

**RISK OF INCARCERATION OF INGUINAL HERNIAS AMONG PAEDIATRIC PATIENTS  
AWAITING ELECTIVE SURGERY AT THE UNIVERSITY TEACHING HOSPITAL, LUSAKA, ZAMBIA**

**by**

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**A dissertation submitted to the University of Zambia in partial fulfilment of the  
requirements of the degree of Master of Paediatric Surgery**

**THE UNIVERSITY OF ZAMBIA**

**LUSAKA**

**2019**

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## ABSTRACT

Inguinal hernias in infants and children are very common. One of their most common complications before surgery is incarceration, a life threatening condition with potential to cause severe short term and long term morbidities like bowel ischaemia, testicular atrophy and its resultant infertility, in future. There appears to be, institutional variability in the rates and risks of inguinal hernia incarceration among infants and children. This study was conducted with a purpose to determine our own institutional risk of inguinal hernia incarceration among infants and children awaiting elective surgery. A retrospective review of infants and children under the age of 17 years, who had undergone inguinal hernia repair or had incarcerated, from January 2015 to January 2017 was performed. Interviewer completed questionnaires were used to abstract data from the clinical records. Three hundred and sixty-four patients were included for analysis, in this study. Descriptive statistics, Pearson Correlation Coefficient, Regression Analysis and Kaplan Meiers Survival Analysis were used. The infants and children were stratified into seven age groups. The incarceration rates and risks were evaluated for each group. The overall incarceration rate was 13.45%. The risk of incarceration was age dependent. It ranged from 0.52 daily risk of incarceration, among neonates, to zero daily risk of incarceration among older children. Neonates were as high as five times more likely to incarcerate as older infants and children. Likewise, younger children had higher risk of inguinal hernia incarceration than older ones. Longer wait times were associated with increased rate and risk of inguinal hernia incarceration. Overall, risk reduction, of inguinal hernia incarceration, of more than 50% could be achieved if inguinal hernia repair was done within 14 days of diagnosis. This study concluded that, the rate of incarceration was high (13.45%). The risk of incarceration was age dependent & higher in neonates (0.52), infants & younger children (0.01). Neonates had as much as 5 times higher risk as other children. Longer wait times, male sex, right sided hernias were associated with higher rates & risks. Older children had no incarceration. The best time to operate is before 3 weeks for neonates, before 2 months for infants & before 4 months for younger children to prevent incarceration.

**Keywords:** *Infants and children, inguinal hernia, inguinal hernia incarceration, risk of hernia incarceration, incarceration rate, hernia repair, hernia surgery, wait time.*

## **AKNOWLEDGEMENTS**

It is not possible to acknowledge all who assisted me in writing this dissertation.

I wish to convey my utmost and sincere gratitude to my supervisors, Professor Munkonge Lupando and Dr Bvulani C Bruce, for helping me reach this far, in my career progression, in spite of their busy schedules and personal commitments. Dr Bvulani has been a constant source of inspiration. His guidance, teaching and supervision has been instrumental throughout this journey. My special thanks are also extended to Dr Sr Margaret M Mweshi for being a fountain of knowledge and support that saw this dissertation into fruition. Last but not the least, my gratitude is extended to The Department of Surgery, The Post-Graduate Forum, The Ethics Committees and The University of Zambia for making this possible.

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## **ABBREVIATIONS AND ACRONYMS**

UTH	University Teaching Hospital
UNZA	University of Zambia
OPD	Outpatient department

## CHAPTER ONE : INTRODUCTION

### 1.1 Background

Paediatric inguinal hernias are usually a protrusion of intra-abdominal contents through a patent processus vaginalis. They are a common inguinoscrotal abnormality in infants and children (Kapur, 1998; Yang, 2011). They occur in 1% to 4% of children aged 1 to 4 years; the incidence may reach 30% in premature infants (Poenaru, 2000; Wright, 2017; Scott, 2010). It is recognised that, in children, the existence from birth of a patent sac, is a common cause of hernia (Lee, 2015).

Most children present with a history of intermittent swelling in the inguinal region; which in males may extend to the scrotum. The presence of a mass or thickening in the inguinal canal or at the level of the inguinal ring is diagnostic. The swelling is usually non tender and readily reducible with gentle pressure. The differential diagnosis for uncomplicated inguinal hernias includes hydrocele and lymphadenopathy. In these cases, however, the inguinal canal will feel entirely normal (Lloyd, 1998; Lee, 2015).

One of the main complications prior to planned surgery is incarceration (Meier, 2003). Acute incarceration of an inguinal hernia is one of the commonest reasons for emergency surgical admission of young children. They present with a tense, tender, irreducible lump in either groin and sometimes with associated vomiting. For this reason, such hernias are commonly, but incorrectly, referred to as strangulated (Palmer, 1978; Lee, 2015). The differential diagnosis of an incarcerated hernia includes inguinal lymphadenitis, torsion of the testicle and acute hydrocele.

The bowel, ovaries or fallopian tubes are the organs that are commonly incarcerated. An incarcerated hernia may progress rapidly to strangulation, a situation where vascular compromise and possibly, infarction of the incarcerated contents have occurred. Fortunately, this occurrence is quite rare.

While the strangulation of incarcerated bowel is almost inevitable if it is neglected, the strangulation and necrosis of an ovary or fallopian tube is less common. Testicular infarction from an incarcerated inguinal hernia is also an unusual presentation and often not considered

in the initial evaluation (Waseem, 2000; Alyami, 2013). The diagnosis of a strangulated hernia can be made by palpating a firm, oval mass in the inguinal canal.

Surgery is the treatment of choice for the inguinal hernias in children. The aim of an operation is to reduce symptoms and to prevent acute complications such as incarceration, strangulation or intestinal obstruction. Watchful waiting is an acceptable short term alternative, but in the long run patients need to be operated upon because of development of symptoms (Nilssen, 2013; Duggan, 2015).

In a patient with acute symptoms of incarceration, reduction of an incarcerated hernia should be attempted, and it can be achieved in the majority of cases. Sedation (with an opiate or short acting benzodiazepine and firm, steady pressure over the hernia for up to half an hour may be necessary. If reduction is successful, the child should be admitted to hospital (because of high risk of recurrence), and surgical correction undertaken one to two days or even a few weeks later (to allow oedema to resolve) (Sonnino, 1992; Lee, 2015). If it cannot be reduced or if the signs of strangulation are present, emergency surgical intervention is mandatory. Under these circumstances resection of a segment of ischaemic bowel may be necessary.

The risk of a recurrent hernia, wound infection, scrotal swelling and injury to the vas deferens are higher for emergency surgical intervention than for elective hernia repair. In addition, the risk of testicular injury is significant in strangulated hernias.

Delay in seeking medical attention may lead to incarceration with development of ischaemia, further leading to gangrene and septicaemia. Reduction of hernia should be done early, not only to preserve bowel but also to avoid pressure on the ipsilateral spermatic cord and prevent testicular ischaemia (Mesrobian, 2004; Abdulhai, 2017).

It is not clear whether prophylactic elective surgery prevents emergency surgery (for incarcerations) (Dahlstrand, 2011). Inguinal hernia is the most common surgical condition requiring surgical intervention in children (Grosfeld, 1989; Andreas, 2003). Some experts have suggested that stricter wait times are required for hernia surgery in infants and children because their incarceration risk is noted to increase significantly if surgery is delayed more than 14 days from the time of diagnosis (Zamakhshary, 2008; Verhelst, 2016). Other researchers have noted no relationship between delayed operation and incarceration rates as those who presented with incarcerations were index presentations and not those on elective lists awaiting surgery. They therefore suggested that strict wait times policy may not benefit all institutions and patients (Baird, 2011; Gholoum, 2010). This means that institutions need to carry out their own studies

to know their own rates and risks of hernia incarceration. Optimal timing of inguinal hernia repair should be based on the institutional inguinal hernia incarceration rate and risks (Lautz, 2011). None of this data is available at The University Teaching Hospital (UTH), Lusaka.

### **Statement of the Problem**

Inguinal hernia is the most common surgical condition requiring surgical intervention in children (Andreas, 2003; Houben, 2015). One of its complications before surgery is incarceration. This complication is associated with significant morbidity, and adds a significant proportion to the overall workload in surgery (Houben, 2015). Paediatric inguinal hernia incarceration rate and risk are an important consideration in the timing of elective hernia repair to prevent incarceration. However, they have not been determined in the past. Previous studies on inguinoscrotal conditions have concentrated on the study of hydroceles among adults.

### **Study Justification**

Scheduling of elective surgery for inguinal hernia repair in children should be done taking into account, the rate and risk of incarceration of inguinal hernias of a particular population, among other. Studies have shown that while some institution have higher rates and risks of hernia incarcerations, others have demonstrated few or no incarcerations among non-index presentations. This means that there is institutional variability in the rates and risks of inguinal hernia incarceration. The rate and risk of inguinal hernia incarceration among children awaiting elective surgery, at our institution (UTH), had not been determined in the past. This study was important to help determine our own institutional experience; consequently helping determine the best time to operate to prevent incarceration.

By determining inguinal hernia incarceration risk, rate and optimal wait times this study may help guide our own local protocol formulation on when best to operate on infants and children to prevent inguinal hernia incarceration.

## **1.4 Research Questions**

1. What is the incarceration rate of inguinal hernias in paediatric inguinal hernia patients at the UTH?
2. What is the incarceration risk of inguinal hernias in paediatric inguinal hernia patients at the UTH?
3. What is the relationship between the wait time for hernia repair and incarceration risk of inguinal hernias in infants and children at the UTH?

## **1.5 Objectives**

### **1.51 General Objectives**

To determine the best time for inguinal hernia surgery to prevent incarceration among infants and children awaiting elective surgery at the UTH in Zambia.

### **1.52 Specific Objectives**

1. To determine the rate and risk of incarceration of inguinal hernias in infants and children at the UTH
2. To determine the relationship between wait times for inguinal hernia surgery and incarceration risk of inguinal hernias in infants and children at the UTH



## **CHAPTER TWO : LITERATURE REVIEW**

This review of literature follows themes generated from the objectives. It captures 5 important issues: reason why it is important to research on incarceration risk and rate, empirical research on the incarceration rates and risks, definition of concepts, and how the incarceration rates and risks have previously been conceptualised or measured. Paragraph on instruments captures background information and evidence for choice of instruments. Controversies surrounding hernia surgeries and anaesthesia.

### **2.1 Incarceration Risk and Incarceration Rate**

Inguinal hernia is a common condition, among infants and children, requiring surgical intervention. According to Ein (2006), an authority in paediatric inguinal hernias, it is believed that these hernias rarely go away, and therefore, virtually all should be repaired.

Hernias constitute a major health problem that has attracted the attention of the researchers, the public and authorities in health economics because of their frequency, potential morbidity, and the magnitude of repair, (Allen, 1998; Nilsson 2013).

A number of researchers (Lau, 2007; Zamakhshary, 2008; Palmer, 2013; Lee, 2015) agree that inguinal hernia in infants and children are as a result of failure of the processus vaginalis to close. There appears strong evidence that morbidity is common and is primarily related to incarceration or damage of testicular vessels during a difficult surgery (Marinkovic, 1998). Fette (2001) and Rajput (1992) support this claim. Multiple studies have shown an overall incarceration rate, in children, to be between 9% and 20%; but may be up to 34% in infants (Gawad, 2014). Other studies, however, reported lower rates of hernia incarceration. These findings point to a pattern of institutional variability and also suggest the need for individual institutions to carry out their own study.

Gholoum (2010) and Houben (2015) defined incarceration as the need for sedation to achieve reduction of irreducible hernia. Lautz (2011) defined it as manual reduction with or without use of sedation. Palmer (1978) defined it as reduction by using either direct pressure or gallows traction in a sedated child. In this study incarceration will be defined according to Lau et al (2007) who defined it as the need for gentle compression with or without the use of analgesia or sedation to aid reduction of the irreducible hernia. This is because this definition is more

embracing and more reflective of our actual clinical practice at the University Teaching Hospital, Lusaka. This definition also goes round the problems of misdiagnoses by previous researchers who used ICD 9/10 and other billing and administrative databases.

Incarceration rate will be defined according to Sulkowski (2016) who defined it as percentage of patients who had a diagnosis of an incarcerated, strangulated or gangrenous inguinal hernia at inguinal hernia repair. This is the definition taken by all previous studies. Incarceration risk will be defined according to Gholoum (2010) who defined daily risk as total number of incarcerations that were not index presentations, divided by the total number of days waiting for elective repair. This, again, appears to have a universal acceptance among previous studies.

In determining the rate and the risk of incarceration many researchers (Baird et al, 2011; Palmer, 1978; Gholoum, 2010) used retrospective analysis of results obtained from institutional and multi-institutional administrative databases. These variables have been measured using 5 independent variables (wait time, age of the patient, sex of the patient, incarceration status and method of treatment). Most of these studies concentrated on incarceration rates and risks in children below 24 months. Incarceration rate and risks have not been clearly determined in the older age groups (see for example, Gholoum, 2010; Lee, 2011; Sulkowski, 2016)

## **2.2 Optimal Timing**

There is controversy regarding the best timing for inguinal hernia repair and delaying surgery is still being practiced. This approach increases the risk of incarceration (see for example, Turk Yilmaz, 2010; Wiener, 1996; Ein, 2006; Marinkovic, 1998). Wiener (1996) state that there is significant variability in at least the perception of timing of surgery with respect to this common condition (inguinal hernia). Similarly, Turk Yilmaz (2010) note that the timing of inguinal hernia repair has not been precisely determined. Whilst these and other such studies report a positive correlation between percentage of hernia incarceration and wait time, there is limited conclusive evidence to support optimal times of 2 weeks or less, in limited resource setting. That is, most of these studies have been done in developed countries. Strict wait times recommended in literature range from 1 week to 3 weeks (see for example, Vaos, 2010; Lautz, 2011; Marinkovic, 1998; Zamakhshary, 2008). Other studies (Sulkowski, 2015) seem to favour no wait time policy.

Considerable debate exists regarding the best time to operate given the need to weigh benefits of preventing incarceration against the risk of anaesthesia and the technical challenges of preterm inguinal canal (Chan, 2016). Advocates of early repair cite potential risks associated with hernia incarceration if repair is delayed. Delaying inguinal hernia repair has been shown to increase the odds that an infant hernia will incarcerate with several studies demonstrating that the risk of incarceration doubles after a prolonged delay (see for example, Zamakhshary, 2008; Lautz, 2011). However, other studies report low rate or no incarceration. It is clear that all these researchers have focussed on the determination of optimal wait times for infants. They seem not to address the wait times for age groups above 2 years old. None of the studies has tried to determine at which age the inguinal hernias are inconsequential with rates or risks approaching that of adults.

Gholoum (2010) and Zamakhshary (2008) note that recent reports have suggested optimal wait times for inguinal hernia repair to prevent incarceration and that these may not be feasible in the context of limited resources. This study provides the basis for comparing results between the developed and the developing countries. However, it does not include provide evidence on which such an assumption is based. This is simply because there are few studies done in developing countries on this subject. This highlights a vital gap that needs to be considered when appraising or validating previous reports.

Gholoum (2010) defined wait time as the period from diagnosis by a health professional to the time of repair. This is the definition this study shall adopt as it has universal acceptance by other previous studies.

Preterm will be defined as birth at less than 37 weeks gestational age. This adopted from Youn (2018) as it is the definition that is used at the University Teaching Hospital in Zambia.

Optimal timing has been conceptualised by using 7 independent variables (gestational age, birth weight, post-conceptual age, incarceration status, post-operative apnea, other postoperative complications, hospital stay), 2 mediators (incarceration risk and rate) and 1 dependent variable (optimal wait time).

## **2.3 Instruments**

Previous studies (Vaos, 2010; Palmer, 1978) have used questionnaires to collect data. This study will adopt instruments from Youn (2018) and Vaos (2010) who used 14 instruments to measure rate, risk of incarceration and optimal timing for hernia repair (gestational age, birth weight, post-conceptual age at surgery, age at surgery, weight at surgery, timing of surgery, operative time, occurrence of incarceration, postoperative apnea, hernia recurrence, testicular atrophy, hospital stay).

The use of these instruments to study incarceration risk, incarceration rate and optimal wait times has been validated by others (Zamakhshary, 2008; Zendejas, 2010; Lautz, 2011; Youn, 2018).

In this study wait time will be the independent variable. Age (post conceptual age, age at time of surgery, gestational age), sex, weight and laterality will be moderator variables. Incarceration risk and incarceration rate will be dependent variables.

In summary, paediatric inguinal hernias are common and have attracted the attention of many researchers. Despite being the most common surgical operation in children, inguinal hernia repair has a number of contentious issues. There is no clear consensus on the optimal time to operate on infants and older children. Incarceration risks and rates findings, thus far, suggest institutional variations. Most studies have been done in developed countries and seem to focus on age groups below 2 years of age. The age at which the incarceration risk is inconsequential is yet to be determined. A number of researchers have done retrospective studies and have recommended prospective studies to validate and refine their findings.

## **2.4 Surgery and Anaesthesia**

There are a lot of issues that stimulate discussion on inguinal hernias among infants and children. Some of these issues include: wait time to surgery, optimal time to operate to prevent incarceration whilst not subjecting the patients to significant risks of anaesthesia, and the complications of surgery, to mention but a few.

The most important reason to operate or repair an inguinal hernia is to prevent incarceration and its long term consequences (Gawad, 2014). Non operative management is a short term but

acceptable alternative (Nilssen, 2013; Duggan 2015). Eventually, the repair has to be done because the patent processus vaginalis rarely obliterates on its own. Some authorities advocate for early inguinal hernia repair citing potential risks associated with incarceration if repair is delayed. However, performing early repair in neonates is associated with anaesthetic complications such as postoperative apnoea and the need for prolonged ventilation. In addition, neonatal hernia surgery is associated with increased technical difficulties as their inguinal canal anatomy is different from that of adults; their cord complex structures are small, too (Sulkowski, 2015). With the current improved levels of anaesthetic critical care, at centres that perform the surgeries regularly, the risk of surgery is much less than the natural progression of the disease. However it is important to note that there are a lot more other factors at play to ensure safe surgery of these patients. Houben (2015) did a study to look at the practice patterns of paediatric inguinal and scrotal surgeries in the academic centres of the United States of America. The findings of the study were that the Senior uro-surgeons were more comfortable doing these operations than the general surgeons. The surgeons were more likely to refer inguinal hernias to a paediatric surgeon if the patient was very young. This study did not look at the outcomes. In other words, while it may be true that the level of comfort operating on hernia patients is variable among surgeons, few studies have looked at the outcomes of surgeries among different surgeons with different experience.

## **CHAPTER THREE : RESEARCH METHODS**

### **3.1 Research Design**

This retrospective cohort study was performed using retrospective reviews of the records of all children under the age of 17 years, who were diagnosed with inguinal hernia at UTH, from January 2015 to January 2017. This 2-year time frame was chosen assuming that any infant or child with a diagnosis of inguinal hernia during this period, who was otherwise healthy, would under-go hernia surgery within a maximum of 2 years. This method was adopted from Zamakhshary (2008), Lautz (2011), Baird (2011).

### **3.2 Study Site**

The study was conducted in the Paediatric surgery units, at D Block of the University Teaching Hospital in Lusaka, Zambia.

### **3.3 Study population**

The target population was all paediatric patients at the UTH, in Lusaka, Zambia. The study population was all the UTH inguinal hernia patients under the age of 17 years that underwent inguinal hernia surgery, and/ or incarcerated, between January 2015 and January 2017.

### **3.4 Inclusion Criteria**

- i. Infants and children, under the age of 17 years, who underwent inguinal hernia surgery between January 2015 and January 2017.
- ii. Infants and children who underwent inguinal hernia surgery after inguinal hernia recurrence.
- iii. Patients who incarcerated before elective surgery but did not under-go surgery.

### 3.5 Exclusion Criteria

- i. Infants and children with initial diagnosis of inguinal hernia; whose post-operative diagnosis was inconsistent with inguinal hernia.
- ii. The infants and children with initial diagnosis of hydrocele and subsequently found to have an inguinal hernia at the time of surgical repair.

### 3.6 Sampling

Consecutive series sampling method was used to recruit all infants and children who were operated on for inguinal hernia or presented with inguinal hernia incarceration between January 2015 and January 2017. This was sampling method was used to eliminate bias.

$$\text{Sample size} = Z_{1-\alpha/2}^2 \frac{P(1-P)}{d^2}$$

$$= 1.96^2 \times 0.40(1-0.40)/0.05^2$$

$$= \text{sample size } 364$$

### 3.7 Data collection tools

Interviewer completed questionnaires were used. The questionnaires contained instruments adopted from Zamakhshary (2008), Lautz (2011) and Zendejas (2010). These instruments contained items that measured the inguinal hernia incarceration rate, incarceration risk and time to inguinal hernia incarceration (see appendix A).

### 3.8 Data Collection Procedure

After ethical approval was obtained, from ERES Converge Ethical Committee, clinical and administrative registers (from the Neonatal Intensive Care Unit, the Paediatric Surgery Ward, the Paediatric Surgery Operating Theatre, the Paediatric Surgery Outpatient and Emergency Department) at UTH, were used to identify infants and children under the age of 17 years, who underwent surgical repair of inguinal hernias between January 2015 and January 2017. The

registers were also used to identify infants and children whose inguinal hernias incarcerated but did not undergo surgery, in the same period. File numbers and other details obtained from the registers were used to link the registers to the patients' files. The files were traced and data was abstracted from them, using an interviewer completed questionnaire (see appendix A).

The patients were stratified into 7 groups according to their age at the time of inguinal hernia diagnosis and booking for surgery. The groups were: (1) < 4 weeks (2) 4 – 24 weeks (3) 25 – 48 weeks (4) 49 – 96 weeks (5) 97 – 240 weeks (6) 241 – 384 weeks (7) > 384 weeks.

The groups were evaluated individually and as a whole cohort.

All patient with initial diagnosis of hernia, but subsequently diagnosed as hernia, intra-operatively, were excluded. All patients with initial diagnosis of hydrocele, and were intra-operatively found with inguinal hernia, were excluded too.

In the evaluation, incarceration was defined as the need for gentle compression with or without the use of sedation or analgesia to achieve hernia reduction. A daily risk of incarceration for each individual group was calculated by dividing the total number of incarcerations that were not index presentations by the total number of days they waited for elective repair.

Wait time was defined as period from initial diagnosis by a health professional to the time of hernia repair. Time to Event was defined as time from onset of symptoms to time of incarceration. End point is time at surgery or incarceration. Time to censoring was defined as time from onset of symptoms to time of surgery.

The statistical analysis was conducted using descriptive statistics, Pearson correlation, logistic regression analysis and Kaplan Meier Survival Curve, using SPSS version 20. The rate and daily risk of incarceration was evaluated for each group.

The limitation of this study was in the use of a retrospective methodology and all the inherent biases associated with this methodology. However, this should not affect generalisation of the results.

### **3.9 Ethical Considerations**

This study was conducted in full compliance to ethical principles. To ensure this ethical approval from ERES Converge Ethics Committee was sought before the study was



commenced. Permission to access the study site was also sought from The University Teaching Hospital Management. Data collected was only handled by the researcher, and privacy was ensured.

## CHAPTER FOUR : RESULTS

A total of 364 patients were identified; the majority of whom were male 335 (92%). Three (4.8%) of the patients were premature. Three hundred and forty-five (94.8%) of the patients had unilateral inguinal hernia; 287 (78.8%) of whom had right inguinal hernia while 19 (5.2%) had bilateral inguinal hernias.

Table 4.1 summarises the incarceration data for the infants and children waiting for surgery between January 2015 and January 2017. The overall rate of incarceration was 13.45% ( $p = 0.002$ ). The rate of incarceration was significantly higher in infants and children below 2 years of age (above 12% as shown in Table 4.1). There was no hernia incarceration recorded among children above 5 years (see Table 4.1 below).

**Table 4. 1 Incarceration data for infants and children awaiting elective surgery**

<b>Age Group (in weeks)</b>	<b>Total number = 364</b>	<b>Non-Incarcerated n = 315</b>	<b>Incarcerated number = 49</b>	<b>Rate of Incarceration = 13.45%</b>	<b>Risk of Incarceration (95% CI)</b>	<b>P value</b>
<b>(1) &lt; 4</b>	62	47	15	24.2%	0.52	.05
<b>(2) 4 – 24</b>	104	86	18	17.3%	0.17	.004
<b>(3) 25 - 48</b>	82	72	10	12.2%	0.08	.081
<b>(4) 49 - 96</b>	53	49	4	7.9%	0.02	.028
<b>(5) 97 - 240</b>	47	45	2	4.3%	0.01	.637
<b>(6) 241 - 384</b>	10	10	0	0%	Approaches 0	.13
<b>(7) &gt; 384</b>	6	6	0	0%	Approaches 0	.486

At the time of hernia repair, the mean wait time from diagnosis to surgery was 25 days, 5 months, 7 months, and 12 months; for the neonates, the up to 6 months, the up to 12 months and the up to 5 years old respectively, as has been shown in Table 4.2.

**Table 4. 2 Wait time and time to incarceration in infants and children waiting surgery**

<b>Group (age in weeks)</b>	<b>&lt;4</b>	<b>4 - 24</b>	<b>25 - 48</b>	<b>49 - 96</b>	<b>97 - 240</b>	<b>241 - 384</b>	<b>&gt;384</b>
<b>Mean Wait Time to surgery</b>	24.8 days	4.77 months	5.16 months	7.26 months	11.77 months	10 months	10.5 months
<b>Mean Time to hernia Incarcer ation</b>	23 days	3 months	4.25 months	6.25 months	10.43 months	No incarceration	No incarceration

Longer wait times were associated with increased rate and risk of inguinal hernia incarceration.

Likewise, there was a positive correlation between the risk of hernia incarceration and wait times from time of hernia diagnosis to time of hernia repair (Pearson correlation 0.407).

For example, the cumulative risk of hernia incarceration was 9.88% at wait time of 20 days compared to 13.47% at wait times of greater than 6 weeks (see Table 4.3 below).

**Table 4. 3 Relationship between wait time to surgery, and the rate and risk of inguinal hernia incarceration**

<b>Characteristic</b>	<b>Total number = 364</b>	<b>Incarcerated number = 49</b>	<b>Non Incarcerated number = 315</b>	<b>Cumulative Rate of Hernia Incarceration</b>	<b>Cumulative Risk of Hernia Incarceration</b>	<b>P value</b>
<b>Time from diagnosis to surgery (weeks)</b>						<b>0.505</b>
<b>&lt;1</b>	8 (Index)	8 (index)	356	2.20%	0%	
<b>1 - 2</b>	3	2	354	2.75%	9.88%	
<b>3 - 4</b>	49	10	344	6.04%	12.09%	
<b>5 - 6</b>	3	2	342	6.32%	14.64%	
<b>&gt;6</b>	302	27	315	7.14%	13.47%	

Table 4.4 shows the relationship between various clinical characteristics and the risk of incarceration. Patients born prematurely showed lower risk of incarceration (0%) compared to those born at term (0.011%). Among the neonates born at term, however, the incarceration risk was higher in those infants less than 41 weeks post conceptual age (0.043%) compared to those older than 41 weeks post conceptual age (0.009% daily risk of incarceration).

Comparing birth weight and risk of incarceration, in table 3, patients with low birth weight had a higher risk of inguinal hernia incarceration (0.016 %) than those with normal birth weight. This was also true in the higher birth weight babies who demonstrated a higher daily risk of incarceration of 0.022%.

As has been shown in Table 4.4, infants and children with normal body weight at time of surgery showed a higher daily risk of hernia incarceration (0.012%) compared to the underweight and overweight (with risks 0.008 and 0.011 respectively).

**Table 4. 4 Factors associated with increased risk of inguinal hernia incarceration**

<b>Characteristic</b>	<b>Total number = 364</b>	<b>Incarcerated number = 49</b>	<b>Non Incarcerated number = 315</b>	<b>Risk of Hernia Incarceration</b>	<b>P value</b>
<b>Gestational Age (obstetric weeks)</b>					0.54
<b>&lt; 37</b>	13	0 (0%)	13 (4.13%)	0	
<b>37 +</b>	351	49 (100%)	302 (95.87%)	0.011	
<b>Post conceptual Age ( Weeks)</b>					0.02
<b>&lt;41</b>	55	12 (24.49%)	43 (13.65%)	0.043	
<b>41 +</b>	309	37 (75.51%)	272 (86.35%)	0.009	
<b>Birth Weight</b>					0.42
<b>&lt;2.5Kg</b>	19	7 (14.29%)	12 (3.81%)	0.016	
<b>2.5 – 3.5Kg</b>	332	38 (77.55%)	294 (93.33%)	0.010	
<b>&gt;3.5Kg</b>	13	4 (8.16%)	9 (2.86%)	0.022	
<b>Weight at Surgery</b>					0.68
<b>Underweight</b>	15	4 (8.16%)	11 (3.49%)	0.008	
<b>Normal Weight</b>	340	42 (85.72%)	298 (94.60%)	0.012	
<b>Overweight</b>	9	3 (6.12%)	6 (1.91%)	0.011	

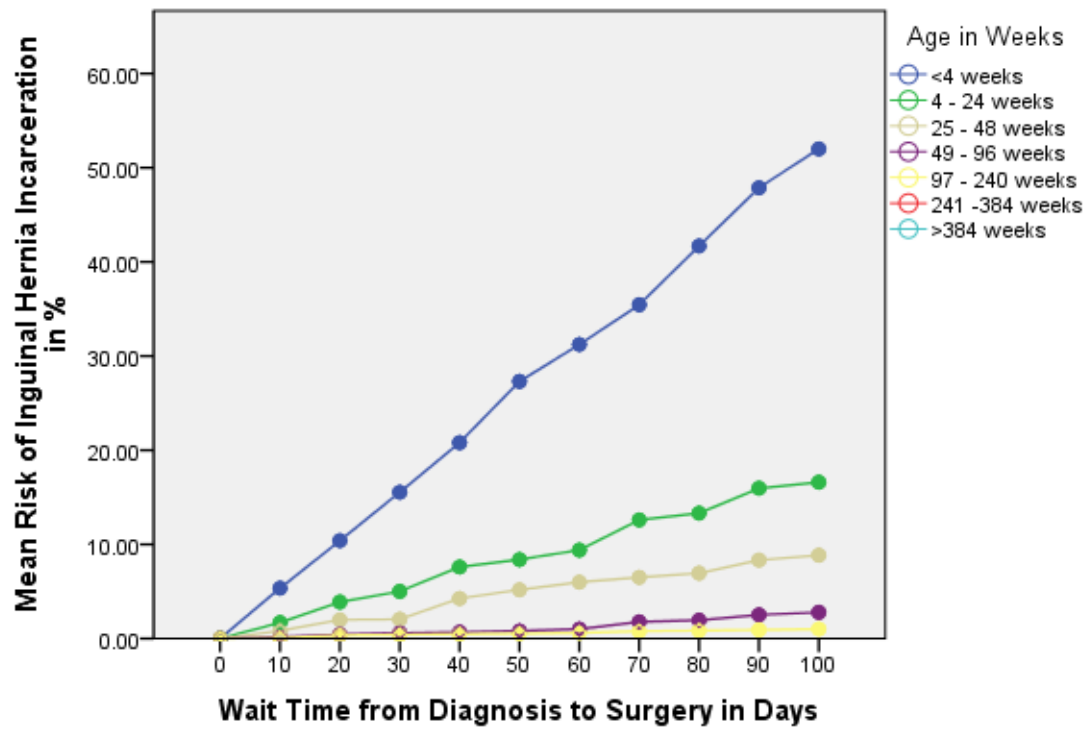
Other clinical characteristics (sex and laterality) and their relationship with the incarceration rate and risk, have been shown in table in the table 4.5 below. Male infants and children showed an increased rate of incarceration (93.33%) compared to females (6.67%). Similarly, the daily

risk of incarceration was higher for male infants and children (0.012%) than females (0.008%). The rate of incarceration was higher among infants and children with right inguinal hernia (79.37%). This was also true for the daily risk of incarceration which was 0.013% among the right inguinal hernia patients; compared to left inguinal hernia (0.011%) and bilateral inguinal hernia patients (0%).

**Table 4. 5 Relationship between clinical characteristics (sex, laterality), and the rate and risk of inguinal hernia incarceration**

<b>Characteristic</b>	<b>Total number 364</b>	<b>Incarcerated = number = 49</b>	<b>Non Incarcerated number = 315</b>	<b>Risk of Hernia Incarceration (95% CI)</b>	<b>P value</b>
<b>Sex</b>					0.002
male	337 (92.58%)	43 (87.76%)	294 (93.33%)	0.012	
female	27 (7.42%)	6 (12.24%)	21 (6.67%)	0.008	
<b>Laterality</b>					0.014
Left	58 (15.93%)	12 (24.49%)	46 (14.60%)	0.011	
Right	287 (78.84%)	37 (75.51%)	250 (79.37%)	0.013	
Bilateral	19 (5.2%)	0	19 (6.03%)	0	

The table below shows wait time risk relationship in each age group. It gives a relationship from which risk reduction can be deduced by adjusting the wait time. Overall, more than 50% risk reduction could be achieved if inguinal hernia repair was done within 14 days of diagnosis, for example (see Figure 4.1 below).



**Figure 4. 1 Risk of inguinal hernia incarceration by wait time and age group**

## CHAPTER FIVE : DISCUSSION

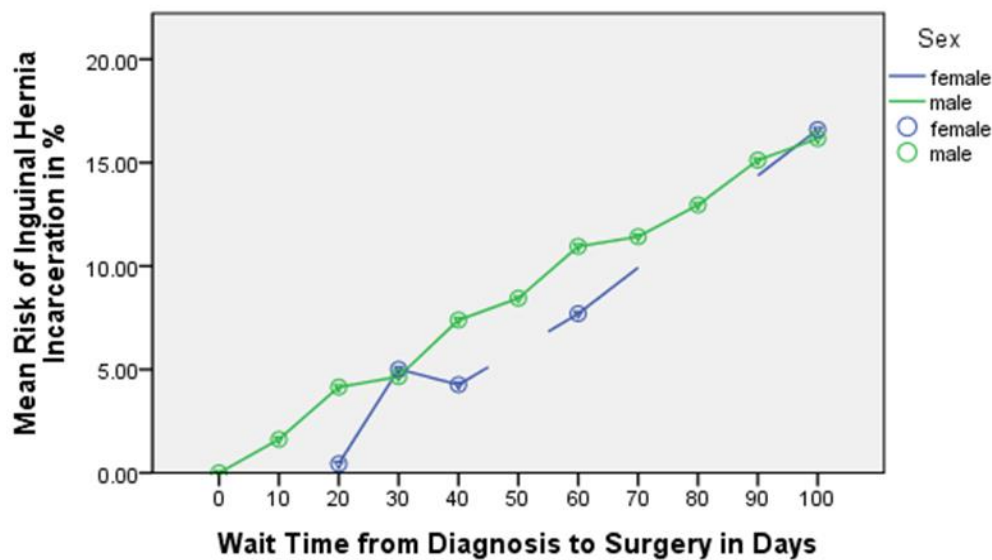
Inguinal hernias are common in infants and children. They affect approximately 5% of all children (Wright, 2017; Scott, 2010). An inguinal hernia will not resolve spontaneously. This necessitates that it be repaired as soon as possible, after diagnosis, to avoid the risk of incarceration or strangulation (Dinesh, 2014). This single centre study demonstrates some findings worth noting: (1) the overall rate of hernia incarceration for infants and children was 13.45% in this study. This is comparable to those rates reported by other researchers (Gholoum, 2010; Copp, 2010). These researchers reported rates between 9% and 34%, depending on the age groups. Our findings are in contrast with Sulkowski (2015) and Lee (2010) who reported no incarcerations in their studies. (2) the rate and risk for inguinal incarceration was found to be age dependent. The variations based on age were significant. This is in contrast to Gholoum et al (2010) who noted no difference in incarceration rates between different age groups. Infants and children below 2 years had increased rates and risk of hernia incarceration. This is in agreement with a lot other studies (Wright NJ, 2017; Manoharan, 2005) which have demonstrated this. Though, the mounting evidence suggests that incarceration is more frequent in the general population of infants with inguinal hernia than in neonates who undergo repair during the initial hospitalisation in previous studies, our neonates had significantly higher rates than the older infants. However, the overall rate was lower than that reported in Lautz, 2011. There was no incarceration among premature neonates and ex-premature inguinal hernia patients. Like in Lee (2011) our risk of incarceration among premature neonates was low compared to term infants. This could mean that more time could be given to the premature infants to allow for maturity to take place before elective repair of their hernias is done.

(3) underweight did not increase the risk. In fact, the opposite was true, as the overweight infants and children demonstrated a higher risk. This finding seems to be particular study.

In contrast to Gholoum et al (2010) most of the hernia incarceration (83.67%) occurred while patients awaited elective surgical repair. This is probably because most of our infants and children have wait times greater than 6 weeks to get elective surgical repair.



Longer wait times and male gender increased the risk of incarceration (see Figure 5.1 below). This has also been demonstrated in other studies (Zamakhshary, 2008; Lautz, 2011).

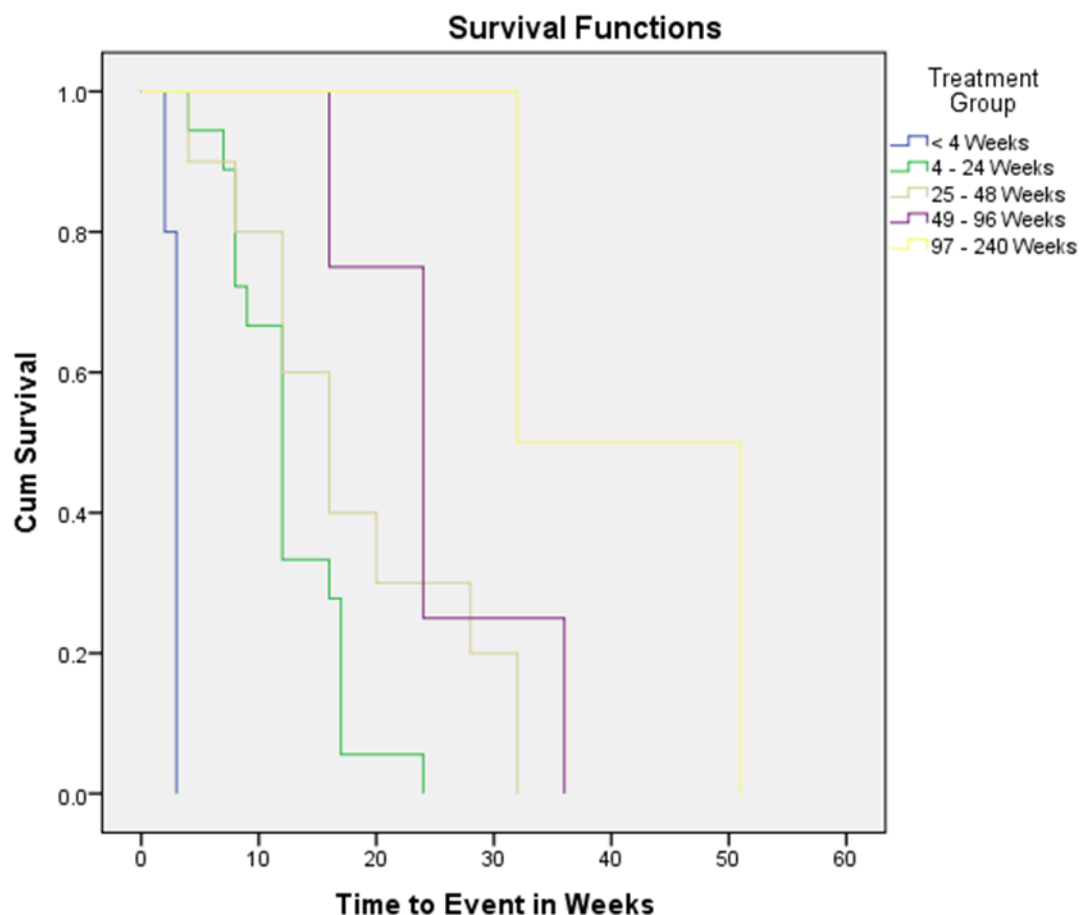


**Figure 5. 1 Risk of inguinal hernia incarceration by wait time and sex**

Males had a relatively shorter wait time (see Figure 5.1 above). This could not be explained like in other studies (Gawad, 2014). It is possible, though, that they were more symptomatic. (4) inguinal hernias were predominant in males. This is in agreement with findings in large series reviewing experience with repair of inguinal hernias which report the male to female ratio as ranging from 3.6: 1 to 6.7:1 (Houben, 2014). Male to Female ratios of up to 10:1 have been documented (Lee, 2015). However, our hernia patients' male to female ratio was much higher (12:1). Hassan (2002) found the same ratio among the Nairobi hernia patients. This could be pointing to a regional ratio, although, these patients were adult inguinal hernia patients. (5) the right inguinal hernia rates were higher than that of the left (see Table 4.2 above). Bilateral inguinal hernias constituted 6.03% of all the inguinal hernia. This was comparable with many researchers (such as Omar and colleagues, 2004; Dinesh, 2014) findings of approximately 4% to 8% of bilateral inguinal hernias. Askarpour (2013) found a much higher figure of 15.24%. This could be as a result of possible over reporting, in his case. Our wait times were comparable to those found by Dinesh (2014) who reported duration of

symptoms ranging from 1 month to 5 years. Young infants, generally had a higher risk of incarceration. No incarceration occurred in children older than 5 years old. This could mean that the incidence of hernias incarceration is significantly lower, if not inconsequential, in older children.

Though there is no clear consensus as to the optimal timing of hernia repair (Gholoum, 2010), there is need for our institutions to reduce the wait time for surgery, though, to 3 weeks or even less, as this could reduce the incarceration rates to more than half the current numbers. Reduction in the incarceration rates would mean reduction in the complications of surgery such as injury to the cord complex, recurrences, post-operative infections and difficult surgeries, to mention but a few. The survival curve below shows the times that each age group starts to incarcerate (see Figure 5.2 below).



**Figure 5. 2 Times at which inguinal hernia incarceration occurred among age groups**

Therefore, these times could be used to book the patients and prevent incarcerations.

There was a negative correlation between the risk and age at operation. There was a positive correlation between risk of incarceration and wait time, male sex, gestational age and laterality. This is in agreement with what other previous studies (Zamakhshary, 2008; Lautz, 2011) have demonstrated. The strength of the relationship was weak for the latter four, though.

## **CHAPTER SIX : CONCLUSION AND RECOMMENDATIONS**

### **6.1 Conclusion**

Inguinal hernia incarceration in infants and children on the wait list for surgery was common in our cohort. The rate of incarceration was high (13.45%). The risk of incarceration was age dependent & higher in neonates (0.52), infants & younger children (0.01). Neonates had as much as 5 times higher risk as other children. Mean wait time was age dependent and ranged from 24.8 days to 10.5 months. Longer wait times, male sex, right sided hernias were associated with higher rates & risks. Mean time to incarceration was age dependent and ranged from 23 days in neonates to up to 10.43 months in children under 5 years. Older children had no incarceration. The best time to operate is before 3 weeks for neonates, before 2 months for infants & before 4 months for younger children to prevent incarceration.

By reducing the wait times to 3 weeks or less, especially for infants and young children, may reduce the number of incarcerations by more than half of the current numbers.

### **6.2 Recommendations**

1. Surgeons should reduce wait time to less than 3 weeks for neonates and less than 2 months for infants and younger children to prevent incarceration.
2. Hospitals should refer neonates born with inguinal hernias to tertiary hospitals for early surgery (before they are 3 weeks old).
3. A holistic Prospective study taking into account all components to evaluate the optimal time and conditions to perform elective surgery for infants and children at UTH, Lusaka, Zambia.

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## APPENDICES

### Appendix A: Measurement Items

#### Record ID:

#### Demographics

Tick where appropriate

##### 1.0 Gestational age at birth

1.1 <37 weeks

1.2  $\geq$ 37 weeks

##### 2.0 Post conceptual age at diagnosis

2.1 <41 weeks

2.2  $\geq$ 41 weeks

##### 3.0 Age at time of operation

3.1 <4 weeks

3.2 4 – 24 weeks

3.3 25 -48 weeks

3.4 49 -96 weeks

3.5 97 -240 weeks

3.6 241 -384 weeks

3.7 >384 weeks

##### 4.0 Sex

4.1 male

4.2 female

##### 5.0 Birth Weight

5.1 < 2.5 Kg

5.2 2.5 – 3.5 Kg

5.3 >3.5 Kg

##### 6.0 Weight at time of operation (with reference to Z score of Under-5 card or BMI)

6.1 Under-weight for age

6.2 Normal weight for age

### 6.3 Over-weight for age

## Inguinal Hernia

### 7.0 Incarceration status

#### 7.1 Incarcerated (irreducible)

#### 7.2 non incarcerated (reducible)

### 8.0 Laterality

#### 8.1 Left unilateral

#### 8.2 Right unilateral

#### 8.3 Bilateral

### 9.0 Intra-operative inflammatory changes if suspected incarceration but spontaneously reduced in the emergency department

#### 9.1 Local tissue oedema

#### 9.2 No local tissue oedema

### 10.0 Wait time for hernia repair

#### 10.1 <1 week

#### 10.2 1 – 2 weeks

#### 10.3 2 – 4 weeks

#### 10.4 4 – 6 weeks

#### 10.5 >6 weeks

## Additional Information

11.0 Date of initial diagnosis: .....

12.0 Date of incarceration: .....

13.0 Date of hernia surgery: .....

14.0 Time to event: .....

15.0 Time to right censoring (time to surgery or loss to follow up): .....

Study Approval Letter from Ethics Committee



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I.R.B. No. 00005948  
F.W.A. No. 00011687

4<sup>th</sup> October, 2017

Ref. No. 2017-Aug-012

The Principal Investigator  
Dr. Mulenga Mulewa  
University Teaching Hospital  
Dept. of Surgery  
BOX LUSAKA.

Dear Dr. Mulewa,

**RE: RISK INCARCERATION OF INGUINAL HERNIAS AMONG PAEDIATRIC PATIENTS AWAITING ELECTIVE SURGERY AT THE UNIVERSITY TEACHING HOSPITAL, LUSAKA ZAMBIA.**

Reference is made to your resubmission dated 17<sup>th</sup> September, 2017. The IRB resolved to approve this study and your participation as Principal Investigator for a period of one year.

Review Type	Ordinary	Approval No. 2017-Aug-012
Approval and Expiry Date	Approval Date: 4 <sup>th</sup> October, 2017	Expiry Date: 3 <sup>rd</sup> October, 2018
Protocol Version and Date	Version-Nil	October, 2018
Information Sheet, Consent Forms and Dates	N/A	October, 2018
Consent form ID and Date	Version-Nil	October, 2018
Recruitment Materials	Nil	October, 2018

Other Study Documents	Checklist.	October, 2018
Number of participants approved for study		October,2018

Where Research Ethics and Science Converge

Specific conditions will apply to this approval. As Principal Investigator it is your responsibility to ensure that the contents of this letter are adhered to. If these are not adhered to, the approval may be suspended. Should the study be suspended, study sponsors and other regulatory authorities will be informed.

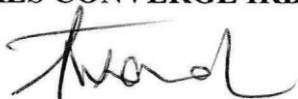
## Conditions of Approval

- No participant may be involved in any study procedure prior to the study approval or after the expiration date.
- All unanticipated or Serious Adverse Events (SAEs) must be reported to the IRB within 5 days.
- All protocol modifications must be IRB approved prior to implementation unless they are intended to reduce risk (but must still be reported for approval). Modifications will include any change of investigator/s or site address.
- All protocol deviations must be reported to the IRB within 5 working days.
- All recruitment materials must be approved by the IRB prior to being used.
- Principal investigators are responsible for initiating Continuing Review proceedings. Documents must be received by the IRB at least 30 days before the expiry date. This is for the purpose of facilitating the review process. Any documents received less than 30 days before expiry will be labelled "late submissions" and will incur a penalty.
- Every 6 (six) months a progress report form supplied by ERES IRB must be filled in and submitted to us.
- ERES Converge IRB does not "stamp" approval letters, consent forms or study documents unless requested for in writing. This is because the approval letter clearly indicates the documents approved by the IRB as well as other elements and conditions of approval.

Should you have any questions regarding anything indicated in this letter, please do not hesitate to get in touch with us at the above indicated address.

On behalf of ERES Converge IRB, we would like to wish you all the success as you carry out your study.

Yours faithfully,  
**ERES CONVERGE IRB**



Prof. E. Munalula-Nkandu  
BSc (Hons), MSc, MA Bioethics, PgD R/Ethics, PhD  
CHAIRPERSON