

Foreign material ingestion in children and the
role of endoscopy in symptomatic patients in
South African Hospitals

Dr Himal Navin Sooka

UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

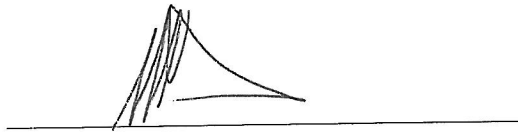


A research report submitted to the Faculty of Health Sciences, University of
the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for
the degree of Master of Medicine

Johannesburg 2019

DECLARATION

I, Himel Navin Sooka, declare that this research report is my own, unaided work. It is being submitted for the Degree of Master of Medicine in Surgery at the University of the Witwatersrand, Johannesburg, South Africa. It has not been submitted before for any other degree or examination at any other University.



24 Day of JUNE 2019 in Johannesburg

DEDICATION

For my parents, Navin and Umi, without whose immeasurable sacrifice, I would not be who I am today.

PRESENTATIONS ARISING FROM THIS STUDY

None

ABSTRACT

Background: Ingestion of foreign material by children is a common problem, and represents some of the most frequent presentations to paediatric casualty departments. The use of clinical signs and symptoms is challenging in determining which patients require urgent foreign body removal, as which patients may be treated conservatively.

Objectives: To 1) describe the aetiology of foreign material ingestion in children, and 2) determine in which symptomatic patients endoscopy may be avoided.

Methods: All children under 10 years who had ingested any foreign material between November 2013 and November 2015 were recruited into the study. Patients were classified as symptomatic or asymptomatic. Symptomatic patients were further sub-classified as mild, moderate, or severe based on clinical signs. All symptomatic patients underwent urgent endoscopy. Asymptomatic patients with foreign bodies lodged in the oesophagus were admitted for semi-urgent removal by endoscopy.

Results: A total of 138 paediatric patients were included in the study. There were a total of 105 solid objects (76%), and 32 fluid material ingested (23%). There was a significant association between symptomatic status and class of material ingested ($p = 0.001$). Endoscopy rate was significantly higher for patients who had ingested foreign objects (85.6%) compared to those who had ingested corrosive materials (36.4%) ($p < 0.0001$).

Conclusion: Endoscopy is mandatory in all symptomatic patients with a history of foreign material, and should be undertaken as soon as possible. No definitive conclusions may be drawn to affect current clinical practice due to the limitation of a small sample size.

ACKNOWLEDGEMENTS

Professor Jerome Loveland, and Dr Deirdre Kruger, for their supervision and guidance with this research paper.

TABLE OF CONTENTS

DECLARATION	ii
DEDICATION	iii
PRESENTATIONS ARISING FROM THIS STUDY	iv
ABSTRACT	v
ACKNOWLEDGEMENTS	vi
LIST OF ABBREVIATIONS.....	viii
LIST OF FIGURES.....	ix
LIST OF TABLES.....	x
CHAPTER 1	1
INTRODUCTION.....	1
1.1 Background.....	1
1.2 Objectives	3
CHAPTER 2	5
METHODS	5
2.1 Patient selection	5
2.2 Data acquisition	6
2.3 Ethical approval.....	6
2.4 Statistical analyses.....	6
CHAPTER 3	8
RESULTS	8
CHAPTER 4	15
DISCUSSION	15
CHAPTER 5	19
CONCLUSION.....	19
REFERENCES	20
APPENDIX 1: Approved Protocol	22
APPENDIX 2: Datasheet.....	32
APPENDIX 3: Ethics Clearance Certificate	34

LIST OF ABBREVIATIONS

GIT – gastrointestinal tract

CHBAH – Chris Hani Baragwanath Academic Hospital

CMJAH – Charlotte Maxeke Johannesburg Academic Hospital

LIST OF FIGURES

Figure 3.1 Distribution of ages of patients presenting with foreign material ingestion.....	9
Figure 3.2 Nature of foreign material ingested.	9
Figure 3.3 Classification of symptoms.	10
Figure 3.4 Proportion of symptomatic patients based on material ingested.	11

LIST OF TABLES

Table 2.1 Grading of mucosal injury at endoscopy	6
Table 2.2 Strength of association for categorical variables.	7
Table 2.3 Strength of association for continuous variables by groups.....	7
Table 3.1 Severity of symptoms and endoscopic grading of patients undergoing endoscopy.....	12
Table 3.2 Severity of symptoms and combined endoscopic grading of patients undergoing endoscopy.....	12
Table 3.3 Diagnostic accuracy of the severity of symptoms for combined endoscopic grading of patients undergoing endoscopy.....	13

CHAPTER 1

INTRODUCTION

1.1 Background

Foreign material ingestion is a common problem in the paediatric population and is the cause for some of the most frequent presentations to paediatric casualty departments. Most cases of foreign material ingestion are accidental and the material most commonly consists of foreign bodies, including coins, batteries, small household plastic objects, and often food boluses, as well as caustic agents, such as household cleaning products. The majority of foreign body ingestion occurs in children younger than five years old^[1] but appears to occur most commonly between the ages of one and two years, when infants are beginning to explore the world around them using touch and taste. Moreover, taste is an important mechanism by which toddlers experience their surroundings and, as a consequence of this normal behavioural development, children are constantly placing all manner of foreign material in their mouths as they explore their surrounding environment. Oftentimes, they present to emergency departments with symptoms related to oesophageal obstruction but on investigation the offending foreign object is not found in the oesophagus, having either passed into the stomach or been expectorated.

The gold standard for removal of impacted oesophageal foreign bodies is endoscopy. Several studies in the literature advocate early removal of foreign bodies within the first 24 hours^[2-6]. When performed by an experienced practitioner, endoscopic removal is safe and has a low rate of major complications^[7]. Success rates as high as 97% for removal of foreign bodies have been reported^[7]. Foreign bodies which are documented to have passed into the stomach usually pose no significant threat and can be allowed to pass through the gastrointestinal tract (GIT) spontaneously without the need for endoscopic intervention^[8].

This is the accepted standard of practice in the setting of South African academic hospitals in Johannesburg, i.e foreign bodies which have passed beyond the pylorus are allowed to pass through the GIT spontaneously.

With regard to management of cases where the impacted foreign body is asymptomatic, a prospective randomized control trial by Waltzman^[9] concluded that patients may be observed for a period of between eight and 16 hours, as up to 30% of these coins would pass through the GIT spontaneously. However, a large proportion of patients (77%) who were observed for this period still required subsequent endoscopy for removal of the coin(s). Another study found an 81% endoscopy rate for the removal of foreign bodies in the oesophagus^[7]. Furthermore, it seems reasonable to deduce that foreign bodies should be extracted endoscopically as soon as possible following ingestion.

Deciding which signs and symptoms are indicative of the presence of severe oesophageal damage secondary to a caustic agent is seemingly futile. A large multicenter observational study found that the presence of three or more symptoms served as an important indicator of severe oesophageal injury, and that this risk increased with an increasing number of signs and symptoms^[8]. Surprisingly however, the positive predictive value of three or more signs or symptoms was only 0.47 in relation to a third-degree lesion (circumferential ulceration or necrosis). Clinical signs and symptoms such as vomiting, drooling, dysphagia or food refusal, dyspnea, and haematemesis have been investigated in a myriad of studies in an attempt to uncover a correlation between the signs and symptoms and the degree of injury^[8,10-12]. A Turkish study found that sialorrhoea and oral injuries were significantly more frequent in patients with high-grade injuries^[12]. The presence or absence of clinical signs is

generally regarded to be of poor assistance to the clinician in formulating a management plan.

The literature advocates prompt and early assessment of patients with caustic ingestion by means of endoscopy^[10,13]. Betalli^[8] also concluded that the most efficient method for evaluating the upper GIT was endoscopy. Riffat^[14] promoted endoscopy at 48 hours after ingestion. His viewpoint was that any potential injury would be more clearly demarcated at this time. No other study investigated or substantiated this parameter.

At the opposite end of the clinical spectrum, it is widely accepted and verified that patients who have ingested caustic agents and are asymptomatic at presentation need not undergo endoscopy and may be managed conservatively^[15,16].

Current clinical practice in the Johannesburg hospitals included in the study consists of observation for patients in whom foreign bodies have been documented to have passed beyond the pylorus. Endoscopy is performed for removal of all foreign bodies obstructing the oesophagus. In cases of caustic ingestion, the need for endoscopy is assessed on an individual basis depending on the clinical status of the patient, in addition to signs suggestive of oesophageal mucosal injury.

1.2 Objectives

In paediatric patients presenting to two hospitals in Johannesburg over a two year period, our objectives for this prospective study were:

1. To describe the aetiology of foreign material ingestion in children under the age of 10 years.

2. To determine in which symptomatic patients endoscopy may be avoided, and which symptoms, if any, may help the clinician in deciding this.

CHAPTER 2

METHODS

2.1 Patient selection

A prospective observational study was performed across the paediatric surgery departments at Chris Hani Baragwanath Academic Hospital (CHBAH) and Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) in Johannesburg, South Africa. Children up to the age of 10 years who had ingested any foreign material and presented to the study sites between November 2013 and November 2015 were invited and consented to be recruited into the study. Children in whom the foreign body had passed beyond the pylorus were excluded from the study.

The degree to which patients were symptomatic or asymptomatic was determined at initial clinical presentation based on signs and symptoms and in line with previous studies investigating caustic and foreign body ingestion in children. Plain chest and abdominal radiographs were performed at presentation to confirm impaction in the oesophagus. Patients were then graded as mild, moderate or severe, based on the number and nature of clinical signs and symptoms at presentation (Appendix 1). All symptomatic patients underwent urgent endoscopy. Asymptomatic patients with foreign bodies lodged in the oesophagus were also admitted for removal of the foreign body by endoscopy on a semi-urgent basis. Endoscopic methods consisted of both rigid and flexible endoscopy.

For those children undergoing endoscopy, a grading system as shown in Table 2.1 for mucosal injuries, as used by Estreta et al. (1986)^[17] and Riffat & Cheng (2009)^[14], was used

to categorise the extent of injury, if any. This grading was applied to all cases of foreign body ingestion, as well as caustic agents.

Table 2.1 Grading of mucosal injury at endoscopy

Level	Description of Grading
Grade 0	No detectable mucosal change
Grade I	Erythema
Grade II	Erythema, sloughing, ulceration, and non-circumferential exudates
Grade III	Deep mucosal ulceration and circumferential mucosal sloughing
Grade IV	Eschar, full thickness changes, or perforation

2.2 Data acquisition

All the data was collected at admission using the datasheets in Appendix 1.

2.3 Ethical approval

Ethical approval was obtained from the University of the Witwatersrand Human Research Ethics Committee (Medical) (clearance number M131017) and from the two hospitals' CEOs.

2.4 Statistical analyses

The X^2 test was used to assess the relationship between asymptomatic or symptomatic status and gender, class of material ingested, as well as between class of material ingested and gender. Fisher's exact test was used for 2x2 tables or where the requirements for the X^2 test could not be met. The strength of the associations was measured by Cramer's V and the phi coefficient, respectively. The scale of interpretation of the strength of association used is shown below in Table 2.2 (Cohen J, 1988)^[18].

Table 2.2 Strength of association for categorical variables.

Cramer's V/phi	Interpretation
0.50 and above	high/strong association
0.30 to 0.49	moderate association
0.10 to 0.29	weak association
below 0.10	little if any association

The relationship between continuous variables, such as age, and asymptomatic/symptomatic status or class of material ingested was assessed by the t-test or non-parametric Wilcoxon rank sum test, as appropriate. The strength of the associations was measured by the Cohen's d for parametric tests and the r-value for the non-parametric tests. The scale of interpretation of the strength of the association used is shown in Table 2.3.^[18]

Table 2.3 Strength of association for continuous variables by groups.

Test statistic	Effect size
0.80 and above	large effect
0.50 to 0.79	moderate effect
0.20 to 0.49	small effect
below 0.20	near zero effect

The predictive relationship between severity of symptoms and endoscopic grading was determined by sensitivity and specificity analysis. Data analysis was carried out using SAS (version 9.4 for Windows). The 5% significance level was used. Sample size calculations were carried out in G*Power^[19].

CHAPTER 3

RESULTS

A total of 138 paediatric patients, who had ingested a foreign material during the 25-month study period between November 2013 and November 2015 were included in the study. The median age (interquartile range [IQR]) of the patients was 26 (18-50) months, with the youngest study participant being eight months old and the oldest of 119 months. The distribution of the ages is shown below in Figure 3.1. Fifty-six-point-five percent of the patients were male.

Material ingested

The most common foreign materials ingested were coins (60.9%), followed by potassium permanganate (13.8%). The remainder of foreign material comprised a myriad of items commonly found around the home. The materials ingested are depicted in Figure 3.2. Grouping these materials broadly, we found that 75.9% of the patients had ingested household items, while the remainder had ingested corrosive materials. The latter group included drain cleaner, Jik, Domestos, floor cleaner, hair relaxant, Jeyes fluid and oven cleaner. In summary, there were a total of 105 solid objects (76%), and 32 fluid material ingested (23%).

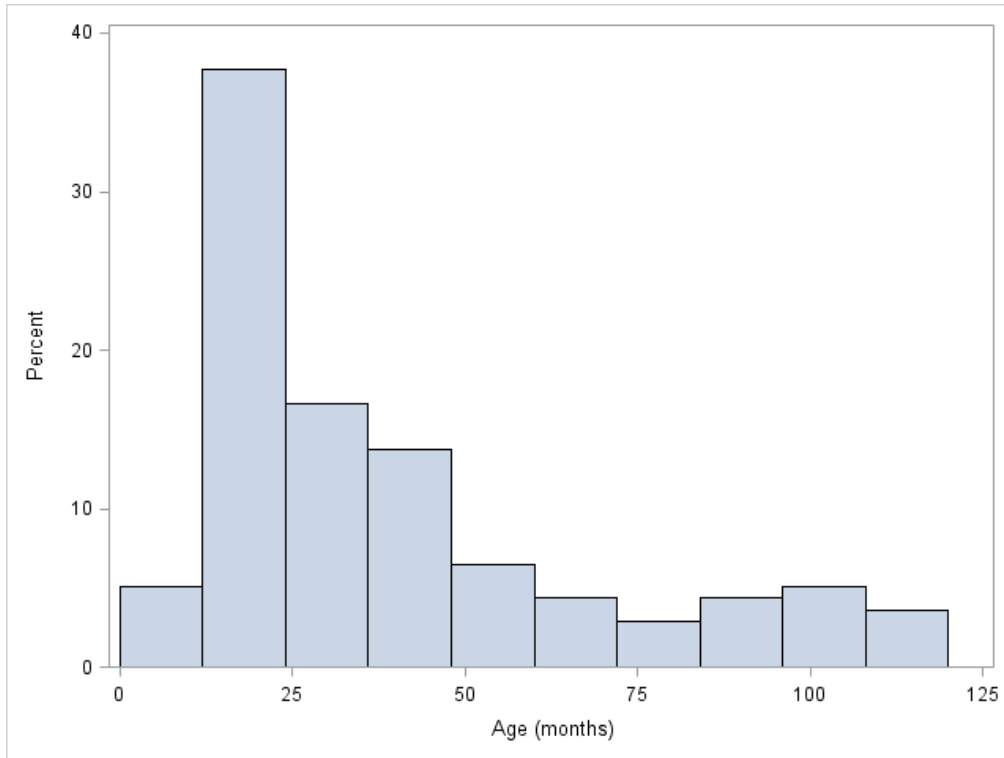


Figure 3.1 Distribution of ages of patients presenting with foreign material ingestion.

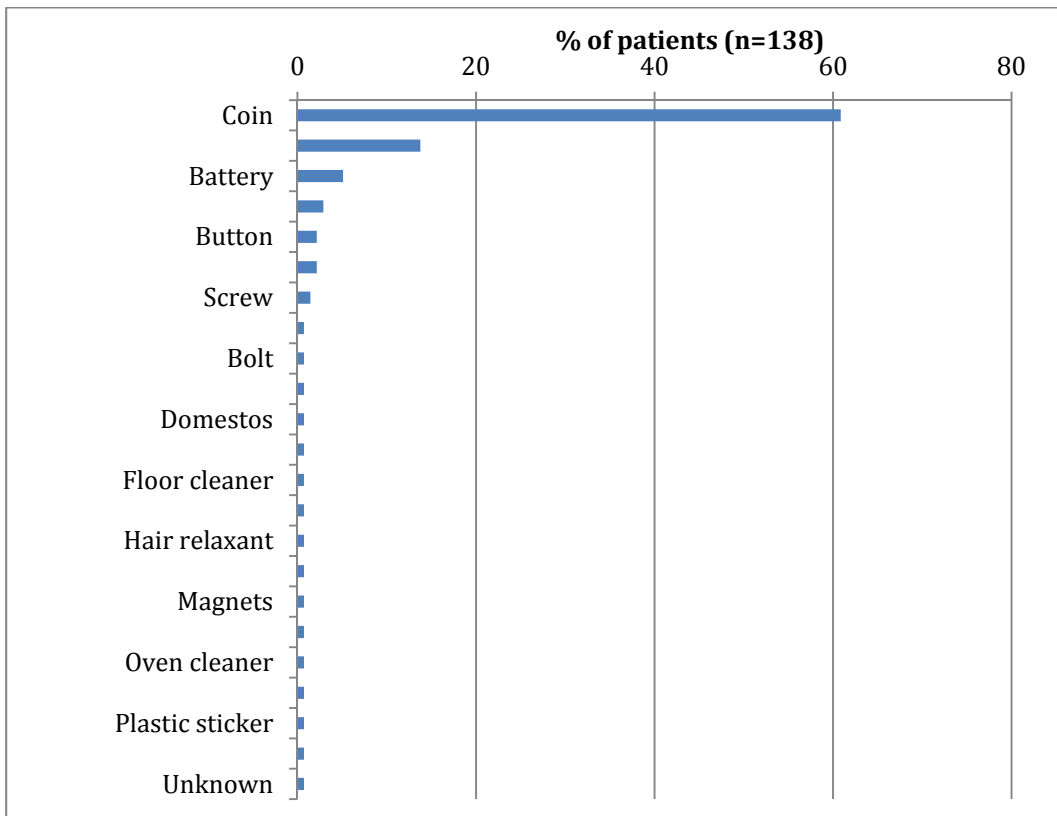


Figure 3.2 Nature of foreign material ingested.

Classification of symptoms

From Figure 3.3, the majority patients were asymptomatic (n=71; 55.8%) at initial presentation to the health care facility. Of the 61 (44.2%) symptomatic patients, the majority were only mildly symptomatic (n=51; 84%), thus only presenting with either one or two symptoms of the following: oral lesions, dysphagia, dyspnoea, drooling, vomiting, stridor and/or haematemesis.

There was no significant difference in the median age of symptomatic and asymptomatic patients (p=0.18), nor was there a significant association between symptomatic status and gender (p=0.86).

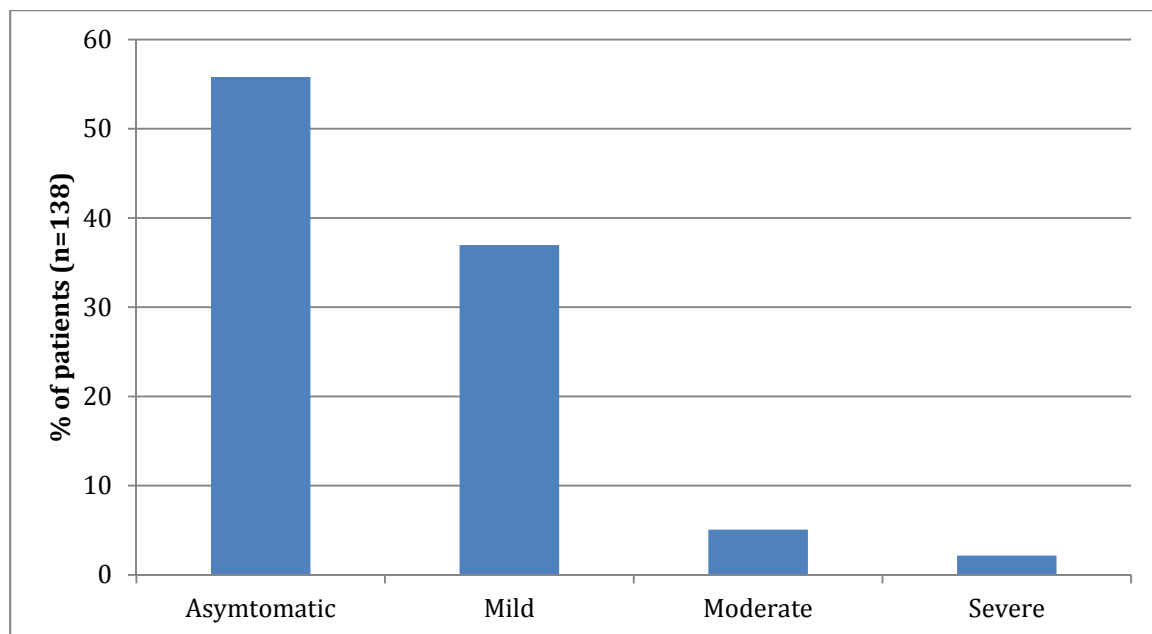


Figure 3.3 Classification of symptoms.

There was a significant, albeit weak association between symptomatic status and class of material ingested (p=0.001; phi coefficient=0.29). From Figure 3.4, the proportion of symptomatic patients was higher in patients who had ingested corrosive materials (69.7%) compared to those who had ingested household items (35.6%).

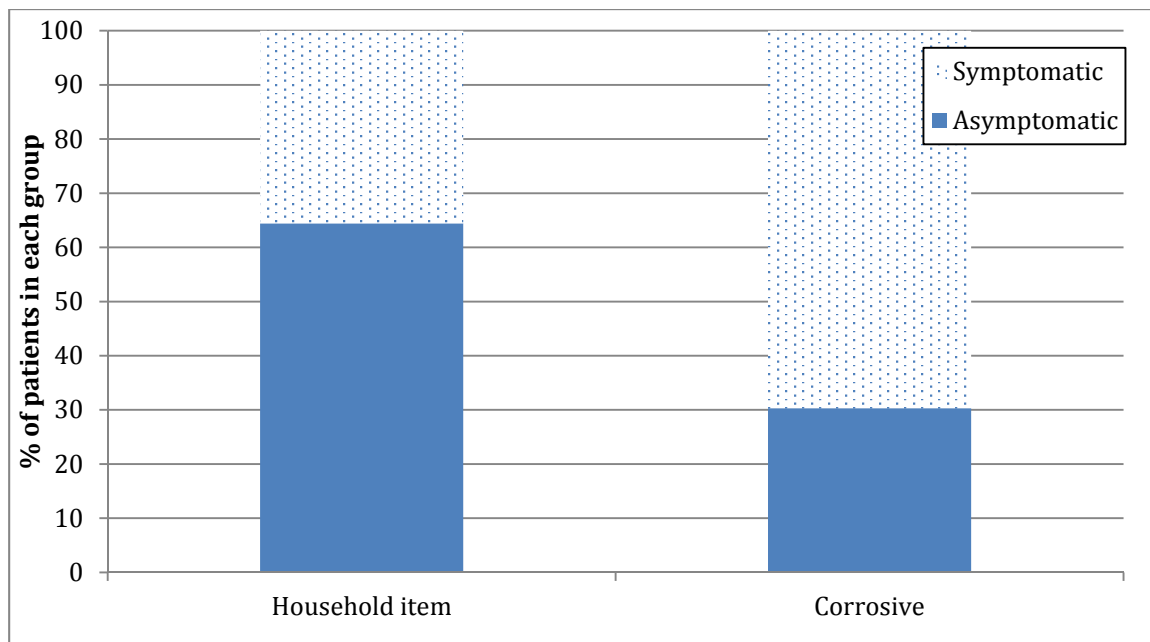


Figure 3.4 Proportion of symptomatic patients based on material ingested.

There was no significant difference in the median age of patients who had ingested household items vs those who had ingested corrosive materials ($p=0.52$). There was no significant association between class of material ingested and gender ($p=0.42$).

The endoscopy rate was significantly higher for patients who had ingested foreign objects (85.6%) compared to those who had ingested corrosive materials (36.4%) ($p<0.0001$; phi coefficient =0.48).

Endoscopy grading

In total, 101 (73.2%) patients received an endoscopy and in seven patients the endoscopic grade of mucosal injury was not recorded. In the remaining 94 patients that were graded, the majority ($n=74$; 78.7%) had a grading of 0. Furthermore, nine patients (9.6%) were found to have a grade 1 mucosal injury, five patients (5.3%) had grade 2 injury, and three patients each (3.2%) for grades 3 (moderate), and 4 (severe). These results are shown in Table 3.1.

Table 3.1 Severity of symptoms and endoscopic grading of patients undergoing endoscopy.

Classification of symptoms	Endoscopic Grade					Total
	0	1	2	3	4	
Asymptomatic	44	6	3	-	-	53
Mild	26	3	2	1	1	33
Moderate	4	-	-	-	1	5
Severe	-	-	-	2	1	3
Total	74	9	5	3	3	94

For further analysis, the severity of symptom classes ‘moderate’ and ‘severe’ were combined due to very small group sizes and compared to the ‘mild’ class. For the same reason, endoscopic grades 2-4 of mucosal injury were combined (Table 3.2).

Table 3.2 Severity of symptoms and combined endoscopic grading of patients undergoing endoscopy.

Classification of symptoms	Endoscopic Grade			Total
	0	1	2-4	
Asymptomatic	44	6	3	53
Mild	26	3	4	33
Moderate/Severe	4		4	8
Total	74	9	11	94

Furthermore, the severity classes ‘mild’, ‘moderate’ and ‘severe’ were combined, and endoscopic grades 0 and 1 were combined to create 2x2 tables so as to calculate sensitivity and specificity (Table 3.3).

Table 3.3 Diagnostic accuracy of the severity of symptoms for combined endoscopic grading of patients undergoing endoscopy.

Classification of symptoms	Endoscopic Grade		Total
	0	1-4	
Asymptomatic	44	9	53
Mild/Moderate/Severe	30	11	41
Total	74	20	94
Sensitivity, % (95%CI)		55 (32 – 77)	
Specificity, % (95%CI)		59 (47 – 71)	
Classification of symptoms	0-1	2-4	Total
Asymptomatic	50	3	53
Mild/Moderate/Severe	33	8	41
Total	83	11	94
Sensitivity, % (95%CI)		73 (39 – 94)	
Specificity, % (95%CI)		60 (49 – 71)	

The very wide confidence intervals (CIs), particularly for sensitivity analyses, is a consequence of the small sample size, and makes drawing conclusions from the data very difficult. Carrying out endoscopy on mild/moderate/severe cases should pick up 55% of grade 1-4 cases, and 73% of grade 2-4 cases.

Mortality and complications

In this study population only one patient died, thus the mortality rate (95% confidence interval) was 0.7% (0.0-4.0%). Among the 137 patients who survived, 48.9% (n=67) returned for their two-week follow-up appointment, whereas only 13.1% (n=18) attended the three-month follow-up appointment. Of the 18 patients who returned at three months, 33.3% (n=6) had one or more complications; five patients (27.8%) developed oesophageal

strictures. One patient required endoscopic dilatation, while another two required feeding gastrostomies.

CHAPTER 4

DISCUSSION

Foreign bodies may become lodged in the oesophagus at the four points of constriction: 1) at the level of cricopharyngeus; 2) where the oesophagus is crossed by the aortic arch anteriorly; 3) where the oesophagus is crossed by the left main bronchus posteriorly; or 4) where the oesophagus traverses the diaphragm. This implies that foreign bodies may easily become impacted within the oesophagus prior to passage into the stomach and GIT. Considering the frequency of accidental foreign body ingestion among paediatric patients, it follows that impaction in the oesophagus is a common finding.

The median age of patients presenting with foreign material ingestion was 26 months in this study. This compares similarly to other studies in the literature which found the predominant age of patients to be under 5 years^[20]. This is the age at which childhood development consists of mouthing. Infants are increasingly mobile at this age and this entails greater access to foreign material within the surrounding environment. Oral exploration is a key developmental stage around this age. Placing hands and other objects in the mouth allows infants to discover the taste and texture of objects, enhancing sensory development of the developing neurological system.

The most common foreign body ingested were coins. This appears to be common to all series in the literature regarding foreign material ingestion in the paediatric population. Special note is made of the number of battery (n=7) and magnet (n=1) ingestions with regard to the increased risk of morbidity associated with these materials. Button batteries cause an oesophageal injury through alkaline leakage which cause caustic damage^[21]. Additionally, button batteries form electrical circuits in the oesophagus, releasing electrical energy which may burn immediately adjacent tissues^[22]. Magnets pose a risk for perforation and fistula formation if not removed expeditiously, due to the magnetic effect across differing parts of the GIT.

Caustic agents form a large proportion of foreign material ingestion, and are a significant cause of morbidity and mortality in both developed and developing countries. The total proportion of foreign material comprising caustic agents was 22.5% in this study (potassium

permanganate, Jik, batteries, drain cleaner). This compares to a rate of 15% of acid/caustic ingestions in the study by Kay^[11]. In the South African context, caustic agent ingestion appears to be linked to storage of these agents in unmarked or seemingly innocuous storage containers or bottles. Children usually ingest these mistaking them for edible foods or potable liquids.

Apart from the predominant percentage of ingestion of coins, the next most frequently ingested material was potassium permanganate at 13.8%. Potassium permanganate is commonly used for the treatment of unpurified water sources, as may be found in a large number of households in South Africa which do not have access to clean water. The potassium permanganate may be stored in solid crystal or liquid form. The form in which it is ingested affects the extent of oral or oesophageal injury. Crystals are typically spat out immediately and generally only cause superficial burns to the lips and oral cavity. Liquid tends to be swallowed, causing severe injury to the oesophagus and stomach. In addition, the purple colour of potassium permanganate is an alluring prospective to an inquisitive child who wishes to quench his or her thirst with a fluid that may resemble a soft-drink.

The vast majority of patients serviced by hospitals included in the study reside within informal dwellings, which predispose to easy access of these substances as safe storage is not always possible within these informal residences. Children are also often left unsupervised for extended periods of time, allowing them unrestricted access to these materials.

Patients' presentation may contrast between completely asymptomatic or potentially life threatening injuries. Parents are often poor historians and it is oftentimes difficult to discern between confirmed and suspected cases of ingestion, especially in asymptomatic patients. In addition, the overwhelming majority of ingestions are unwitnessed. This consequently presents a challenge to the healthcare practitioner with regards to appropriate and timeous management of these children.

The association between symptomatic status and class of material ingested revealed that the proportion of symptomatic patients was higher in patients who had ingested corrosive materials compared to those who had ingested household items. This is in keeping with the potential toxic nature of corrosive materials versus the relatively innocuous nature of foreign

bodies and other household items that were commonly ingested, with the exception of batteries and magnets.

The endoscopy rate of 73,2% in this study compares similarly to that of the studies by Ayogdu^[7] and Waltzman^[9] which had rates of 77% and 81% respectively. This includes all endoscopies for removal of foreign bodies as well as assessment for mucosal injury in caustic and corrosive ingestions. Evidence from these studies thus suggests that endoscopic removal is necessary in the majority of cases for expedient management, especially since endoscopy is associated with high success rates for removal of impacted foreign bodies.

The current protocol in our department for management of these cases is removal in the operating theatre under a general anaesthetic. Foreign bodies are removal with rigid endoscopy, whereas caustics and corrosives are assessed by means of flexible endoscopy. This differs to other recognized techniques in other centres of removal, for example removal using a Foley's catheter which is passed beyond the foreign body, the bulb is then inflated and the catheter is withdrawn, along with the foreign body.

Of all of the patients who underwent endoscopy, seventy-eight percent had no identifiable mucosal injury at endoscopy. Despite almost a quarter of ingestions encompassing caustic agents, severe mucosal injury grade (grades 3-4) was seen in 6.4% of all patients who underwent endoscopy. When viewed in the context of the complications, this rate is similar to the complication rate seen at three month follow up.

The one mortality comprised a child who had ingested sulphuric acid in the form of drain cleaner. The child presented clinically with respiratory distress, room air saturation of 67%, and haematemesis, and bilateral pneumothoraces. Following intubation and insertion of intercostal drains, flexible endoscopy revealed severe oropharyngeal burns, severe oesophagitis, haemorrhagic gastritis, with full thickness necrosis and perforation of the posterior gastric wall. A laparotomy was performed to address the gastric perforation. The child was subsequently admitted to the Paediatric Intensive Care Unit (ICU). Following a period of approximately 6 weeks, and multiple endoscopies which revealed progressively worsening stricturing of the oesophagus, the child underwent and oesophagostomy and feeding jejunostomy, but ultimately demised from sepsis in the ICU.

Follow up at three months was low (13.1%). One presumes that one of the reasons for this is that patients were well and suffered no ill sequelae of their foreign material ingestion. Socioeconomic constraints must also be taken into account as a factor for patients having difficulty following up on a regular basis, unless the child is overtly unwell and in need of dire medical attention.

The proportion of symptomatic patients was significantly higher in patients who had ingested corrosive materials (69.7%) compared to those who had ingested household items (35.6%). This implies that those patients which had ingested corrosive substances are more likely to be symptomatic at presentation than those who had ingested foreign bodies comprising of household items. Furthermore, 20% of these symptomatic patients had mucosal injuries of grades 2, 3 and 4 at endoscopy. In contrast, only 5.7% of asymptomatic patients had similar endoscopic findings. Therefore, endoscopic evaluation in symptomatic patients should be performed urgently so as to facilitate assessment of mucosal injury.

CHAPTER 5

CONCLUSION

There is no doubt that endoscopy is mandatory in all symptomatic patients with a history of caustic ingestion. As for those who have ingested foreign bodies and remain asymptomatic, endoscopy may be delayed. In light of the high endoscopy rate for patients in this study(73.2%), endoscopy should nonetheless be undertaken as soon as possible to remove the foreign body. This study is limited by the small sample size, and as such, no definitive conclusions may be drawn to affect current clinical practice.

REFERENCES

1. Bronstein AC, Spyker DA, Cantilena Jr LR, Green JL, Rumack BH, Heard SE, et al. 2007 Annual report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 25th annual report. *Clin Toxicol (Phila)* 2008 Dec;46(10):927–1057. doi: 10.1080/15563650802559632
2. Panieri E, Bass DH. The management of ingested foreign bodies in children—a review of 663 cases. *Eur J Emerg Med.* 1995 Jun;2(2):83-7
3. Shivakumar AM, Naik AS, Prashanth KB, Yogesh BS, Hongal GF. Foreign body in upper digestive tract. *Indian J Pediatr.* 2004 Aug; 71:689–93. doi: 10.1007/BF02907744.
4. Uyemura MC. Foreign body ingestion in children. *American family physician.* 2005 July 15;72(2), 287–91.
5. Lin C, Chen A, Tsai J, Wei S. Endoscopic removal of foreign bodies in children. *Kaohsiung J Med Sci.* 2007 Sep;23(9):447-52.
6. Yalcin S, Karnak I, Ciftci AO, Senocak ME, Tanyel FC, Buyukpamukci N. Foreign body ingestion in children: an analysis of pediatric surgical practice. *Pediatr Surg Int.* 2007 Aug;23(8):755-61. Doi:10.1007/s00383-007-1958-y.
7. Aydoğdu S, Arıkan C, Cakir M, Baran M, Yüksekaya HA, Saz UE, Arslan MT. Foreign body ingestion in Turkish children. *Turk J Pediatr* 2009 Mar-Apr, 51(2), 127–32.
8. Betalli P, Falchetti D, Giuliani S, Pane A, Dall'Oglio L, de Angelis GL, Caldore M, Romano M, Gamba P, Baldo V. Caustic ingestion in children: is endoscopy always indicated? The results of an Italian multicenter observational study. *Gastrointest Endosc.* 2008 Sep;68(3), 434–9. doi: 10.1016/j.gie.2008.02.01.
9. Waltzman ML, Baskin M, Wypij D, Mooney D, Jones D, Fleisher G. A randomized clinical trial of the management of esophageal coins in children. *Pediatrics.* 2005 Sep;116(3), 614–9. doi:10.1542/peds.2004-2555.
10. Gupta SK, Croffie JM, Fitzgerald JF. Is esophagogastroduodenoscopy necessary in all caustic ingestions? *J Pediatr Gastroenterol Nutr.* 2001 Jan;32(1):50-3.
11. Kay M, Wyllie R. Caustic ingestions in children. *Curr Opin Pediatr.* 2009 Oct;21(5):651-4. doi: 10.1097/MOP.0b013e32832e2764.
12. Kaya M, Ozdemir T, Sayan A, Arıkan A. The relationship between clinical findings and esophageal injury severity in children with corrosive agent ingestion. *Turkish J Trauma Emerg Surg.* 2010 Nov;16(6):537-40.

13. Gaudreault P, Parent M, McGuigan MA, Chicoine L, Lovejoy FH. Predictability of esophageal injury from signs and symptoms: a study of caustic ingestion in 378 children. *Pediatrics*. 1983 May;71(5): 767-70.
14. Riffat F, Cheng A. Pediatric caustic ingestion: 50 consecutive cases and a review of the literature. *Dis Esophagus*. 2009;22(1):88-94. doi: 10.1111/j.1442-2050.2008.00867
15. Gorman RL, Khin-Maung-Gyi MT, Klein-Schwartz W, Oderda GM, Benson B, Litovitz T, McCormick M, McElwee N, Spiller H, Krenzelok E. Initial symptoms as predictors of esophageal injury in alkaline corrosive ingestions. *Am J Emerg Med*. 1992 May;10(3):189-94.
16. Lamireau T, Rebouissoux L, Denis D, Lancelin F, Vergnes P, Fayon M. Accidental caustic ingestion in children: is endoscopy always mandatory? *J Pediatr Gastroenterol Nutri*. 2001 Jul;33(1), 81–4.
17. Estrera A, Taylor W, Mills LJ, Platt MR. Corrosive burns of the esophagus and stomach: a recommendation for an aggressive surgical approach. *Ann Thorac Surg*. 1986 Mar;41(3):276-83.
18. Cohen, J. (1988). *Statistical Power Analysis*. Second Edition. Academic Press, Inc., New York.
19. Faul, F., Erdfelder, E., Lang, A.-G., & Buchner, A. (2007). G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behavior Research Methods*,39, 175-191.
20. Jayachandra S, Eslick GD. A Systematic review of paediatric foreign body ingestion: presentation, complications, and management. *Int J Pediatr Otorhinolaryngol*. 2013 Mar;77(3):311-7. doi: 10.1016/j.ijporl.2012.11.025.
21. Votteler TP, Nash JC, Rutledge JC. The hazard of ingested alkaline disk batteries in children. *JAMA*. 1983;249:2504-6.
22. Tanaka J, Yamashita M, Yamashita M, Kajigaya H. Esophageal electrochemical burns due to button type lithium batteries in dogs. *Vet Hum Toxicol*. 1998;40:193-6.

APPENDIX 1: Approved Protocol

TITLE

Foreign material ingestion in children and the role of endoscopy in symptomatic patients in South African Hospitals

Candidate name: Dr Himal Sooka

Student number: 0401241F

Degree: MMed

Supervisor's name: Professor Jerome Loveland

Supervisor's qualifications: FCS(SA), Certificate in Paediatric Surgery(SA)

Supervisor's position: Head of the Department of Paediatric Surgery, Chris Hani Baragwanath Academic Hospital

Co-Supervisor's name: Dr Deirdré Kruger

Co-Supervisor's qualifications: BSc, PGCert Healthcare Education, PhD (UK)

Co-Supervisor's position: Specialist Research Scientist & Research Coordinator (Surgery), Department of Surgery, Wits Medical School.

INTRODUCTION

Foreign material ingestion is a common problem in the paediatric population, and is the cause for some of the most frequent presentations to paediatric casualty departments. The foreign material comprises mostly foreign bodies and caustic agents. Most cases of ingestion are accidental. Foreign body ingestion appears to occur most commonly between the ages of 1 and 2 years, when infants are beginning to explore the world around them, generally by a process known as mouthing. Taste is an important mechanism by which toddlers experience their surroundings. As a consequence of this normal behavioral developmental, children are constantly placing all manner of foreign material in their mouths.

Foreign bodies may become lodged in the oesophagus at the four points of constriction: at the level of cricopharyngeus; where the oesophagus is crossed by the aortic arch anteriorly; where it is crossed by the left main bronchus posteriorly; and where it traverses the diaphragm. The gold standard for removal of impacted

oesophageal foreign bodies is endoscopy. Several studies in the literature advocate early removal of foreign bodies within the first 24 hours^[1-5]. When performed by an experienced practitioner, endoscopic removal is safe and has a low rate of major complications^[6]. Success rates as high as 97% for removal of foreign bodies have been quoted in some studies^[6]. Rounded foreign bodies which are documented to have passed into the stomach usually pose no significant threat and can be allowed to pass through the gastrointestinal tract spontaneously without the need for endoscopic intervention^[7]. This is the accepted practice in the setting of South African hospitals.

With regards to endoscopy in cases of asymptomatic foreign body ingestion with impaction in the oesophagus, a prospective randomized control trial by concluded that patients may be observed for a period of between 8 and 16 hours, as up to 30% of the foreign bodies – in this case the foreign bodies were coins – would pass spontaneously^[8]. However, in that study, a significantly large proportion of patients who were being observed for this period - 77% - still required endoscopy thereafter for removal of the coin/s. An 81% endoscopy rate for the removal of foreign bodies in the oesophagus was found in a study by Aydoğdu et al., (2009) thus lending evidence to the notion that endoscopic removal is inevitable in the majority of cases. Therefore, it seems reasonable to conclude that foreign bodies be extricated by means of endoscopy as soon as possible following ingestion. In a healthcare system as overburdened as that found in South African hospitals, a period of observation may not be feasible, significantly affecting the length of stay in hospital for these patients.

Caustic agents form a large proportion of foreign material ingestion, and are a significant cause of morbidity and mortality in paediatric patients in both developed and developing countries. In the South African context, caustic agent ingestion appears to be linked to storage of these agents in unmarked or seemingly innocuous storage containers or bottles. Children usually ingest these mistaking them for edible foods or potable liquids. Patients' presentation may contrast between no obvious injury or symptoms to potentially life threatening injuries. Parents are often poor historians and it is difficult to discern between confirmed and suspected cases of ingestion. This consequently presents a challenge to the healthcare practitioner with regards to appropriate and timeous management of these children.

Attempting to decide which signs and symptoms are indicative of the presence of severe oesophageal damage from the caustic agent is seemingly futile. A large multicenter observational study found that the presence of three or more symptoms served as an important indicator of severe oesophageal injury, and that this risk increased with an increasing number of signs and symptoms^[8]. Surprisingly however, the positive predictive value of three or more signs/symptoms was only 0.47 in relation to a third degree lesion (circumferential ulceration or necrosis). Clinical signs and symptoms such as vomiting, drooling, dysphagia or food refusal, dyspnea, and haematemesis have been investigated by a myriad of studies in an attempt to uncover a correlation between signs/symptoms and degree of injury^[7,9-11]. A Turkish study found that sialorrhoea and oral lesions were significantly more frequent in patients with high-grade injuries^[11]. A review of 378 paediatric cases of caustic ingestion by Gaudreault et al.(1983) found that 12% of asymptomatic children had severe oesophageal burns, whereas 82% of symptomatic children had no oesophageal burns. This provides compelling indications that the presence of absence of clinical signs is of poor assistance to the clinician in formulating a management plan.

The literature advocates prompt and early assessment of patients with caustic ingestion by means of endoscopy^[9,12]. Betalli et al. (2008) also concluded that the most efficient method for evaluating the upper gastrointestinal tract (GIT) was endoscopy. Riffat & Cheng (2009) promoted endoscopy at 48 hours after ingestion. Their viewpoint was that any potential injury would be more clearly demarcated at this time. No other study investigated or substantiated this parameter.

At the opposite end of the clinical spectrum, it is widely accepted and verified that patients who have ingested caustic agents and are asymptomatic at presentation need not undergo endoscopy and may be managed conservatively^[14,15]. Taking the results of Gaudreault et al.(1983), it appears possible that there is a sub-group of symptomatic patients in whom endoscopy may not be necessary, as 82% may have no injury.

Therefore, the aim of this study is to determine in which symptomatic patients endoscopy may be avoided, and which symptoms, if any, may help the clinician in deciding this.

STUDY OBJECTIVES

- To describe the aetiology of foreign material ingestion in children under the age of 10 in a South African context
- To establish the subgroup of symptomatic patients in which endoscopy may be avoided
- To determine the morbidity of foreign material ingestion in children

METHODS:

- *Design:* Prospective observational study
- *Site of study:* The study will be conducted across the paediatric surgery departments at two hospitals, namely Chris Hani Baragwanath Academic Hospital (CHBAH) and Charlotte Maxeke Johannesburg Academic Hospital (CMJAH)
- *Study population:* Children up to 10 years of age who have ingested any foreign material will be recruited into the study
- *Sampling:*
 - A sample of at least 100 patients will be obtained. It is expected that this sample will be obtained within a period of approximately 2 years from commencement of this study.
 - Inclusion criteria: any child up to 10 years of age who has ingested foreign material and whose parents/guardians consent to partaking in the study
 - Exclusion criteria:
 - Any child for whom consent is not obtained to be enrolled into the study
 - Children in whom foreign bodies have passed beyond the pylorus
- *Measuring instrument:* The degree to which patients are symptomatic or asymptomatic will be determined at initial clinical presentation based on signs and symptoms as used in various previous studies investigating caustic and foreign body ingestion in children. X-rays will be done at presentation to confirm impaction in the esophagus, as well as to exclude perforation. This will be documented in a

datasheet – Appendix 1. To determine the subgroup of patients in which endoscopy may be avoided (Objective 2), all symptomatic patients will be graded as mild, moderate or severe based on the number and nature of clinical signs and symptoms at presentation. All symptomatic patients will undergo endoscopy pending informed consent from their parents/legal guardian. The role of endoscopy in these subgroups will then be assessed on the basis of findings at endoscopy.

Asymptomatic patients will be admitted for a period of observation. Should they develop further symptoms, they too will undergo endoscopy as necessary.

- Foreign bodies lodged in the oesophagus will be removed at the earliest opportunity under a general anaesthetic. Following removal, the scope will be reinserted and the oesophageal mucosa re-examined for any signs of injury.

For those children undergoing endoscopy, a grading system for mucosal injuries as used by Estreta et al. (1986), and Riffat & Cheng (2009) will be used to categorise the extent of injury, if any.

Table 1 Grading of mucosal injury at endoscopy	
Grade 0	No detectable mucosal change
Grade I	Erythema
Grade II	Erythema, sloughing, ulceration, and non-circumferential exudates
Grade III	Deep mucosal ulceration and circumferential mucosal sloughing
Grade IV	Eschar, full thickness changes, or perforation

Findings at endoscopy will then be correlated with the clinical signs and symptoms to determine which signs, if any, are suggestive of esophageal injury.

- *Data collection:* A datasheet – see Appendix 1 – will be used to collect the information pertaining to patient demographics, the nature of the foreign material ingested (caustic, corrosive, foreign body etc.), and the management plan prescribed for the patient on admission. Those patients who require endoscopy will have a further datasheet – Appendix 2 – which details the findings at endoscopy. Furthermore, all patients will have another datasheet – Appendix 3 - completed at follow up at two weeks and three months. Follow-up appointments will be booked

for specific dates at discharge and these appointments will be confirmed telephonically the day prior to the follow-up appointment. Data will be collected for a period of 2 years, or sooner once a sample of 100 patients has been obtained.

- *Pilot study:* a pilot study will not be undertaken
- *Sources of bias:*
 - Performance bias: an attempt will be made to minimise performance bias by having paediatric surgical registrars perform the admission and endoscopy of patients recruited into this study
 - Transfer bias: it is possible some patients may be lost to follow up in the course of this study. An attempt will be made to contact them telephonically should this occur

DATA ANALYSIS

Once completed, each datasheet will be captured electronically on the paediatric surgery database, SimplifyMD, on a bi-weekly basis. SimplifyMD is a secure online database which is password protected, thus ensuring security of data collected, as well as collating data from both CHBAH and CMJAH in one place. Hard copies of the datasheets will also be filed and stored in a secure office at both study sites. The statistical program Statistica will be used to analyse the data once collection is complete. At all stages of the study, data capturing will be verified by the study supervisor.

ETHICS

As this study is fundamentally focused on paediatric patients up to the age of 10 years old, consent will be obtained from the parents/legal guardians of study participants. An application for ethics approval will be obtained from the Human Research Ethics Committee (HREC) of the University of the Witwatersrand.

TIMING

PROCESS	Aug	Sep	Oct	Nov	Oct 2013 - Oct 2015	Nov 201 5	Dec 201 5	Jan 201 5
Project idea	X							
Literature review	X	X						
Prepare protocol		X	X					
Protocol deadline			23/10/ 13					
Protocol assessment				06/11/ 13				
Ethics application			30/09/ 13					
Collecting data					x			
Data analysis						x	x	
Writing up - thesis						x	x	x
Writing up - paper								x

The period of data collection will span 2 years, or less if the goal sample size of 100 patients is achieved sooner.

FUNDING

All expenses will be borne by myself, as well as the Department of Paediatric Surgery, University of Witwatersrand.

Expenses anticipated:

- Petrol for transport between CMJAH and CHBAH for data collection and review of patients at follow-up visits
- Stationery: printing and photocopying of data sheets, informed consent; pens; pencils; files/binders for storage of data sheets

REFERENCES:

1. Panieri E, Bass DH. The management of ingested foreign bodies in children-a review of 663 cases. *Eur J Emerg Med.* 1995 Jun;2(2):83-7
2. Shivakumar AM, Naik AS, Prashanth KB, Yogesh BS, Hongal GF. Foreign body in upper digestive tract. *Indian J Pediatr.* 2004 Aug; 71:689-93. doi: 10.1007/BF02907744.
3. Uyemura MC. Foreign body ingestion in children. *American family physician.* 2005 July 15;72(2), 287-91.
4. Lin C, Chen A, Tsai J, Wei S. Endoscopic removal of foreign bodies in children. *Kaohsiung J Med Sci.* 2007 Sep;23(9):447-52.
5. Yalcin S, Karnak I, Ciftci AO, Senocak ME, Tanyel FC, Buyukpamukci N. Foreign body ingestion in children: an analysis of pediatric surgical practice. *Pediatr Surg Int.* 2007 Aug;23(8):755-61. Doi:10.1007/s00383-007-1958-y.
6. Aydoğdu S, Arikan C, Cakir M, Baran M, Yüksekaya HA, Saz UE, Arslan MT. Foreign body ingestion in Turkish children. *Turk J Pediatr* 2009 Mar-Apr, 51(2), 127-32.
7. Betalli P, Falchetti D, Giuliani S, Pane A, Dall'Oglio L, de Angelis GL, Caldore M, Romano M, Gamba P, Baldo V. Caustic ingestion in children: is endoscopy always indicated? The results of an Italian multicenter observational study. *Gastrointest Endosc.* 2008 Sep;68(3), 434-9. doi: 10.1016/j.gie.2008.02.01.
8. Waltzman ML, Baskin M, Wypij D, Mooney D, Jones D, Fleisher G. A randomized clinical trial of the management of esophageal coins in children. *Pediatrics.* 2005 Sep;116(3), 614-9. doi:10.1542/peds.2004-2555.
9. Gupta SK, Croffie JM, Fitzgerald JF. Is esophagogastroduodenoscopy necessary in all caustic ingestions? *J Pediatr Gastroenterol Nutr.* 2001 Jan;32(1):50-3.
10. Kay M, Wyllie R. Caustic ingestions in children. *Curr Opin Pediatr.* 2009 Oct;21(5):651-4. doi: 10.1097/MOP.0b013e32832e2764.
11. Kaya M, Ozdemir T, Sayan A, Arikan A. The relationship between clinical findings and esophageal injury severity in children with corrosive agent ingestion. *Turkish J Trauma Emerg Surg.* 2010 Nov;16(6):537-40.
12. Gaudreault P, Parent M, McGuigan MA, Chicoine L, Lovejoy FH. Predictability of esophageal injury from signs and symptoms: a study of caustic ingestion in 378 children. *Pediatrics.* 1983 May;71(5): 767-70.

13. Riffat F, Cheng A. Pediatric caustic ingestion: 50 consecutive cases and a review of the literature. *Dis Esophagus*. 2009;22(1):88-94. doi: 10.1111/j.1442-2050.2008.00867
14. Gorman RL, Khin-Maung-Gyi MT, Klein-Schwartz W, Oderda GM, Benson B, Litovitz T, McCormick M, McElwee N, Spiller H, Krenzelok E. Initial symptoms as predictors of esophageal injury in alkaline corrosive ingestions. *Am J Emerg Med*. 1992 May;10(3):189-94.
15. Lamireau T, Rebouissoux L, Denis D, Lancelin F, Vergnes P, Fayon M. Accidental caustic ingestion in children: is endoscopy always mandatory? *J Pediatr Gastroenterol Nutri*. 2001 Jul;33(1), 81–4.
16. Estrera A, Taylor W, Mills LJ, Platt MR. Corrosive burns of the esophagus and stomach: a recommendation for an aggressive surgical approach. *Ann Thorac Surg*. 1986 Mar;41(3):276-83.

APPENDIX 2: Datasheet

Study participant number: _____

Age (in months): _____

Date of ingestion: _____

Gender: Male
 Female

Material ingested: Acid
 Alkali
 Foreign body
 Other Specify _____

How was the material stored? _____

What is the material used for? _____

Signs & symptoms: Asymptomatic
 Oral lesions Specify Erythema
 Swelling
 Ulceration

Dysphagia/food refusal
 Dyspnoea
 Drooling
 Vomiting
 Stridor
 Haematemesis

Classification of symptoms: Mild (2 signs/symptoms)
 Moderate (>2 signs/symptoms)
 Severe (haematemesis, peritonism, haemodynamic instability, acidosis, signs of perforation)

Management plan: Admit for observation
 Admit for endoscopy

ENDOSCOPY DATASHEET

Participant number		
Date performed		
Findings	Grade 0	No detectable mucosal change
	Grade I	Erythema
	Grade II	Erythema, sloughing, ulceration, and non-circumferential exudates
	Grade III	Deep mucosal ulceration and circumferential mucosal sloughing
	Grade IV	Eschar, full thickness changes, or perforation

APPENDIX 3: Ethics Clearance Certificate



HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M131017

NAME: Dr Himal Sooka
(Principal Investigator)

DEPARTMENT: Department Surgery
Chris Hani Baragwanath Hospital

PROJECT TITLE: Foreign Material Ingestion in Children and the
Role of Endoscopy in Symptomatic Patients
in South African Hospitals

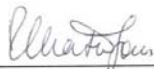
DATE CONSIDERED: 25/10/2013

DECISION: Approved unconditionally

CONDITIONS:

SUPERVISOR: Professor J Loveland

APPROVED BY:



Professor PE Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 25/04/2014

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Secretary in Room 10004, 10th floor, Senate House, University.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES