster dose of vaccine may not be needed in the population of infants vaccinated for hepatitis B in Sri Lanka.

There were no identified factors associated with an inadequate level of seroconversion following Hepatitis B immunization in infants.

Further studies with a larger sample size are needed to detect the overall prevalence of non-responders among infants in Sri Lanka.

### Limitations

The study was limited to one MOH area to minimize other factors affecting the vaccine efficacy. Thus, the results of this study cannot be generalized. The total study sample size was small and the percentage of non-responders was even smaller and caused difficulties in applying statistical tests, including that for ethnicity.

### Funding for equipment and consumables

Research and Higher Degrees Committee of Faculty of Medicine, University of Ruhuna provided financial assistance for test kits. The additional booster dose of hepatitis B vaccine was arranged with the co-operation of Epidemiological Unit, Sri Lanka and MOH, Bope-Poddala.

Authors declare no conflicts of interests.

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# Drug costs of patients admitted to a government hospital; share of public and private expenditure

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## ABSTRACT

**Introduction:** Government hospitals are expected to provide free health service which includes drugs for in-patients. However, in practice, in-patients have to purchase drugs from outside when they are treated in government hospitals. The objective of the study was to investigate the drug expenditure of patients during their stay in government hospitals.

**Methods:** Cost incurred by 189 patients who were treated in a pediatric unit, a medical unit and a surgical unit in Teaching Hospital, Karapitiya for 3 - 10 days were studied. Details of drug cost incurred by patients were collected by interviewing patients, from BHTs, the hospital pharmacy and private pharmacies. Data were collected in two phases - from May to June and October to November in 2015.

**Results:** The average cost for drugs for a patient was Rs. 1,406.00, Rs. 3,204.00, Rs. 3,678.00 and from government per a patient was Rs. 548.00, Rs. 1,239.00, Rs. 885.00 in pediatric, medical and surgical units respectively. Private expenditure on drugs is significantly higher than that from the government expenditure in all units. The highest percentage was spent for antibiotics both by the government (74%) and by the patients (67.5%). The highest antibiotic cost was recorded in the surgical unit. Surgical unit shows the highest per day difference of expenditure on drug by government and by patient. This difference widened with the number of hospitalised days.

**Conclusions:** Study shows that patients spent more than the government on drugs and the highest fraction of this is for antibiotics. The highest burden is reported among patients admitted to the surgical unit.

**Keywords:** *Drug cost, in-patient, government hospital*

## Introduction

The Sri Lankan government takes considerable effort to finance and strengthen the healthcare services to ensure the efficient delivery of free health care to its citizens. Compared to other South Asian countries, Sri Lankan government spends more from country's total expenditure on the development of health sector (1). Expenditure for health is about 4% of the gross domestic product (GDP) of Sri Lanka (2).

Annual government expenditure on health is around 216 billion according to the budgetary allocation in 2016 (3). Majority of government expenditure is spent on maintaining public health delivery system island-wide. In-patient care is mainly funded by the government and about 75% of total national health expenditure is spent on in-patient care (1).

Even though the government provides free healthcare for its citizens, it is well known that patients themselves also bear a part of the expenditure incurred for drugs and investigations. Therefore, the objectives of the study was to estimate the expenditure for drugs while being treated in a government hospital, to compare the personal and government expenditure on drugs and to analyse the cost according to different drug categories and number of days hospitalised.

## Methods

The study was conducted in two phases due to the possible variation of drug availability in government hospitals. First phase was from May to June and second was from October to November in 2015. It was a descriptive cross-sectional study conducted using records of in-patients in a surgical unit, a medical unit and a pediatric unit in Teaching Hospital Karapitiya, Sri Lanka. Information about drugs used by patients was recorded from patients' bed head tickets. The Prices of drugs provided by hospital were taken from records in the indoor pharmacy of the hospital. Patients' personal expenditure on drugs was collected by interviewing patients and their close relatives. Costs of drugs were traced using payment bills and by obtaining price list from private pharmacies. The study was limited to the patients with a hospital stay between 3 to 10 days. Statistical analyses were performed using SPSS. The ethical approval for the study was obtained by the Ethical Review Committee, Faculty of Medicine, University of Ruhuna, Sri Lanka.

## Results

The records of 66, 62 and 61 patients from medical, surgical and pediatric units respectively were used for the study.

### Estimation of average drug cost

The average cost borne by the patient and the government for drugs in each unit studied are shown in table 1. Patients' expenditure on drugs is significantly higher than that of the government in all units ( $p < 0.05$ ).

The average drug costs borne by the patient and by the government were significantly different between pediatric and medical units ( $p < 0.05$ ). The average drug costs borne by the patient and by the government were not significantly different between pediatric and surgical units as well as between medical and surgical units. Compared with other two units, the surgical unit showed the highest difference in drug expenditure between patient and government ( $p < 0.05$ ).

### Drug cost on various drug categories

Drug expenditure was categorized according to the type of drug used (Table 2). The highest percentage was spent on antibiotics, both by the government (74%) and the patients (67.56%). The highest expenditure for antibiotics was recorded in the surgical unit and the lowest in the pediatric unit.

### Variations of drug cost with the duration of hospital stay

Per day expenditure difference between patient and the government according to number of days hospitalised is shown in Figure 1. This per day expenditure difference increases significantly ( $p < 0.05$ ) with the number of days hospitalised in surgical unit but not in other two units. Per day expenditure difference for antibiotics between patients and the government is also increased with the number of days hospitalised in the surgical unit but not the other two units. There is no such change in expenditure with the duration of hospitalisation for other type of drugs.

### Seasonal variation of antimicrobial drug cost

The average patient antibiotic expenditure had decreased significantly (from Rs. 6,144.00 to Rs 4,577.00) while the government expenditure on antibiotics had increased significantly (from Rs. 1,640.00 to Rs. 2,184.00) from first phase to the second phase of the study. Similar variation was not seen for other drug types.

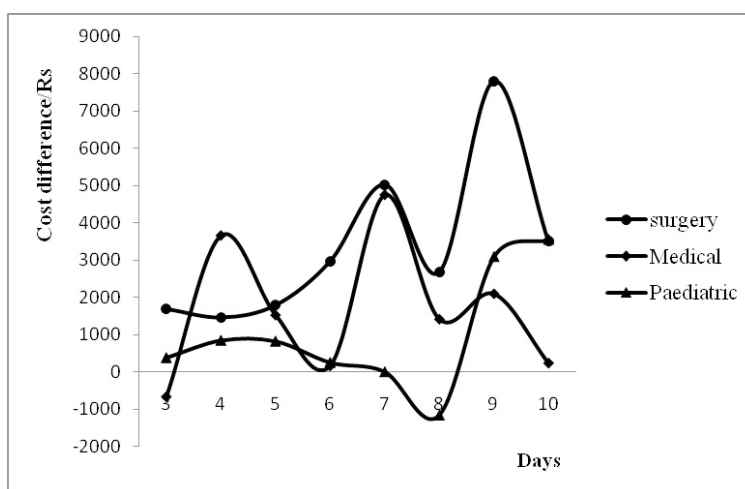
**Table 1:** The average drug cost by a patient and the government in pediatric, medical and surgical units

Pediatric	Patient	1,406.00	71%
	Government	5,48.00	29%
Medical	Patients	3,204.00	72%
	Government	1,239.00	28%
Surgical	Patients	3,678.00	81%
	Government	885.00	19%
Total	Patients	8,288.00	76%
	Government	2,672.50	24%

**Table 2:** Average drug cost (Rs.) and percentages according to various drug categories in three units

		GIT	Antibi.	Endo.	CNS	CVS	Nut. Bl.	Respi.
Paediatrics	Patient	91.00 (7.23%)	962.00 (76.40%)	19.00 (1.50%)	59.00 (4.68%)	22.00 (1.74%)	39.00 (3.09%)	67.00 (5.32%)
	Govern	11.00 (2.07%)	368.00 (69.23%)	2.00 (0.37%)	6.00 (1.13%)	0.50 (0.09%)	140.00 (26.34%)	4.00 (0.75%)
Medical	Patients	122.00 (3.74%)	2063.00 (63.22%)	351.00 (10.76%)	44.00 (1.35%)	455.00 (13.94%)	45.00 (1.38%)	183.00 (5.61%)
	Govern	25.00 (2.03%)	921.00 (74.94%)	13.00 (1.06%)	41.00 (3.34%)	15.00 (1.22%)	189.00 (15.38%)	25.00 (2.03%)
Surgical	Patients	413.00 (11.46%)	2464.00 (68.41%)	303.00 (8.41%)	229.00 (6.36%)	148.00 (4.11%)	13.00 (0.36%)	32.00 (0.88%)
	Govern	29.00 (3.34%)	657.00 (75.60%)	8.00 (0.92%)	20.00 (2.30%)	7.00 (0.80%)	146.00 (16.8%)	2.00 (0.23%)

(GIT - cost for drugs related to GIT, Antibi - cost for Antibiotic drugs, Endo - cost for drug related to Endocrine system, CNS - cost of drugs related CNS, CVS - cost of drug related to CVS, Nut. Bl - cost for Nutrition and blood related product/drugs, Respi. - cost for drug related to Respiratory system)



**Figure 1:** The variation of per day drug cost difference (cost borne by patient minus cost borne by government) with number of hospitalised days.

## Discussion

The present study indicates that the patients have to spend a considerable amount of money to purchase drugs during hospitalisation in a government hospital. The total drug expenditure borne by the patient is higher than that of the government. Several factors may have contributed to this. Unavailability of drugs in government hospitals, high price of the drugs when purchased from private pharmacies and usage of trade names in prescriptions can be contributory factors.

It is well known that drugs are often not available in government hospitals due to limited funds. Probably because of that, government provides limited number of drugs to particular unit even without paying much attention on the demand of that unit. This fact is exemplified by the finding that the government expenditure is lowest for the surgical unit (19% Vs. 28% and 29%) which has highest total drug expenditure and highest patient expenditure.

The difference between patient and government expenditure increased significantly with the duration of hospital stay in the surgical unit compared to other units. Therefore patients have to bear higher cost if they stay for a longer period in the surgical unit compared to the other units. As stated above, patient's fraction of the drug cost is high in the surgical unit and it will be more with prolonged stay in the surgical unit due to the government being unable cover the drug expenditure. It indicates that the expenditure on drugs by the government is not on the demand of each unit but probably depends on limited fund availability.

This study shows that government spent considerably different amounts on antibiotics during two phases of the study. The discrepancy of availability of antibiotics in government hospital between two phases of the study can be one reason for this difference. This possibility is further strengthened with the fact that when antibiotic expenditure of the government is higher during the second phase of the study, probably due to the availability of them in government hospital, patient spent less. The possible variation of antibiotic availability in two phases suggests that government hospitals were unable to maintain continuous supply of antibiotics. Procedural disturbances in

health ministry which are often highlighted in the mass media, can be one reason for this inability to maintain continuous supply of some drugs (4).

The price of the medicines available in the local market was not regulated until new legislation was introduced in November 2016. The drug prices in private pharmacies are mainly determined by market forces and influenced by factors other than the production cost (5). When patients buy drugs from private pharmacies, they have to purchase them at a considerably higher cost. However, when health department purchases drugs through a tender procedure, low cost options are given the priority. Probably, that can be one reason for higher drug cost for the patients than the government.

The expenditure on antibiotics contributes considerably to the total expenditure on drugs for both patient and the government in all three units. More than 60% of total drug expenditure was on antibiotics by both the patient and by the government. Expenditure on antibiotics is proportionately higher in the surgical unit compared with other units. The cost difference between patient expenses and the government expenses is highest in the surgical unit and that is mainly due to high cost incurred on antibiotic purchasing in the surgical unit. Increase of expenditure by patient with the duration of stay is also considerably higher in the surgical unit compared to other two units and this is mainly due to increased expenditure on antibiotics. This reflects the frequent use of costly antibiotics to the patient which is questionable most of the time (6-8).

The other possible contributory factor for higher drug expenditure by the patients is usage of trade names when prescribing. Even though not studied extensively in the current study, most of drugs prescribed to buy from outside pharmacy are in brand names. This totally depends on prescribers' interest on brand names. It is a well-known fact that branded drugs are expensive than generic drugs in Sri Lankan market (9). Hence, expenditure incurred by patient is higher than that by the government in case of the same drug. But, whether this high expenditure on branded drugs is really beneficial for patient or not is controversial question (10).

### Conclusions

Patients' expenditure on drugs is higher than that of government in all three units. Comparing all drugs, expenditure on antibiotics is the highest from the patient as well as from the government. Surgical unit has the highest difference of drug expenditure between patient and government compared to other two units and this discrepancy is increased with the number of days hospitalised.

### Conflicts of interest

There are no conflicts of interest disclosed.

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# Metabolic profile, obesity and overweight among Sri Lankan males with ischaemic heart disease: A single centre experience

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## ABSTRACT

**Introduction:** Obesity is a significant risk factor for ischaemic heart disease (IHD). Asians who are not overweight or obese tend to have IHD and develop metabolic derangements in their early life. We investigated the presence of metabolic derangements and overweight and obesity in male patients with IHD in comparison to a control group.

**Methods:** Two hundred and six male patients with IHD at the Cardiothoracic Unit and the Coronary Care Unit and 103 male controls at the Surgical Units, Teaching Hospital Karapitiya were included. Demographic data, anthropometric measurements and blood samples were collected. World Health Organization (WHO) cut-off values defined for Asians were used to define obesity using body mass index (BMI) and waist circumference (WC). Plasma glucose, serum lipids and high-sensitivity C-Reactive protein (hs-CRP) were estimated. Group comparison was done using appropriate statistical tests. Controlling for age (adjustments) was done for anthropometric variables and biochemical variables before comparison.

**Results:** The proportions with overweight or generalised obesity defined by BMI were not significantly different in both patient groups {patients with angiographically-proven coronary artery disease and first acute ST-elevation myocardial infarction (STEMI)} compared to controls (all  $p > 0.05$ ). However, the proportion of patients with central obesity was higher in patients with angiographically-proven coronary artery disease ( $p = 0.044$ ), while a difference was not observed in patients with STEMI ( $p = 0.193$ ). The mean concentration of plasma glucose, serum lipids and hs-CRP were significantly higher in patients compared to controls (all  $p < 0.05$ ).

**Conclusions:** Proportions of patients with overweight and generalised obesity were not significantly higher in both patient groups compared to controls. However, the proportion of patients with central obesity was significantly higher among patients with angiographically-proven coronary artery disease group compared to the controls.

**Keywords:** *Anthropometry, ischaemic heart disease, males, metabolic profile, obesity, Sri Lanka*



## Introduction

Obesity is defined as excess body fat and is a significant health problem which is known as a major risk factor for ischaemic heart disease (IHD) (1-2). Body mass index (BMI) is used to define the generalised obesity among the anthropometric parameters (3). Waist circumference measures central obesity that reflects visceral fat (4). World Health Organization (WHO) has recommended cut-off values for these parameters to define obesity and to identify increased cardiovascular risk (5). Asians who are not overweight or obese tend to have IHD and develop metabolic derangements such as dyslipidaemia, diabetes mellitus or prediabetes and chronic systemic inflammation in their early life (6). The availability of research data is limited to evaluate the usefulness of common anthropometric measurements to assess the overweight and obesity at the local set up. Therefore we wanted to compare the proportion of patients with obesity and metabolic derangements between two groups of patients with IHD and hospital-based controls who did not have clinically manifested coronary artery disease.

## Methods

This was a hospital-based, case-control study which included 103 male patients with first clinically manifested acute ST-elevation myocardial infarction (STEMI) and 103 male patients with angiographically-proven coronary artery disease (CAD) awaiting coronary artery bypass grafting at Teaching Hospital, Karapitiya, Sri Lanka. The control group consisted of 103 male surgical patients awaiting minor surgeries with normal Electrocardiogramme at General Surgical Units, Teaching Hospital, Karapitiya. Patients and the controls in the age range of 30 to 70 years were recruited. Common exclusion criteria for three groups of participants were history of recent surgery or major trauma within three months or a history of acute coronary syndrome in the past three months, malignancy, chronic inflammatory disorders, current acute severe infections (C-reactive protein level more than 10 mg/dL) and dementia or any structural damage to the central nervous system.

An interviewer-administered questionnaire was used to collect the relevant information from the study subjects. The principle investigator, a medically qualified doctor collected the data using the same instruments. Weight, height and waist circumference measurements were obtained according to the standard protocols (7). Serum lipids and plasma glucose were estimated based on spectrophotometry based techniques (ProDia International, UAE). High sensitivity-CRP was estimated using turbidimetry (CRP XL WIDE RANGE, DIAgAM, Rue du Parc Industriel, 7822, Ghislenghien, Belgium). Generalised obesity was defined using BMI according to the cut-off values ( $\geq 25 \text{ kg/m}^2$ ) given for Asians by WHO (8). Waist circumference of 94 cm, set by WHO was used to define central obesity of males (9). Data were analysed using Minitab version 15 for Windows. Controlling for age (adjustments) was done for anthropometric variables and biochemical variables before comparison.

Two-proportion test and independent two sample t-test were used in the analysis. Significance level was defined as 0.05. Ethical clearance was obtained from the Ethical Review Committee of Faculty of Medicine, University of Ruhuna, Sri Lanka. Informed written consent was obtained from all the participants before the data collection. Conduct of the research project was according to the Declaration of Helsinki. Confidentiality of data was strictly maintained.

## Results

Table 1 shows a comparison of baseline characteristics of the two categories of patients and controls. The mean concentration of plasma glucose, serum lipids and high sensitivity C-reactive protein (hs-CRP) were significantly higher in patients of both groups compared to controls (all  $p < 0.05$ ).

Table 2 shows the comparison of overweight, generalised obesity and central obesity among the two groups of patients and controls according to WHO defined cut-off levels for Asians.

**Table 1:** Comparison of baseline characteristics of two patient categories vs. controls

Characteristics	Controls n = 103	Angiographically proven CAD n = 103	<i>p</i> value	STEMI patients n = 103	<i>p</i> value
Age (years)	52 ± 11	57 ± 8	0.001	54 ± 8	0.201
BMI (kgm <sup>-2</sup> )	22.4 ± 5	23.9 ± 3	0.008*	21.2 ± 3.6	0.055†
Waist circumference (cm)	75.9 ± 10	87.9 ± 7	0.001*	76.9 ± 9.9	0.462†
Regular physical activity	15 (14.6%)	17 (16.5%)	0.267	14 (13.6%)	0.433
hs-CRP (mg/L)	1.7 ± 0.6	3.4 ± 1.62	0.001	3.7 ± 0.84	0.001
TGs (mmol/L)	1.5 ± 0.8	2.5 ± 1.0	0.001	2.1 ± 1.0	0.001
TCh (mmol/L)	5.2 ± 1.6	5.9 ± 2.8	0.022	6.0 ± 2.4	0.001
HDL-Ch (mmol/L)	1.4 ± 0.6	1.1 ± 0.5	0.001	1.1 ± 0.5	0.001
LDL-Ch (mmol/L)	3.1 ± 0.5	3.9 ± 1.2	0.001	4.5 ± 2.4	0.001
PG (mmol/L)	5.1 ± 0.6	5.5 ± 1.4	0.007	6.0 ± 2.06	0.001

\*Remained significantly different after the age-adjustments. †Become significantly different after age-adjustment. Comparison was made between the two patient groups and the control group separately. Two-proportion test and Independent sample *t*-test were used in the analysis. Data presented as frequencies, percentages and mean ± SD. CAD = Coronary artery disease, BMI = Body mass index. STEMI = ST-elevation myocardial infarction. hs-CRP = High sensitivity-C-reactive protein, TGs = Triglycerides, TCh = Total cholesterol, HDL-Ch = High density lipoprotein cholesterol, LDL-Ch = Low density lipoprotein cholesterol, PG = Plasma glucose.

**Table 2:** Comparison of overweight, generalised obesity and central obesity among patients and controls according to WHO defined Asian cut-off levels

Category	Controls (n = 103)	Angiographically- proven CAD patients (n = 103)	<i>p</i> value	STEMI patients (n = 103)	<i>p</i> value
<b>Body mass index (kg/m<sup>2</sup>)</b>					
< 18.5 – underweight	17 (16.5%)	0 (0.0%)	0.001	26 (25.2%)	0.121
18.5 - 22.9 – normal	45 (43.7%)	43 (41.7%)	0.778	52 (50.5%)	0.327
23 - 24.9 – overweight	20 (19.4%)	31 (30.1%)	0.074	13 (12.6%)	0.182
≥ 25 – obesity	21 (20.4%)	29 (28.2%)	0.192	12 (11.7%)	0.085
<b>Waist circumference (cm)</b>					
< 94	96 (93.2%)	87 (84.5%)	0.044	100 (97.1%)	0.193
≥ 94	7 (6.8%)	16 (15.5%)	0.044	3 (2.9%)	0.193

Data presented as frequencies and percentages. CAD = Coronary artery disease, BMI = Body mass index. STEMI = ST-elevation myocardial. Comparison was made between the two patient groups and the control group separately. Two-proportion test was used in the analysis.

The proportions with overweight or obesity were not significantly different in both patient groups {patients with angiographically-proven coronary artery disease and patients with first acute ST-elevation myocardial infarction (STEMI)} defined by BMI compared to controls (all  $p > 0.05$ ).

However, the proportion of patients with central obesity was higher in patients with angiographically-proven coronary artery disease ( $p = 0.044$ ), while a difference was not observed in patients with STEMI ( $p = 0.193$ ).

## Discussion

According to the findings of our study, in spite of the presence of coronary artery disease and related metabolic derangements, the proportion of patients with generalised obesity assessed by BMI is not significantly higher in the patient groups compared to controls. However, the percentage of patients with central obesity assessed by waist circumference among those with angiographically-proven coronary artery disease showed a significant difference. Interestingly, patients in the underweight category had developed STEMI. Although obesity and overweight were not highly prevalent in both disease groups, there were biochemically identified metabolic changes among the patients.

The relationship and the behavior of anthropometric parameters, body compositions and body fat are different in various ethnic groups across the world population. Asians generally have high fat content for a given BMI and hence, they have an increased risk of CAD and metabolic disease (10). Therefore, it is debatable whether the defined cut-off values of these anthropometric parameters accurately reflect the amount of body fat or visceral fat. In certain instances BMI is known to overestimate the degree of obesity in people with lower body fat percentage and higher lean body mass (11) or sometimes underestimate and reflect as low body fat especially in Asians (6). If WHO defined cut-off values for Europeans are used for Asians (5) the detection rate of overweight and obesity could be further lowered.

A recent study done on Koreans revealed that the individuals with normal weight obesity (normal BMI with high body fat by body composition assessment) had subclinical atherosclerosis (12). The probable explanation for the observation is that atherosclerosis and related metabolic alterations are mainly driven by visceral fat which is not reflected by BMI. A study done on Indians showed that Asian Indians have excess cardiovascular risk at normal BMI and WC values. It suggests that definitions of "normal" ranges of BMI and WC need to be revised for Asian Indians (13). In spite of normal BMI, Asians tend to have impaired cardiovascular metabolic profile which is associated with subclinical vascular inflammation (14).

There are few local studies done to assess the validity of the current cut-off values of the BMI and WC to define the obesity. One study revealed that BMI and WC values of 24 kg/m<sup>2</sup> and 92 cm can be considered appropriate cut-off values when detecting central obesity in Sri Lankan premenopausal women (15). Another study suggested that mean BMI and WC for Sri Lankan males as 21.1 kgm<sup>-2</sup> and 78 cm and they further commented that Sri Lankans have a higher prevalence of obesity which may not be detected by the WHO defined guidelines for Asians (8,16). Moreover, they found that the percentage of Sri Lankan adults in the overweight, obese and centrally obese categories were 25.2%, 9.2% and 26.2% respectively (16). A multi-national study demonstrated that there are possibilities of frequent discordances between BMI, WC and visceral fat mass among different ethnic and racial groups (4). However, Sri Lanka experiences double burden of nutritional disorders and further lowering the cut-off value of BMI to define the obesity is dubious, because detection of underweight and under-nutrition may get influenced. Therefore, the incorporation of the metabolic markers with obesity in the assessment of cardiometabolic risk could be an option.

Dyslipidaemia, elevated blood glucose and inflammation are known to increase the risk of atherosclerosis and IHD (17). Metabolic alterations that occurs in the individuals with normal body anthropometry is said to be due to the increased fat content in the body especially the visceral fat (14). Both patient groups showed significant metabolic alterations in the present study. The prevalence of diabetes mellitus in Sri Lanka was nearly 11%, while 1/5<sup>th</sup> of the adult population was suffering from dysglycaemia (18, 19). A recent local study has found that metabolic syndrome as a common health concern among Sri Lankan adults and prevalence of metabolic syndrome in adult males was 18.4% (20).

## Conclusions

Compared to controls, the proportions of patients with overweight and generalized obesity in both patient groups with ischaemic heart disease were not significantly higher, though they had related metabolic derangements. However, the proportion

of patients with central obesity was significantly higher among patients with angiographically-proven coronary artery disease group compared to the control group. This could be due to the fact that Sri Lankans may develop ischaemic heart disease even without obesity since they are metabolically impaired or existing obesity is underestimated by the cut-off levels used.

### Recommendations

We wish to recommend larger multi-center studies which should include body composition assessment.

### Limitations

Use of hospital based control group is a limitation of this study.

### Acknowledgements

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### Conflict of Interest

None.

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# The art and the science of history-taking and physical examination: Its relevance in modern day medicine

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## ABSTRACT

History taking and physical examination which started as the bedrock of practice of clinical medicine many centuries ago has been challenged by advancement of practice of medicine through research and development, sociocultural changes, changes in patient and public expectations, amongst many other changes that have occurred over the centuries. These changes have accelerated during the last 100 years and transformed way doctors manage their patients with a tendency to distance from their patients and depend more than ever on machines in planning and executing their management. This article threads through these developments and discusses how such changes affected conventional approaches to history taking and physical examination.

*“Medicine is a science of uncertainty and an art of probability” - Sir William Osler*

It is important to realise that practice of medicine developed as an art when the process of history taking and physical examination formed the only pathway leading to a diagnosis of the illness, rather than the disease.

### **Important milestones**

For few millennia, people have practised medicine as a profession in diverse parts of the world such as China, Egypt, India and Mesopotamia. Most of the ancient practice of medicine was not rational and the prospect of recovery rested in the faith of mythical gods of different cultures. Hippocrates (~460 - 370 BC) who lived in the island of Kos near Greece is considered to be the ‘*Father of Medicine*’ as he was the first person to believe that diseases were caused by natural causes rather than been determined by the god. However, his concepts were based on a theory of ‘*Humorism*’, but detailed inaccurate information about anatomy and physiology. Hippocratic medicine was notable for its strict

professionalism, discipline, and rigorous practice. The Hippocratic School gave importance to clinical observation and documentation (1). Hippocrates and his followers were first to describe many diseases and medical conditions.

Hippocratic medicine was practiced over many centuries without a sound understanding of its scientific basis with good doctor-patient interaction which involved history taking and physical examination evolving into an elaborate art over many centuries. This interaction formed a major part of doctor-patient relationship. In the civilized world, as there were no specific curative therapies up until the twentieth century though this relationship in itself played a major therapeutic role and doctors played multiple roles as the healer, witness to suffering, interpreter of symptoms and a provider of comfort and compassion.

Two important milestones in techniques of physical examination - percussion and auscultation - started as an art and embraced scientific thinking and interpretation with refinement of techniques and understanding of physiological, anatomical and pathophysiological basis of different acoustics. Leopold von Auenbrugger, was an Austrian

physician who introduced percussion as a diagnostic technique. This technique of percussive diagnosis had its origins in testing the level of wine casks in the cellar of his father's hotel by listening to dullness to percussion. Rene Laennec, a French Physician, the inventor of the stethoscope while walking down a street in Paris, he saw some children holding their ear to one end of a stick while the opposite end was scratched with a pin; the stick transmitted and amplified the scratch. Laennec presented his findings and research on the stethoscope to the Academy of Sciences in Paris, and in 1819 he published his masterpiece on the use of stethoscope in medicine (2).

Many changes leading to modernisation of clinical medicine can be attributed to Sir William Osler (1849 - 1919), a Canadian who is arguably the "Father of Modern Medicine". One of his outstanding contributions includes revolutionising the medical curriculum of the United States and Canada, synthesizing the best of the English and German systems (3). Osler adapted this system to the English system by teaching all medical students at the bedside. He was instrumental in establishing Johns Hopkins School of Medicine in 1893. He held the position of Professor of Medicine in four reputed universities - McGill, Pennsylvania, Johns Hopkins and Oxford. He described many diseases and signs of which some bear his name. One of his outstanding works is the textbook of clinical medicine published in 1892 titled '*The Principals and Practice of Medicine*' going into many editions as the standard textbook in clinical medicine for medical students and doctors in Britain, Canada and United States for over a century (4).

Although doctor-patient relationship was built on such good faith, the downside was the lack of standards of care, quality control and accountability making patients vulnerable to quackery. Over many centuries medicine was practiced as a trade rather than a profession and the services were available only to affluent members of the society. As a matter of fact, there was no mechanism that would ensure that best care for the patient would be made available anywhere in the world until American Medical Association which was established in 1847 undertook the development of "*Code of Medical Ethics*" as its first task.

### ***The influence of science***

#### ***Rise of the scientific paradigm and dominance of the biomedical model***

During the last few centuries, medical care has been revolutionised by the discoveries of the circulation of the heart and vascular system, the germ theory of disease, cell theory with its application to the effects of disease on tissues and organs as well as the discovery of drugs and pharmaceuticals, devices and equipment (5).

In eighteenth and early nineteenth centuries with clinical reasoning switching to the biomedical model arising out of many scientific discoveries, it attributed diseases purely to physical changes in the body, with absence of symptoms being equated to absence of illness and a state of health. Beyond the 19<sup>th</sup> century the roles of the doctor as perceived by the patient expanded to domains such as an evidence based practitioner, service provider and professional. This has led to changes of healthcare practices and societal expectations. Doctors' status and capabilities rose with their scientific knowledge, newer anaesthetics and surgical techniques, effective drugs, new devices and pharmaceuticals. Classifications based on the signs and symptoms of disease became the primary focus rather than the patient's suffering. The body was increasingly seen as a machine, and the disease, not the patient's experience of illness became the object of study and treatment. These made doctors to lose their modesty and become proud and paternalistic with the patient becoming a passive recipient of care (6). The Flexner Report of 1910 also transformed the nature and process of medical education in the United States with a resulting elimination of proprietary schools and the establishment of the biomedical model as the gold standard of medical training (7).

#### ***Challenges to the biomedical model and rise of the biopsychosocial model***

The biomedical model was challenged in the latter part of the twentieth century by psychoanalysts (Carl Rogers and others) who believed that many symptoms and somatic presentations of illness can arise due to unhappiness (8). There were many other shortcomings of the biomedical medical model as well. Those were: i) it's 'paternalistic' nature with loss of patient autonomy and increase of doctor's

power, ii) failure to build any ‘therapeutic relationship’ which would otherwise have fostered better compliance and expedited recovery, iii) inability to capture or understand non-verbal language, iv) difficulties doctors would encounter with regards to explaining the illness when they could not arrive at a diagnosis, v) doctor-centeredness, leading a doctor-centred agenda with closed-ended questions in a structured format leaving little room for the patient to express his or her suffering as desired, especially on matters such as ideas, concerns and expectations, vi) tendency for patients to be perceived more as clients or customers and the practice of medicine becoming more a business than a profession, vii) lack of room for patient feedback on matters such as safety, efficiency, effectiveness, timeliness and equity, viii) failure to address physicians civic obligations, and ix) tendency for doctors to acquire high credibility within their profession leading to loss of self-regulation and loss of accountability (by not coming under supervision of any professional or regulatory body for supervision) (9). Biomedical model also encouraged development of dichotomy between science and art of medicine: researchers were more interested in science, while clinicians were more devoted to art. Such dichotomy is bound to fail to deliver best care for the patient as practicing medicine without attention to science would have been foolish, and caring human beings without attention to professionalism, compassion and empathy would have been unkind. Taking such deficiencies in the biomedical model into consideration, one of the advocacies came from Engel who suggested the need for a new medical model that linked science and humanism and used the term ‘bio-psycho-social-cultural model’ (10). This approach integrated information concerning ‘what was the matter with the patient’ and ‘what mattered to the patient’. The biopsychosocial concept of health, or ‘Whole Person Health’, or holistic care, was affirmed in the World Health Organisation’s Alma-Ata Declaration in 1978, a major milestone of the 20<sup>th</sup> century, defining health as a state of complete physical, mental, and social wellbeing, and not merely the absence of disease or infirmity’ (11).

However, bio-psycho-social model cannot be applied to all clinical encounters when contextuality

is taken to consideration. As physicians, it is important to consider contextuality during history taking and physical examination. Taking contextuality to account, Thomas Szasz and Marc Hollender described three basic models of doctor-patient relationship: i) ‘*activity-passivity*’, whereby the physician does something to an inert or unresponsive patient as when the patient is in delirium or in coma or has acute trauma or is under anaesthesia or if the patient is an infant; ii) ‘*guidance-cooperation*’, in which the physician tells the patient what to do and the patient complies as in patients with pneumonia or myocardial infarction or acute asthma; and iii) ‘*mutual participation*’, whereby the physician helps the patient to help him or herself and the patient participates as a partner as in long term management of diabetes or hypertension (12).

#### ***Drivers that changed its practice in modern times***

There have been many changes in the way we approach patients due to scientific developments that have occurred in the past, especially during the last 100 years. Some such developments are highlighted below. These scientific developments seem to challenge the artful manner we handle patients during clinical encounters.

#### ***Teamwork and specialisation***

Towards the end of last century, another challenge to the way how doctors treat patients occurred with the development of ‘team-based’ approach in which the tasks previously carried out by the doctor himself / herself alone, came to be shared by allied health personnel working as members of the caring team. This multi-disciplinary approach though effective and efficient has disjointed the breadth of care that is traditionally provided by family practitioners. It also changed the way doctors perceive their role by shifting to an approach of confining services in detail only to certain aspects of the management, thereby compartmentalisation of care. As expectations of such services by the patient, family, hospital and the public became high, it added stress to doctors making their behaviour defensive at times. Thus, increased specialisation in the organisation of care resulted in great benefits of expertise but also weakened continuity



of longitudinal relationships for patients due to segmentation of delivery of care with failure to deliver holistic care (13). These changes have escalated the cost of care and increased the complexity of management, especially in patients with multiple comorbidities.

### ***Dawn of an era of evidence-based medicine and development clinical practice guidelines***

Another factor that influenced the art and science of practice of modern day clinical medicine is the emergence of the concept of Evidence-Based-Medicine (EBM) that was pioneered by American-Canadian physician David Sackett, in early 1990s. With this the approach, practice of clinical medicine became more objective, contrary to the process of management that was based on clinical judgement which depended more on clinical wisdom. Sackett argued that evidence-based practice was the integration of individual clinical expertise with the best available external clinical research evidence and its judicious application to the care of individual patients (14). Based on EBM various healthcare institutions and medical association have drawn 'best practice advice' known as clinical practice guidelines. However, whether practice of EBM alone is the ideal recipe to address individual issues in a given patient is debatable (15).

### ***Need for accountability to the society***

During the latter part of the twentieth and twenty-first century with increasing public awareness of doctors' responsibilities and increase in transparency of healthcare delivery, public agitation in instances of malpractice increased and doctors became more vulnerable to litigation. In the United Kingdom, the King's Fund (an independent charity in the UK) in 2010 included views of lay people, amongst the various stakeholders, to define the basis for a moral contract between the medical profession and society in achieving the goals of best care for both the population as a whole and for the individual (16).

### ***The Internet and democratisation of knowledge***

In the twenty-first century with the explosion of information available, patients, carers and the public became more aware of clinical knowledge regarding

diseases, treatments that are available including latest developments, and the process of delivery of healthcare. In short, the Internet became the biggest medical library in the world. As result of such awareness many changes occurred in the way clinical medicine is practiced in developed countries. These include; i) increase in prior knowledge of the patient with respect to the illness for which the he / she is seeking treatment, making room for shared decision making and paving the way for 'client-provider' type of consultations compared to previously practised 'doctor-patient' relationship, ii) breakdown in the trust patients have in doctors and the healthcare delivery due to horror stories in the internet about unsafe drugs and medical errors, and iii) increased access to advice and algorithms regarding self-care available in the Internet leading to patient-empowerment to handle their own illnesses.

In addition to changes described above on part of patients, the way doctors manage their patients too have changed radically with the advent of the Internet. These include electronic medical records, maintenance of electronic medical databases, gathering of medical knowledge and information sharing with colleagues, patients and careers. These developments seem to distance patient further away from the traditional 'doctor-patient' relationship. For example, during consultations doctors seem to focus more on the computer screen than looking at the patient, thereby losing opportunities to develop rapport as well to recognise non-verbal cues - which are important aspects of history taking. Another disadvantage of electronic data storage is the tendency to data leakage leading to loss of confidentiality.

### ***Medical errors, litigation and medical defence***

WHO defines patient safety as the prevention of errors and adverse effects in patients associated with health care (17). Medical negligence encompasses medical errors as well as acts of omission. In December 1999, the Institute of Medicine of United States reported that medical errors cause up to 98,000 deaths and more than 1 million injuries each year in the United States alone (18). With medical errors not being infrequent, there is heightened vigilance on part of patients, carers and the public of

such occurrences. Therefore, patient-safety has now become the centre stage of good medical practice leading to litigation of doctors who are caught of malpractice. This has led to doctors being more defensive by paying substantial amounts of money for medical insurance cover, which in turn inflates consultation fees and hospital charges. In order to reduce the risk of litigation, doctors also over investigate patients to ensure that nothing gets left out and as a result patient charges get escalated. These events often set in a vicious circle leading to lack of equity and affordability to so many who deserve more attention to their ill health.

### ***Emphasis on communication skills, medical ethics and professionalism***

Research on consultations of doctors in 1980s have shown that high control styles of communication to be common, with interruption of patients only 18 seconds into the consultation with important information being missed (19). Doctors often turn out to be poor listeners and patients are not informed of the diagnosis and the plan of management in simple lay language before they wrap up the consultation. 'Tomorrow's Doctors' published by the UK GMC in 2009, spells out competency level of communication skills required by a doctor (20). With the public becoming more aware of medical matters, patients prefer to be involved in shared decision making (exercising autonomy), whilst factoring other basic principles of ethics such as beneficence, non-maleficence and justice. Patients and carers expect them to be handled with empathy and compassion. In addition, the public expects the doctors to practice with respect and be responsible and accountable in whatever duties they perform, with recognition of their limitations and the need to improve with further training. All these together can be called medical professionalism and the modern society has high expectations of professionalism from doctors.

### ***Globalisation, information technology and consumerism***

Information technology is now widely available in most countries along with more modern approaches to disease including new drugs, new devices and new techniques that are being designed in developed

countries. These innovations are often made available for healthcare globally, including developing countries within a short time. Information technology enables patients and their carers to be more aware of options available to them, giving a choice in selecting their doctor for consultation. This kind of consumerism to a great extent depends on factors such as availability of choice of doctors, financial status of the patient and healthcare facilities that are at hand. In short, as mentioned by Sigerist, "the physician's position in society is never determined by the physician himself, but by the society he is serving" (21).

### ***Concluding remarks***

In the sphere of medical research and development many advances are taking place every day giving a different dimension to the manner in which we manage our patients. These developments include use of gene sequencing and genetic diagnosis; multi-slice MRI scanning, functional PET scanning and other cutting edge imaging techniques; robotic surgery; nanotechnology; artificial intelligence; precision medicine with genetic and molecular profiling; organ transplantation; stem cell therapy; 3-D printing of organs; bio-artificial hearts, lungs, trachea and kidneys; to mention a few. Use of this ever increasing armamentarium in no doubt will benefit survival of our patients and improve morbidity and mortality statistics but we need to ponder whether it could replace the kindness and compassion that we as physicians could bestow upon our patients. With the dawn of an era where computers and other forms of artificial intelligence are on the verge of taking over the task of diagnosing and making decisions on management of our patients, we physicians seem to distance ourselves from our patients more and more. Can we rebuild or create a new progressive era for medicine, and practice the art and science of medicine the way it was done, whilst retaining our commitment to science, building back and reinforcing our obligations of service to the society, artful practice, humility, and professional autonomy in the way it prevailed for centuries?

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# Functional abdominal pain disorders in children: Bridging the gap

*Galle Medical Association Oration 2018*

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In early twentieth century, Sir George Frederic Still, known as the father of British Paediatrics, wrote; “I know of no symptom which can be more obscure in its causation than colicky abdominal pain in childhood”. Today, a century later, colicky abdominal pain in children still remains an symptom which is often difficult to understand and management is a challenge. Half a century later, Dr. J Apley, another British Paediatrician, studied abdominal pain among children extensively named this symptom complex as “recurrent abdominal pain syndrome of childhood”

He defined it as “at least three episodes of abdominal pain, severe enough to affect their activities over a period longer than three months” His findings formed the main guidelines for the paediatricians and researchers dealing with this problem for the next half of the century.

Dr. John Appley found that 10.5% of British schoolchildren were suffering from RAP in 1958. Since then it has been studied all over the world, including Asian countries, and has been reported to occur in 8-12% of school-aged children. According to previous epidemiological studies RAP is the second commonest painful health problem in school-aged children, only second to a headache.

Several studies have shown 75 % to 90% of the RAP patients are suffering from none- organic type of RAP. When a child presents with organic pain, the clinician may be able to objectively test for, and diagnose, a physical cause for that pain. This is not the case with non-organic pain, as there is no definitive test. The investigation, at best, will only exclude organic disease it will not prove a functional origin. Therefore, the diagnosis of non-organic pain

abdominal pain is both intellectually and medically challenging.

The vast majority of children and adolescents with recurrent abdominal pain have functional gastro-intestinal disorders. Functional gastrointestinal disorders are defined as “chronic or recurrent gastrointestinal symptoms, which are not explained by structural or biochemical abnormalities”. It is a spectrum of clinical presentation diagnosed by symptoms based on Rome criteria.

The road to the development of the Rome criteria for FGIDs began from a landmark meeting in Rome. In 1988, During the 12<sup>th</sup> International Congress of Gastroenterology in Rome a working team was set up to create guidelines for the management for IBS. This decision has revolutionized the approach to FGIDs by deviating the previous “diagnoses of exclusion” approach and introducing the “diagnoses of inclusion” approach. The first edition of Rome-Rome I was published in 1994 which outline the symptom-based diagnostic criteria for 21 FGIDs. Rome I diagnostic criteria was revised and in 1999 Rome II was published. Rome II included the diagnostic criteria for paediatric FGIDs for the first time. Rome III was published in September 2006 which is a nearly thousand-page document written by a collaborative effort of 82 international experts. The Rome III classification includes 28 adult and 17 paediatric diagnostic entities. The new Rome IV which was released on May 2016, is evidence-based, multicultural oriented and with clinical applications.

There are four functional gastrointestinal disorders, which are presented as the abdominal pain as the predominant symptom. Therefore Irritable bowel syndrome, abdominal migraine, Functional

dyspepsia, Functional abdominal pain are known as functional abdominal pain disorders. In Rome IV, the label of abdominal pain-related functional gastrointestinal disorders (AP-FGIDs) was replaced by the term functional abdominal pain disorders (FAPDs).

Despite the high prevalence, underlying pathophysiology of this condition is poorly understood and effective treatment options are lacking. During this presentation, I would like to discuss Epidemiology, risk factors pathophysiology, the impact of the disease. Finally the management of the functional abdominal pain in children.

### Epidemiology of FAPDs

The first Part my presentation is dedicated to the epidemiology of functional abdominal pain disorders. A recent meta-analysis of 58 epidemiologic studies on abdominal pain conducted from 1957 to 2014, including nearly two hundred thousand children, reported a global pooled prevalence of 13.5 %. According to different continents, the pooled prevalence was more stable, though was slightly lower in European studies and generally higher in studies from South-America and Asia. Most studies conducted in Europe, Asia and the USA did not show significant association between the socioeconomic status and the disease. However very few studies have reported the prevalence of FAPDs in 5 to 12 age group. Therefore an epidemiological study was conducted to determined the Sri Lankan prevalence in 5 to 12 age group. The findings of the epidemiological study were published as abstracts in 5<sup>th</sup> Asian neurogastroenterology and motility meeting in Osaka, Japan and The 14<sup>th</sup> Asian Pan-Pacific Society for Pediatric Gastroenterology, Hepatology and Nutrition meeting in Bangkok, Thailand.

The study was carried out using a self-administered parental questionnaire in western province of Sri Lanka. We have used standard and internationally accepted tools in data collection. All questionnaires were translated, validated and pretested in the native language (Sinhala).

Main parts of the research questionnaire included,

- Rome III questionnaire for paediatric functional gastrointestinal disorders

- Family impact questionnaire [Preds QL Family Impact Module - Version 2]
- Health-related quality of life inventory [Preds QL Paediatric Quality of life Inventory-version 4 for child report]
- Child abuse questionnaire (self-report form for children older than 13 years)
- Healthcare consultation details report

The questionnaires were filled with the help of the research assistants, which increased the accuracy and validity of the research. A total of 1000 children recruited from four randomly selected schools. 653(65.3%) correctly filled questionnaires were included in the analysis. The prevalence FAPDs was 12.6% in 5 - 12 age group. There were 82 children who fulfilled criteria for the FAPDs.

FAPDs was significantly prevalent in females. The commonest FAPDs subtype was Functional abdominal pain followed by IBS. The Prevalence of an Abdominal migraine was less than 1% in our cohort.

The pain profile showed that majority of the children had

- Moderate to severe pain, lasting less than one hour for less than 3 months duration.
- Duration of abdominal pain was more than one year in 25% of children.
- Duration of abdominal pain was significantly higher in females children

However, the severity of pain, duration of one pain episode and frequency of abdominal pain were not significantly different between males and females. Pain in another site, abdominal fullness and headache were the most common associated symptoms. However, there was no statistically significant difference between males and females with related to associated symptoms. Epigastric and periumbilical were the commonest sites for abdominal pain. However, most of the previous studies have reported the periumbilical area as the commonest site of abdominal. Higher prevalence of functional dyspepsia in this cohort who have epigastric pain may have contributed to the observed deviation in our study.

### Risk factors and pathophysiological mechanisms in functional abdominal pain disorders

Second part is dedicated on risk factors and pathophysiological mechanisms in functional abdominal pain disorders. Rome IV has several recognized groups of risk factors that are associated with FAPDs. It is suggested that most of them complexly blend with other identified pathophysiological mechanisms to potentiate their effects at both central to generate symptoms.

I have assessed gender, exposure to the child abuse, early life events, and genetic factors as risk factors. At 5<sup>th</sup> Asian neurogastroenterology and motility meeting, Osaka, Japan abstract was presented with related to the risk factor I have studied. Previous, school-based epidemiological study have shown that except from five to six-year age group, females had a higher prevalence of FAPDs in our study. This dominance in females was reported in all different continents across the world. In addition to that, the predominance of females has been also described in other functional complaints, like functional constipation and headache. Effect of sex hormones and higher visceral sensitivity have been proposed as contributing factor for female predominance in

Functional pain. However, our sample includes children of a very young age who do not have a full female hormone profile. Therefore, the exact cause for the observed female predominance is not apparent in our study.

The findings related to the exposure to abuse as a risk factor were published in the Journal of Tropical Pediatrics which is indexed in science citation index .

This publication has received the national research council merit award for scientific publication.

School-based study was conducted in 13 - 18 aged school children by using self-administered child questionnaire. The written consent was obtained from parents. Assent was also obtained from children in addition to parental consent

A total of 1855 questionnaires were distributed and 1850 (99.7%) properly filled questionnaires were included in the study.

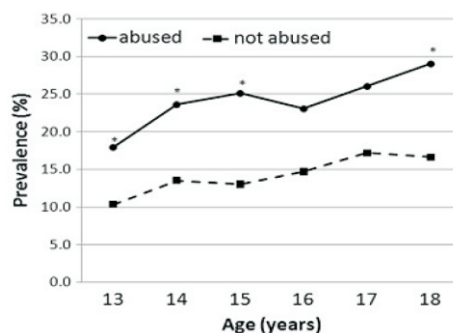
The prevalence of FAPDs was significantly higher in children exposed to all three main types of abuse physical, emotional and sexual abuse (Table 1). Observation was noted across the all age groups we have assessed (Figure 1).

**Table 1:** Prevalence of FAPDs according to the type of abuse

Type of AP-FGID	Physical abuse		Emotional abuse		Sexual abuse		Any type of abuse	
	Yes n (%)	No n (%)	Yes n (%)	No n (%)	Yes n (%)	No n (%)	Yes n (%)	No n (%)
IBS	36 (7.7%)*	55 (4.0%)	37 (8.5%)*	54 (3.8%)	10 (18.9%)*	81 (4.6%)	59 (8.5%)*	32 (2.8%)
FD	5 (1.1%)	6 (0.4%)	3 (0.7%)	8 (0.6%)	0	11 (0.6%)	6 (0.9%)	5 (0.4%)
AM	10 (2.1%)	27 (1.9%)	16 (3.7%)*	21 (1.5%)	2 (3.8%)	35 (2.0%)	18 (2.6%)*	19 (1.6%)
FAP	49 (10.4%)	131 (9.5%)	61 (14.0%)*	119 (8.4%)	8 (15.1%)	172 (9.7%)	82 (11.8%)*	98 (8.5%)
AP-FGD total	95 (20.2%)*	210 (15.1%)	109 (25.0%)*	196 (13.8%)	18 (34.0%)*	287 (16.2%)	155 (22.4%)*	150 (13.0%)

\* $p < 0.05$  compared to not abuses, unpaired t-test

IBS = irritable bowel syndrome, FD = functional dyspepsia, AM= Abdominal migraine, FAP=functional abdominal pain, AP-FGD= abdominal pain predominant functional gastrointestinal diseases



**Figure 1:** Prevalence of FAPDs according to the exposure of abuse

In addition to that those with functional abdominal pain, exposed to abuse had a significantly higher severity score for bowel symptoms.

Very few researchers have studied the relationship between child abuse and functional pain disorders during the childhood, especially among teenagers. None of those previous studies has assessed the impact of abuse on symptom profile. This novel finding indicates the importance of child abuse in developing FAPDs. The Rome committee have used the result of this study and included child maltreatment as a risk factor in Rome IV guidelines.

Second risk factor I have assessed was early life events. Using a parental questionnaire, details of ELE were obtained from 182 children with FAPDs in the 5 - 12 age group. 571 children were included in the control group. Prenatal complications were significantly higher in the FAPD group. Gestational diabetes and pregnancy-induced hypertension were the most common antenatal complications. Post-natal complications were also significantly higher in the FAPDs group. In addition to that receiving PBU care were significantly higher in the FAPDs group. The current study has added pre-natal and post-natal complications to the list of early life events associated with FAPDs. These findings signify the fact that adverse life events occurring during the fetal period and the neonatal period which is a vulnerable period for developing neurons may be an important contributory factor for the development of FAPDs. However, the duration of the gestational period was not different between FAPDs and control group. Another ELE significantly associated with FAPDs was low in the birth order. That means elder children in the family are more prone to develop the disease. Having a family member with a history of chronic abdominal or any other chronic pain was also significantly higher in FAPDs group. Adult studies have revealed a large number of genes associated with FAPDs especially with IBS and IBS patients are more likely to have a family history of similar illness. Our study has strengthen the idea of familial predisposition in FAPDs.

### **Pathophysiology of FAPDs**

In this 3<sup>rd</sup> part, I want to highlight the pathophysiological mechanism behind the symptom generation. Pathophysiology of FGIDs is a grey area

in gastroenterology. Even with the highly advanced modern technologies, pathophysiological mechanisms of FGIDs are not yet clearly understood. The recognized pathophysiological mechanisms include

- visceral hypersensitivity
- dysmotility
- immunological dysfunction
- altered gastrointestinal microbiota
- altered intestinal permeability
- genetic factors
- psychosocial disturbance

Rome IV has described FAPDs as a disorder of gut-brain interaction. However most of the proposed mechanisms do not correlate with the clinical symptoms.

I have studied the Gastric motility and autonomic functions as the pathophysiological mechanisms.

Motility studies have repeatedly shown Abnormalities in the gastrointestinal motor function as a potential pathophysiological mechanism in FAPDs. Dilated gastric antrum at fasting period, delayed gastric emptying, impaired initial distribution of a meal, impaired gastric accommodation to a meal and antral hypomotility have been reported as the abnormal motility patterns.

Autonomic nervous system is an integral part of the brain-gut axis that is involved in regulation of gastrointestinal motility. It is the one of the first mechanism investigated as a pathophysiology mechanism in functional pain. The Role of autonomic system in symptom generation is a controversial point. Available literature has shown that autonomic activity may present as normal, hypofunction or hyperactive status in functional abdominal pain in children. However, the relationship between autonomic function and gastric motility has not been studied in children. This phase of the study has been presented as four abstracts in 1<sup>st</sup> federation of neurogastromotility meeting at Guangzhou, China, 5<sup>th</sup> Asian neurogastroenterology and motility meeting, Osaka, Japan. A journal article is under review process in the World Journal of Gastroenterology as an invited article.

We have recruited 100 children with FAPDs for the laboratory study. Diagnosis were confirmed with thorough clinical and investigations procedures. Their motility and autonomic parameters were compared with 50 age, sex-matched healthy children. We were adhered to strict laboratory protocols to minimize investigators bias, environmental and diurnal variational impact on those physiological parameters. After a test meal, same time of the day, gastric motility parameters were measured by a previously validate real-time USS method in using a high-resolution real-time scanner. All gastric motility parameters were assessed by the same investigator who was blind to the diagnosis and results of the autonomic function tests results. Seven motility parameters were measured including gastric emptying rate and motility index as main motility parameters.

Four bedside, non-invasive, autonomic test were conducted to assess autonomic functions which were described by Ewings. Those test were previously used and validated for children. All the tests were conducted in thermo-neutral conditions (26C) and at the same time of day (9.30 a.m. - 10.30 a.m.) in all the children. All the readings were recorded by a single observer to eliminate interpersonal bias.

Gastric motility results have shown that Gastric emptying rate, frequency of antral contractions, amplitude of antral contractions and motility index were significantly impaired in affected children (table 2).

In all four types of FAPDs main motility parameters gastric emptying rate and motility index were lower than the controls. There was a correlation between some motility parameters with pain parameters. In contrast to the motility, autonomic parameter were not significantly different between two groups (Table 3).

We have found that in the control group, several autonomic parameters were correlated with the motility.

This has indicated the intact physiological relationship between gut and brain in healthy children. In contrast to that, any of the autonomic parameters did not correlate with any of the motility parameters in FAPDs indicating affected children gut has failed to respond to the autonomic commands from the brain.

We named this phenomenon as functional extrinsic denervation in FAPDs.

During the laboratory study I have investigated relationship between BMI and motility. Childhood obesity is a global pandemic. Several studies have shown the association between obesity and functional gastrointestinal disorders in children.

However, none of the studies have given a clear explanation for the development of functional gastrointestinal disorders in obese children. Therefore, we have assessed the Body mass index as a risk factor for FGIDs. Abstracts was presented at 7<sup>th</sup> European paediatric gastrointestinal motility meeting at Sorrento Italy and annual academic session of PSSL. It has won the best paper award in annual academic session of PSSL.

It has found that Children with more than 15 BMI had significantly larger Fasting antral area, antral area in 1 min after a test meal and antral area in 15 min after a test meal. That indicates the presence of large stomach in both fasting and fed state in children with high BMI. Furthermore, positive correlation was observed in BMI and Antral area after 1 minute and Antral area after 15 minutes after the test meal. The Postprandial antral dilatation is indicated by antral area in 1 min after a test meal and antral area 15 minute after a test meal. Riezzo *et al.*, has also found marked postprandial antral dilatation in dyspeptic children. Our finding of abnormalities in antral motility parameters propose a possible pathophysiological mechanism for the development of FAPDs in obese children.

Based on laboratory observations, we have proposed a disease model named as automatic stomach in FAPDs to explain the symptom generation in FAPDs.

This model was presented in 5<sup>th</sup> Asian neurogastroenterology and motility meeting, Osaka, Japan. Development of theoretical, etiopathogenic mechanisms involved automatic stomach and its consequences are shown in the figure 2.



**Table 2:** Comparison of gastric motility parameters between FAPDs and control groups

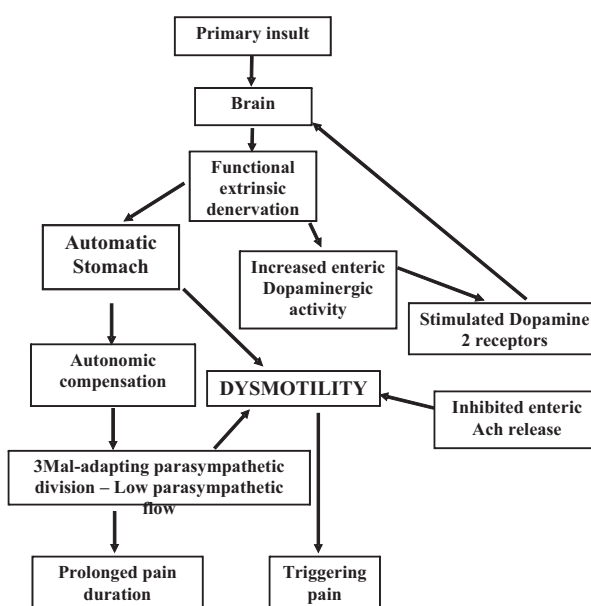
Gastric motility parameter	AP-FGIDs (n=100) Mean (SD)	Controls (n=50) Mean (SD)	p value*
Fasting antral area (cm <sup>2</sup> )	1.7 (0.9)	1.6 (0.9)	0.34
Antral area in 1min (cm <sup>2</sup> )	9.4 (2.5)	10.1 (3.4)	0.14
Antral area in 15min (cm <sup>2</sup> )	5.1 (1.9)	5.4 (10.5)	0.80
Gastric emptying rate (%)	45.7 (15.0)	59.6 (15.2)	< 0.0001
Frequency of antral contraction (/3min)	8.3 (1.0)	9.4 (0.7)	< 0.0001
Amplitude of antral contraction (%)	48.7 (12.2)	58.2 (14.9)	< 0.0001
Antral motility index	4.1 (1.2)	6.4 (6.6)	< 0.0001

\* Mann-Whitney U test

**Table 3:** Comparison of autonomic parameters between FAPDs and control group

Autonomic test	Measurement	AP-FGIDs (n=100) Mean (SD)	Controls (n= 50) Mean (SD)	p value*
Resting heart rate (beats/min)	Resting heart rate (beats/min)	89.8 (12.3)	87.9 (15.1)	0.43
Heart rate response to deep breathing	Maximum-minimum heart rate (beats/min)	31.3 (10.9)	31.8 (11.5)	0.79
Lying to standing heart rate response	30:15 ratio	1.22 (0.2)	1.26 (0.2)	0.51
Valsalva manoeuvre	Valsalva ratio	1.5 (0.3)	1.6 (0.3)	0.17
Postural blood pressure change	Fall in SBP (mmHg)	-6.3 (7.0)	-2.6 (8.6)	0.21

\* Mann-Whitney U test



**Figure 2:** Development of theoretical, etiopathogenic mechanisms involved automatic stomach in FAPDs (Karunanayake, Rajindrajith, de Silva, Gunawardena Devanarayana, 2019)

Primary insults diminishing the extrinsic (autonomic) control over the stomach lead to automatic stomach in susceptible children who may have altered physiological mechanism as a result of early life events. Stress, psychosocial factors or infection may be acting as a primary insult. The behaviour of the uncontrolled automatic stomach and inhibited Ach release via dopamine 2 receptors may lead to development dysmotility. Abdominal pain is triggered by the Motility abnormalities. In the process, compensatory mechanism may try to gain control. We have no evidence on this statement in the current study.

However, the high parasympathetic flow may be the autonomic compensation demonstrated in previous studies BY Jorgensen *et al.*, 1993 . Parasympathetic system failing and maladaptating as indicated by low parasympathetic flow. Parasympathetic maladaptation prolongs the duration of pain episode and may worsen the motility abnormalities. In a nutshell, Automatic stomach model would describe FAPDs are an “emerging rebel group when the local government (Gut) trying to get freedom from the empire (Brain)”.

### Impact of FAPDs

I will focus on the impact of FAPDs during the 3<sup>rd</sup> segment of the presentation.

Chronic abdominal pain affects child life in many ways. Epidemiological studies have shown that 10% to 15% of affected children have reported the recurrent and chronic nature affects their wellbeing. Several studies have clearly illustrated that FAPDs reduces quality of life of affected children. In addition to that, Sagawa and co-workers point out that some FAPDs affect quality of school work as well . Furthermore, one-third of the affected children continue to experience pain at least for five years. Finally, poorly managed children with FGIDs continue to have symptoms during adulthood and that is clearly linked with IBS in adults.

There is a very significant impact of FGIDs on health care systems. US Studies has shown that more than half of new pediatric gastrointestinal clinic patients met the Rome 3 criteria for more than 1 FGIDs and noted low yield from basic investigations. Functional dyspepsia had always been the most expensive FAPD to treat. Those data clearly illustrate

the healthcare burden and rising costs of FAPDs on the health budgets of countries. During the previously described epidemiological study, impact of the disease on 5 to 12 age group was assessed by using the parental questionnaires. This phase of the study has been presented as four abstracts in 1<sup>st</sup> federation of neurogastro motility meeting at Guangzhou, China, 5<sup>th</sup> Asian neurogastroenterology and motility meeting, Osaka, Japan.

Some degree of disturbances to child activities due to abdominal pain was reported in nearly 80% of children with FAPDs. The majority of them reported to have disturbances in schooling. Sleep disturbances were recorded in 75 % of the affected children. Anorexia was reported in 75 % of children. Engaging in hobbies were the least affected activity which was 68.3%. Both males and female children were equally affected in their daily activities. Health relate quality of life was assessed as the second indicator of the disease impact. Health-related quality of life (HRQOL) is a subjective, multidimensional concept to assess impact on disease. Child HRQOL is the final outcome of interactions with various social contexts surrounding him or her. The quality of life assessment scale we used (PedsQL) was composed of 23 items comprising four dimensions:

- physical functioning
- emotional functioning
- social functioning
- school functioning

Total score is computed out of 100. Higher scores indicate better functioning.

Our study has shown except social functioning domain all other domains and total HRQOL was significantly impaired in affected children. Although social functioning domain was low in FAPDs, it was not statistically significant. Social functioning is a measure to assess the individual's ability to maintain social relations. However, there is evidence to suggest that chronically ill children do not differ from their healthy peers in social adjustment as suggested by Spieth and Harris .

Family play a major role in the development in FGIDs in biopsychosocial model of FGIDs. Surprisingly, we have found no epidemiological studies investigating the family impact I 5 to 12 age group. For the first time, we have reported the impact

of FGIDs on the family. The tool we used, The parent report of the PedsQL 2.0 family impact module was composed of 36 items comprising eight dimensions: Total score is computed out of 100. Higher scores indicate less family impact.

Although FGIDs are benign diseases, parents of affected children have shown significantly lower scores which indicating a high family impact. Apart from daily activity and social domains, all other domains have shown lower scores compared with healthy children.

Burden on the health care system is an important factor in health economy. We have evaluated the health care consultations in FAPDs which is an indirect measure of the burden on health economy. Healthcare consultations were significantly higher in FAPDs group. In 5- 12 age group, 40% FAPDs children had nearly 3 healthcare consultations during the past one year for abdominal pain. Multiple logistic regression analysis showed that nausea and presence of a family member with chronic pain was significantly associated with healthcare consultations. A negative correlation was observed between the total HRQOL score and healthcare consultations for abdominal pain. However, the majority of the children did not seek consultations for abdominal pain. It may an indicator of the prevalence of "silent sufferers" in the community.

### **Management of FAPDs**

In this Final part of my presentation I will focus on the management of FAPDs. As the first step for diagnostic workup, it is essential to devote adequate time for the history and physical examination as pathophysiological mechanisms underlying FAPDs remain unclear and currently no diagnostic biomarkers exist. History taking should include details of abdominal pain, infectious episodes or stressful events associated with the onset of symptoms, psychosocial history, dietary triggers, history of previous treatments, and family incidence of gastrointestinal diseases. Physical examination should include thorough general examination to identify evidence of an organic disease. Careful attention needs to be paid to growth parameters as well. Detailed abdominal examination, perianal, and rectal examination are also crucial in confirming the diagnosis of FAPDs. Only when alarm symptoms or

so-called red flags are present which may indicate an organic disease diagnostic testing are recommended.

It has been demonstrated that numerous laboratory investigations are performed during common diagnostic workup of children with FAPDs, without detecting clinically meaningful abnormalities, but with additional inconvenience and cost. There is the possibility of finding some false positive investigations, and frequently treated for a disease that actually does not exist. The failure in acknowledging this was already playfully called Ulysses' syndrome, in allusion to the Greek mythological hero Ulysses fought in the Trojan war but afterwards took 10 years, with many dangerous and pointless adventures, before he got back to where he had started. Similarly, the unnecessary and uncritical use of laboratory examinations, leading to long investigation journeys, and making the child and his/her family go through an unnecessary, expensive, and sometimes dangerous expedition, whose end is the starting point. However When clinicians or families require further reassurance, few judicial investigations can be performed. When no atypical clinical features are present, abdominal ultrasonography does not have significant diagnostic value.

The goal of management of functional abdominal pain disorders in children and adolescents is return to normal function rather than complete elimination of pain. When symptoms persist and disrupt a child's wellbeing, pharmacological or non-pharmacological treatment should be considered.

Education, demystification, and reassurance play key roles in the management of FAPDs, starting with explanation of the diagnosis to the child and caregivers followed by Prevalence of FGDs, Benign clinical course, intermittent nature of symptoms. It is important to stress to the change parents response to child's pain

Most children outgrow symptoms. it is important hat physicians develop a positive therapeutic alliance with the patient and the family during the initial visit. This endeavour should be used to educate patients and parents on possible underlying pathophysiological mechanisms and reasonable expectations on treatment outcome.

Both pharmacological and non-pharmacological methods have been experimented on FGIDs.

However Therapeutic options for FAPDs are often limited. It is apparent that Lack of understanding in the pathophysiology, heterogeneity of the diseases and multifactorial pathological mechanisms have contributed to non-availability of effective treatment modalities. Interventions such as amitriptyline has shown no benefits over placebo. Mebeverine, Famotidine, cyproheptadine, and rifaximin had only shown a modest effects and long term follow up data on treated children were not available. There is no convincing evidence that dietary interventions such as increasing the fibre content in the diet or a low FODMAP diet help in the management of childhood FAPDs. Other interventions such as guided imagery and hypnotherapy therapy are time-consuming and need specially trained professionals and therefore, difficult to implement in busy clinical settings. In such a context, finding a potentially effective, widely available, low-cost therapeutic agent has far-reaching benefits to children.

We have conducted a randomized controlled clinical trial on value of domperidone in functional abdominal pain in children. The trial was published in *Journal of Pediatric Gastroenterology and Nutrition* which is indexed in science citation index .

Several factors favours our selection of domperidone as a therapeutic agent.

Repeated finding of gastrointestinal motor abnormalities among children with FAPDs. Favourable results were reported in adult studies. According to the proposed "Automatic stomach model, functional extrinsic denervation is affecting gastric motility by increasing the dopaminergic inhibition on the gastrointestinal motility via DAR2 receptors. Therefore Domperidone – dopamine 2 receptor blocker can block the one pathway leading to the dysmotility. Several previous studies have supported our idea to attack enteric dopaminergic system.

Consecutive patients belonging to 5 - 12 year age group who were eligible were recruited from paediatric outpatient clinics at teaching hospital, Ragama. All recruited patients were assessed by a Consultant Paediatrician. All patients were screened for organic diseases using history, examination (including growth parameters), stool microscopy, urine microscopy and culture, full blood count, C-reactive protein, liver and renal function tests.

Special investigations performed based on findings of the initial evaluation and investigation in some patients included upper and lower endoscopy. A baseline electrocardiogram was also performed to rule out cardiac conduction abnormalities. Patients were not screened for coeliac disease and lactose intolerance since they are extremely rare in Sri Lanka. Children and parents were instructed not to change the diet or lifestyle of the child once the subjects were included into the trial.

All 100 children with AP- FGIDs recruited were randomized, using computer-generated random numbers, into two groups (50 in a group) irrespective of the symptom severity and gastric motility status. The intervention group received domperidone 10 mg (brand name Motilium®) 3 times per day, 30 minutes before meals for 8 weeks. The control group received a placebo in same dosing regimen for the same duration. The placebo was identical to domperidone tablet in physical appearance and taste. A diary was provided to document adherence to treatment, severity, frequency and duration of symptoms and interruption of activities. Primary outcomes were measured at the beginning, completion of treatment course (8 weeks) and at 6 months. Secondary outcomes were measured before treatment and at the end of 8 weeks. Both patients, parents and investigators were blind for the treatments and investigation results. Ethical approval for this study was obtained from the Ethical Review Committee of the Faculty of Medicine, University of Kelaniya. The trial was registered in the Sri Lanka Clinical Trial Registry. Two primary and two secondary outcomes were assessed.

Primary outcomes measured was cure and patient reported general improvement .

Cure was defined as,

Abdominal pain episodes less than 4 per month,

Severity of abdominal pain is less than 25 mm in the visual analogue scale,

No interruption of activities due to abdominal pain

Improvement was defined as overall satisfaction and satisfactory relief.

Decrease in pain severity and increase in gastric motility were measured secondary outcomes.

We have assessed 162 patients. Based on inclusion and exclusion criteria we have recruited 100 children for the study. 50 patients were allocated for each arm of the study. At the end of 8 weeks of treatment 89 patients completed the trial. We followed them up to 6 months and 79 patients responded for 6<sup>th</sup> month follow up. This response rate at the end of 8<sup>th</sup> week and 6<sup>th</sup> months have given adequate power for analysis. Data were analysed using intention to treat analysis. According to the analysis after 8 week of treatment children treated with domperidone have shown significant improvement. At the end of 6<sup>th</sup> month, both cure and improvement rate were significantly higher in domperidone group. Significant improvement were seen in pain reduction and motility index as the secondary outcome in domperidone (table 4).

And we compared the primary and secondary outcomes in domperidone group according to the baseline motility parameters (table 5).

When primary outcomes were compared between children with normal motility and those with abnormal motility, percentage with cure and improvement of overall condition were not significantly different after administration of domperidone at 8 weeks and 6 months. When secondary outcomes were compared, reduction in pain severity was not different between the two groups. Domperidone resulted in significant improvement of gastric emptying rate and antral motility index in children with normal gastric motility. Therefore domperidone can be prescribed irrespective of the motility status. Safety and adverse effects during the trial also important.

One patient developed a skin rash during the trial. This presentation was not considered as an adverse effect of treatment. The child completed the trial without further problems. No treatment-associated adverse events were noted during the trial period.

**Table 4:** Primary and secondary outcomes after interventions in 8<sup>th</sup> week and 6<sup>th</sup> month

Outcome		Domperidone group (n=50)	Placebo group (n=50)	p value
<b>Primary outcome</b>	<b>At 8 weeks</b>			
	Cure	22 (44.0)	14 (28.0)	0.096*
	Improvement	37 (74.0)	25 (50.0)	0.013*
	<b>At 6 months</b>			
	Cure	30 (60.0)	19 (38.0)	0.028*
	Improvement	44 (88.0)	33 (66.0)	0.009*
<b>Secondary outcome</b>	<b>At 8<sup>th</sup> week</b>			
	% reduction of pain severity	54.1 (35.8)	29.7 (50.2)	0.008†
	% improvement in gastric emptying	14.8 (7.6)	7.4 (11.2)	0.423†
	% improvement in antral motility index	27.5 (5.3)	7.2 (4.4)	0.029†

\* Chi-square test

† Independent- sample t test

**Table 5:** Primary and secondary outcomes after 8 weeks of interventions according to the baseline motility parameters

Outcome	Domperidone		p value	Placebo		p value
	Normal motility (n=26)	Low motility (n=24)		Normal motility (n=22)	Low motility (n=28)	
Primary out come						
Cure	13 (50.0)	9 (37.5)	0.374*	5 (22.7)	9 (32.1)	0.462*
Improvement	20 (76.9)	17 (70.8)	0.624*	10 (45.4)	11 (39.2)	0.369*
Secondary out come						
% reduction of pain severity	75.8	65.2	0.402	-56.6	-41.4	0.412†
% improvement in gastric emptying	55.6	39.4	0.001	-10.8	34.9	0.410†
% improvement in antral motility index	5.1	4.3	0.037	4.06	4.38	0.627†

\* Chi-square test

† Independent- sample t test

## Conclusions

In conclusion,

The FAPDs is a common disorder with female predisposition in 5-12 age group.

Impact of AP-FGIDs are severe enough,

- to reduce health-related quality of life in affected children.
- to increase health care seeking behaviour and cause a significant impact on the families of affected children.

Early life events are an important risk factor.

Main gastric motility parameters assessed were significantly lower in children with FAPDs. Assessment of autonomic functions in FAPDs show neither a significant difference compared to the control group nor a correlation with gastric motility abnormalities. Extensive investigations are of limited value in diagnosing. Because proposed pathophysiological mechanisms are usually not revealed by usual investigations. Domperidone, a prokinetic drug, has shown promising, long-lasting therapeutic value in management of functional abdominal pain in children. Therapeutic value of domperidone is not related to baseline gastric motility status. Therefore it can be prescribe without performing motility studies.

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## Extrapulmonary tuberculosis presenting as a dumbbell tumour of the chest wall


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### Introduction

Tuberculosis gives rise to a significant impact on the healthcare burden in tropical countries where it can present in a variety of ways. The commonest site of tuberculous infection is the lung, while extra-pulmonary tuberculosis (TB) is observed only among 15% to 20% of all cases mostly among immune-suppressed patients (1). Musculoskeletal system is one of the well-known sites for extra-pulmonary TB which accounts for nearly 1% to 3% of all TB cases (2-4). Chest wall tuberculosis is a rare entity of musculoskeletal TB constituting only 1% to 5% of musculoskeletal TB (3, 4). These sort of uncommon presentations are even rare among young immune competent adults. Being such rare we seldom suspect tuberculosis in young adults with no predisposition and presenting with minimal symptoms. Therefore, this case opens up new stream of thinking which is crucial in early recognition and early commencement of specific treatment for a potentially fatal disease.

### Case report

A 30-year old otherwise healthy female presented with a painful swelling on her back of the chest which she had noticed about three months prior to the presentation. She noticed that it is increasing in size but denied any fever or constitutional symptoms, cough or weight loss. She was apparently well with normal appetite and had no past history or exposure to TB.

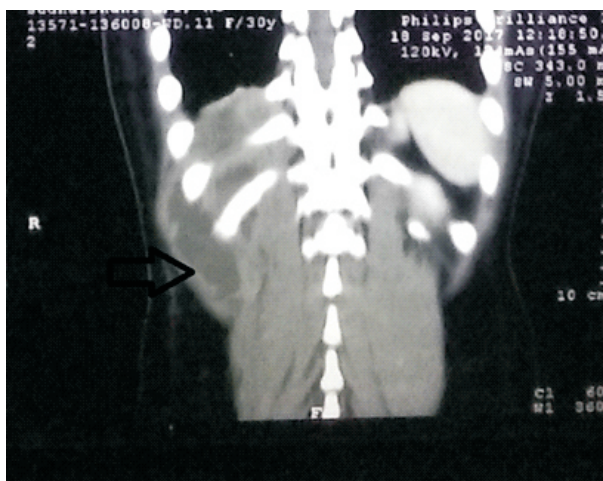
The clinical examination was unremarkable except for a fluctuant cystic lump over the posterior chest wall. It was mildly tender and had a maximum dimension of 10 cm and the overlying skin appeared normal. Her basic blood tests showed normal hematological and biochemical profile except for elevated ESR of 78 mm/1<sup>st</sup> hour with a CRP of 69 u/L. The patient did not have diabetes. The chest radiograph was normal and her sputum samples were negative for acid fast bacilli and the Mantoux test was positive with a reading of 15mm. Ultrasound scan of the lump revealed a cystic intramuscular mass in the back of the right side of the chest wall with extension to the right perinephric space (Figure 1). The subsequent CT scan of the chest and abdomen revealed a large multilobulated intramuscular abscess in the back of the right lower chest and upper abdomen (Figure 2) mainly involving the latissimus dorsi muscle measuring 12cm craniocaudally and 5cm transversely. The CT scan further described the deep extensions of the abscess to the T<sub>10</sub> – T<sub>11</sub> intercostal space and it extended to the pleural space causing a small empyema. It is further extended through the T<sub>11</sub> – T<sub>12</sub> intercostal space into the peritoneum to result in a small pus collection posterior to the Gerota fascia of the right kidney without any involvement of the perinephric fat (Figure 3).

With the positive Mantoux and CT evidence of a cold abscess she was started on anti TB drugs without much improvement. Subsequently we decided on surgical excision of the cold abscess.

The histology of the abscess wall revealed granulomatous inflammation with caseous necrosis, further confirming diagnosis of tuberculosis. The anti TB drugs were continued for six months under the care of respiratory team and she showed complete recovery. The wound healed without any complication such as sinus tract formation. She was well and was back to her usual health when we reviewed her six months after completing anti TB drugs.



**Figure 1:** Ultrasound scan showing perinephric extension of the abscess



**Figure 2:** Coronal view of the CT showing intramuscular mass in the back of the right side of the chest wall with extension to the right perinephric space.



**Figure 3:** CT abdomen showing the intramuscular abscess extending into the peritoneum and posterior to the Gerota fascia of the right kidney

### Discussion

It is well-known that chest wall TB can present as a “cold abscess.” A cold abscess is described in literature as a swelling without much inflammation (5). These abscesses are made up of caseous material (6) that results from necrosis of tissue due to chronic inflammation caused by tuberculous bacilli.

Skeletal muscles are not known to get involved even in cases of disseminated tuberculosis (7) as skeletal muscle is considered to be an unfavorable site for the survival of mycobacteria reasoning out why this type of TB is rare (7,8,9). According to literature though rare, the skeletal muscles which were involved in the course of TB were the pelvic muscles, anterior abdominal wall muscles and paraspinal muscles where the infection was due to secondary spread from bone or joint infection (7,9,10). In such a background, the primary infection of the Latissimus dorsi muscle is an unusual form of tuberculosis. The extension of the abscess to both the retroperitoneal as well as the pleural spaces gave rise to the ‘dumbbell’ shape to it making this presentation further interesting. Such extension of intramuscular cold abscess of the Latissimus dorsi has not been reported earlier.

Several mechanisms are described in the literature to explain the possible ways of tuberculous bacilli gaining access to the chest wall. In an institutional study by Faure *et al.*, described eighteen patients with chest wall cold abscess (CWCA) in which 83% had a history of tuberculosis(1), while Kyu



Do Cho, *et al.*, reported 12 out of 16 patients (11). This observation strongly supports a theory of activation of a dormant tuberculous focus leading to haematogenous dissemination (3-5, 12) as a possible mechanism. In the same study active pulmonary TB was seen in 33% of the patients (1). Another possible mechanism is that the direct extension from lymphatics of the chest wall (1,5,12). This mechanism is supported by the finding of continuity of chest wall collections into enlarged caseous intrathoracic lymph nodes (1,6) in about 50% of patients with CWCA. They were mainly the internal mammary nodes that were involved. Cold abscesses of chest wall are generally solitary though multiple lesions are not surprising (5,11). Most of the time they resemble either a pyogenic abscess or a chest wall tumor. This close resemblance, make CWCA difficult to diagnose. In such a setting CT is thought to be ideal for evaluating tuberculous chest wall lesions (6). With a CT the nature and the extent of soft tissue involvement can be studied. Accompanying intrathoracic adenopathy and bone erosion are also well documented in CT (6). Histological examination is important in establishing a diagnosis of tuberculosis as well in excluding other diagnoses. This might help the diagnosis of tuberculosis by showing caseating granulomas with giant cells or revealing acid-fast bacilli in a direct smear or growing *Mycobacterium tuberculosis* in a culture. Needle aspiration might not be much reliable as the aspirated material may not contain typical giant cells or acid-fast bacilli. And this procedure has a low diagnostic yield (1,5). Therefore, when there is a strong clinical suspicion surgical biopsy becomes the gold standard (5).

There is no consensus regarding optimal therapeutic management for CWCA. Some recommend standard anti-tuberculous drugs alone (13,14) and some recommend surgical procedures while best results were reported when both were combined since it is proven to reduce the recurrences (1,4, 13, 14). Six-month chemotherapy regimen is supposed to be adequate with successful surgical excision. In the case of non-operated patients, 9 to 12 month duration regimens are commonly used (2,14). The surgical method of choice is supposed to be a radical or wide excision though it lacks adequate supportive data (1, 4, 11). Even though only a few patients respond to anti-tuberculous medication,

medical treatment should be tried first before attempting a surgical approach. After 1 - 3 months of medical treatment, surgical resection should be considered if the lesion fails to improve or gets worsened. Though TB is common in our part of the world, the management of this type of rare forms of the disease is totally based on available literature evidence which is also limited to few case reports or series. Therefore we consider reporting this kind of successfully treated cases is of utmost importance. Further evidence is necessary to shed light in to this area as these presentations may be seen in tropics more frequently.

### Conclusions

Chest wall tuberculous cold abscess is a rare form of extrapulmonary TB. Prompt suspicion in a tropical setting with excision when it is large or when there is no significant improvement with oral anti-TB medication, may hasten recovery. Obtaining histological specimens to detect TB would help to confirm and refute other diagnoses in tropical setting where other pyogenic abscesses are frequently observed.

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# Laparoscopic splenic cystectomy

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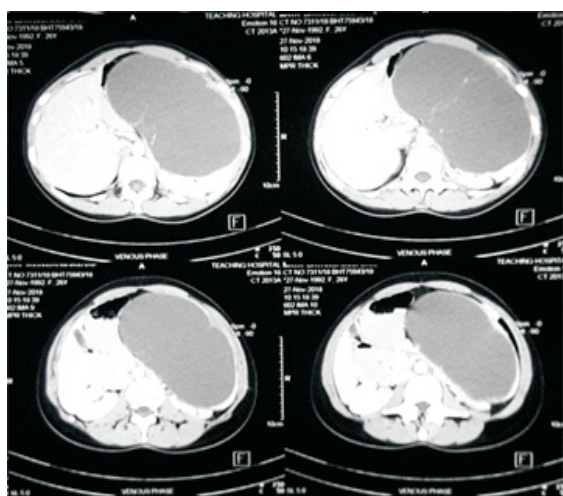
## Introduction

Splenic cyst is a rare condition identified and characterised by imaging methods such as ultrasound and computerised tomography in patients presenting with upper abdominal discomfort. The classification of splenic cysts is based on the work of Fowler and Martin (1). Splenic cysts classified as Type I primary or “true” cysts, or as Type II secondary splenic cysts or “pseudocysts.”

Splenic cysts larger than 5 cm are symptomatic and need excision for diagnostic purposes. Laparoscopic excision preserving spleen is preferred as it is associated with lower morbidity. We present a case report of a twenty six year old female who underwent a laparoscopic excision for a splenic cyst.

## Case report

A 26-year old female presented with vague upper abdominal pain and distention. On cross contrast enhanced sectional imaging she was found to have a large splenic cyst (Figure 1).



**Figure 1:** Cross sectional CT imaging of the cyst

Cyst was subjected to ultrasound guided aspiration and the cytological analysis of aspirated fluid showed benign cells. Repeat ultrasound scan in 2 months revealed reappearing of the cyst. Informed consent was obtained for laparoscopic excision.

## Procedure

### Patient Positioning

After general anesthesia with endotracheal intubation patient was placed on right lateral position with flexion of right upper limb over the chest to expose the left side of the abdomen.

### Ports Placement

Three 5 mm ports and two 10 mm ports were inserted using following landmarks (Figure 2).

### Identifying and demonstration of anatomical landmarks

Following anatomical structures were identified; stomach, colon, spleen with cyst, gastrocolic and gastrosplenic ligaments.

### Surgical Dissection

Cyst contents were aspirated using a sucker. Nearly 900 ml of straw coloured fluid was aspirated. The aspiration facilitated dissection. Gastrocolic and gastrosplenic ligaments were divided by ultrasonic dissector. Cyst wall was identified separately from splenic tissue and dissected by using an ultrasonic dissector and bipolar diathermy. In some areas a thin slice of splenic tissue had to be incorporated to ensure complete excision. Specimen was then retrieved through 10 mm port after small extension

of the incision. A tube drain was inserted through 5 mm port.

The patient was managed on the first day in the high dependency unit. She had minimal analgesic requirements and oral feeding was commenced on same day. She was discharged on the fourth post-operative day.

Histopathology revealed a benign primary epithelial cyst with a cuboidal cell lining no aetiological factor revealed.

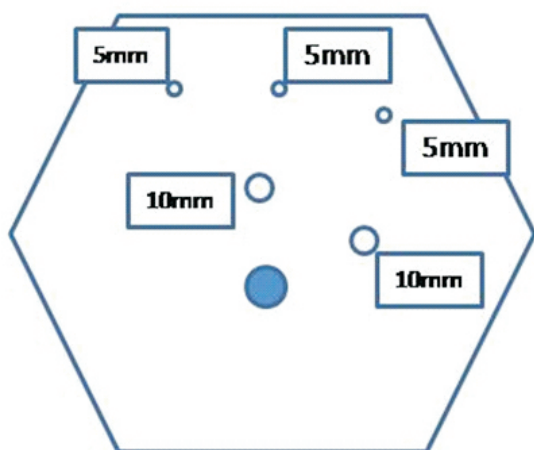


Figure 2: Port positioning for the procedure

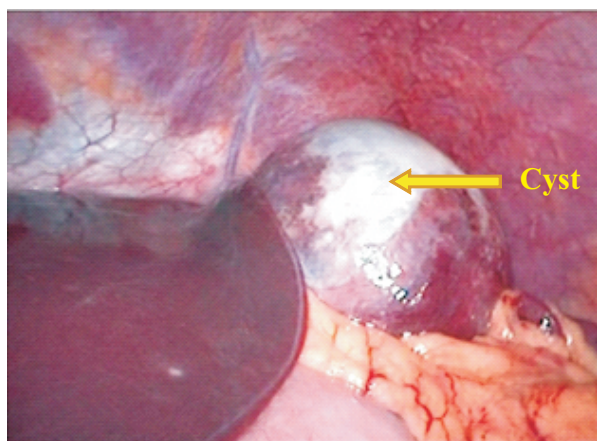


Figure 3: Laparoscopic appearance of the splenic cyst

**Discussion**

The occurrence of splenic cysts is rare. Most are asymptomatic and detected incidentally.

Splenic cysts are classified as True cysts (Type I) and Pseudocysts (Type II). Type I cysts are distinguished from Type II cysts by the presence of an epithelial

lining. Primary or true cysts include both parasitic and nonparasitic aetiologies. Nonparasitic cysts can be further subdivided into congenital (epithelial), vascular, and neoplastic cysts. Type II “pseudocysts” are most commonly due to blunt trauma, infection or infarction.

According to size and symptoms, most of them can be managed conservatively with serial imaging at follow up. But large symptomatic cysts need surgical management which is diagnostic and therapeutic. Indications for operative intervention include cysts with a diameter > 5 cm and those which are symptomatic (2). Open surgery was the mainstay of treatment in the past and splenectomy was considered as the treatment of choice. With the introduction of minimally invasive surgery laparoscopic methods have gradually evolved (3). Salky *et al.*, first reported laparoscopic deroofing of a splenic cyst in 1985 (4). It has reduced morbidity when compared with the traditional laparotomy approach (5). The patient being discussed here had a large symptomatic cyst which was successfully excised, laparoscopically, conserving the spleen.

**Conclusions**

Laparoscopic removal of benign splenic cysts offers an effective and minimally invasive alternative to the traditional laparotomy. It allows reduction in postoperative pain and length of hospitalization, improved cosmesis, minimal bleeding and preservation of splenic function.

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