PRACTICES OF ABDOMINAL FASCIAL CLOSURE AND RELATED COMPLICATIONS FOLLOWING ELECTIVE MIDLINE LAPAROTOMY AT MUHIMBILI NATIONAL HOSPITAL

By

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A Dissertation Submitted in Partial Fulfillment of the Requirements for the Award of the Degree of Masters of Medicine (Surgery) of the Muhimbili University of Health and Allied Sciences

Muhimbili University of Health and Allied Sciences

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CERTIFICATION

The undersigned certifies that he has read and hereby recommends for acceptance of dissertation entitled **Practices of Abdominal Fascial Closure and Related Complications Following Elective Midline Laparotomy at Muhimbili National Hospital,** in fulfillment of the requirements for the degree of Master of Medicine (Surgery) of Muhimbili University of Health and Allied Sciences.

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Dr. M. Mchembe

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Date: _____

DECLARATION AND COPYRIGHT

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Lastly, thanks to my fellow postgraduate students in the department of surgery for their cooperation in preparing this dissertation.

DEDICATION

This dissertation is dedicated to my parents **Onesphor** and **Anna-Maria**, to my beloved wife **Leonida** and to my sons **Raniero** and **Vianney**.

ABSTRACT

Background: Midline laparotomy is the commonest approach for abdominal operations. The techniques and sutures used for abdominal fascial closure following elective midline laparotomy differ among surgeons and among centres worldwide. Faulty techniques and/or suture materials used may lead to a wide range of complications, some with devastating outcomes.

Objectives: This study was intended to determine the practices of abdominal fascial closure and related complications following elective midline laparotomy at MNH.

Methods: This was a hospital based descriptive prospective study. It included patients who underwent elective midline laparotomy in the units of general surgery, urology and gynaecology between April 2011 and November 2011. All patients were followed up after surgery which lasted until January 2012.

Results: One hundred and forty eight patients were eligible for analysis. Among these, 130 (87.8%) were females and 18 (12.2%) were males. The overall average age was 44.7 (SD 13.9) years and ranged from 15 to 90 years. Continuous fascial closure was performed in 147 (99.3%) patients while in only one patient interrupted closure was performed. Likewise, mass closure was favoured (99.3%) as opposed to layered closure (0.7%). Vicryl was the commonly used suture material, 78 (52.7%) patients; followed by prolene 46 (31.1%) patients and PDSII 24 (16.2%). Sutures with size number 1 were used in all patients except one where suture with size number 0 was used. Duration of follow up after surgery varied from 2 months to 9 months; mean duration being 5.8 months (SD 2.0 months). Twelve (8.1%) patients encountered complications; 11 patients had one complication each while one patient had two complications. Complications reported were persistent wound pain (6), wound sepsis (5) and stitch sinus (2). The use of prolene was associated with persistent wound pain, p-value = 0.026; and in fact had higher overall complication rates, p-value = 0.002

Conclusion and Recommendations: Uniformity on the techniques of fascial closure after elective midline laparotomy does exist among surgeons in MNH; however the use of different sutures to serve this purpose reflects lack of consensus. Prolene use is associated with persistent wound pain. Factors influencing selection of sutures should be addressed. Long term follow up is crucial for patients who undergo midline laparotomy to assess the occurrence of incisional hernia.

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LIST OF ABBREVIATIONS

MUHAS …… Muhimbili University of Health and Allied Sciences

MNH ……. Muhimbili National Hospital

PDS …….. Polydioxanone Suture

OHS …….. Open Heart Surgery

SPSS ……. Statistical Package for Social Sciences

CI ……. Confidence interval

IPPM ……... Intramural Private Practices for Muhimbili

CHAPTER ONE

INTRODUCTION

1.1 Preamble

Various approaches have been employed to access the abdominal cavity during abdominal surgeries. Several types of incisions can be made to access the abdominal cavity guided by the type of surgery to be performed, one of them being midline incision; which is commonly used in abdominal operations.[1] There are nine layers in the anterolateral abdominal wall, from outside: skin, subcutaneous tissue, superficial fascia, external oblique muscle, internal oblique muscle, transversus abdominis muscle, transversalis fascia, preperitoneal adipose tissue and peritoneum. In the midline the three layers of muscles are adherent together by way of their aponeuroses to form the linea alba; which is attached superiorly onto xiphoid process and inferiorly onto symphysis pubis. In performing midline incision a vertical cut is made through the linea alba. Abdominal muscles relax and contract with respiration and the abdominal wall conforms to the volume of abdominal viscera. There is an abdominothoracic rythym. Normally, during inspiration, when the sternum moves forward and chest expands, the anterior abdominal wall also moves forward. Post laparotomy patients require adequate analgesia to maintain normal abdominothoracic rythym.

1.2 Techniques of wound closure

Abdominal wound closure following midline incision entails reconstructing these layers by different techniques using different suture materials. The goals of fascial closure include even distribution of tension along suture lines and maintenance of tensile strength across the wound until tissue tensile strength is adequate.[2] Closure can be achieved by reconstructing peritoneum and musculoaponeurotic layer separately or by mass closure in which all the fascial layers, are closed together leaving skin, which is closed separately.[1] The latter technique is widely accepted as the standard abdominal wall closure. The ideal abdominal wound closure provides strength and a barrier to infection, in addition it should be efficient to perform and comfortable for the patient.[3]

Fascial closure can be accomplished with continuous or interrupted sutures. With either technique, it is important not to place excessive tension on the fascial tissues and the knots must be square to be secure. Whipple and Elliott[4] indicated that tying sutures too tightly caused strangulation of the tissue with ischaemic necrosis and was the most common error in abdominal wound closure. Ischaemia causes delayed healing or non-healing and increased risk of wound infections. Equally, insufficient tension on the suture may result in failure to oppose the wound edges and inadequate haemostasis.[5]

Selection of a wound closure technique must also take into account the dynamic changes in wound length during distention which may lengthen the wound to some degree. A continuous suture can accommodate this increase in the length of the incision by having an adequate reserve of suture length in the wound. Consequently, a continuous suture distributes its tension throughout the wound, limiting the forces on the tissues encircled by the suture. With interrupted closure, the suture cannot easily accommodate these changes in incisional length, and the tension remains isolated to each suture loop.[4] Time can be saved by closing the fascia in continous rather than interrupted fashion without causing an increase in post operative wound separation or hernia formation.[6]

Wound disruptions are frequent as a result of fascial tearing at the site of suture, thus placing the sutures furrther from the cut edges reduces the risk of disruption. Sanders and colleagues[4] reported that placing sutures 5mm from the cut edges of the fascia wounds burst much more easily than placing 1 to 2cm from the fascial edges. The optimal depth of the suture bite is advocated to be at least 4mm and the ideal interval between the sutures be 6mm. Three-throw square knots are recommended and free suture end should be cut 3mm from the knot; applying to both continuous and interrupted sutures.

1.3 Sutures for fascial closure

Suture material is a foreign body implanted in humans, so it is liable to elicit tissue reaction just like other foreign bodies do. Skillful closure requires knowledge on proper technique as well as physical characteristics and properties of these suture materials.

The ideal suture has the following characteristics:[2] sterile, all-purpose (composed of material that can be used in any surgical procedure), causes minimal tissue injury or tissue reaction, easy to handle, holds securely when knotted, high tensile strength, favourable absorption profile and resistant to infection.

Unfortunately, at present, no single material can provide all of these characteristics. In different situations and with differences in tissue composition throughout the body, the requirements for adequate wound closure require different suture characteristics. However, all sutures should meet the following fundamental qualities;[2] sterility, uniform diameter and size, pliability for ease of handling and knot security, uniform tensile strength by suture type and size and freedom from irritants or impurities that would elicit tissue reaction.

Suture materials are categorized on the basis of material used, tensile strength, configuration, absorbability and time to degradation.[7] In terms of configuration they are composed of either single strand or multiple strands. Monofilament suture is made of a single strand. This structure is relatively more resistant to harboring microorganisms. The monofilament sutures exhibit less resistance to passage through tissue than multifilament suture. Great care must be taken in handling and tying monofilament suture because crushing or crimping of this suture can nick or weaken the suture and lead to undesirable and premature suture failure.[2]

Multifilament suture is composed of several filaments twisted or braided together. These materials are less stiff but have a higher coefficient of friction. A multifilament suture generally has greater tensile strength and better pliability and flexibility than monofilament suture. Because multifilament materials have increased capillarity, the increased absorption of fluid may act as a tract for pathogens introduction.[2]

Depending on absorbability, sutures may be absorbable or non-absorbable. The former provide temporary wound support, until the wound heals well enough to withstand normal stress. Absorption occurs by enzymatic degradation in natural materials and by hydrolysis in synthetic materials. Hydrolysis cause less tissue reaction compared to enzymatic degradation.[2,7] Accelerated absorption may occur in patients with fever, infection, or protein deficiency and may lead to an excessively rapid decline in tensile strength.[2] It may also occur in a body cavity that is moist or filled with fluid or if sutures become wet or moist during handling prior to implantation. Absorbable sutures may be natural or synthetic.

Natural absorbable sutures include; collagen - derived from the submucosal layer of bovine small intestine; surgical gut, plain - tensile strength is maintained for 7-10 days post-implantation and absorption is complete within 70 days; surgical gut, chromic - tensile strength is maintained for 10-14 days. The absorption rate is slowed by chromium salt (90 days).

Synthetic absorbable sutures include; polyglactin 910 (Vicryl) - braided multifilament suture coated with a copolymer of lactide and glycolide (polyglactin 370). Tensile strength is approximately 65% at 14 days. Absorption is minimal for 40 days and complete in 56-70 days. It causes only minimal tissue reaction. Polycaprolate (Dexon II) - made from polyglycolic acid, it has similar tensile strength and absorption profile as vicryl. Polyglecaprone 25 (Monocryl) - monofilament suture that is a copolymer of glycolide and e-caprolactone. It has superior pliability, leading to ease in handling and tying. Tensile strength is high initially, 50-60% at 7 days, and is lost at 21 days. Absorption is complete at 91-119 days. Polydioxanone (PDS II) - polyester monofilament suture made of polydioxanone. This suture provides extended wound support and elicits only a slight tissue reaction. Tensile strength is 70% at 14 days and 25% at 42 days. Wound support remains for up to 6 weeks. Absorption is minimal for the first 90 days and essentially complete within 6 months. Maxon has a similar tensile strength and absorption profile PDSII.

Non-absorbable sutures elicit a tissue reaction that results in encapsulation of the suture material by fibroblasts. They can be natural or synthetic. Natural non-absorbable sutures include; surgical silk - made of raw silk spun by silkworms. It has superior handling characteristics. Although classified as a non-absorbable material, silk suture becomes absorbed by proteolysis and is often undetectable in the wound site by 2 years. Tensile strength decreases with moisture absorption and is lost by 1 year. The problem with silk suture is the acute inflammatory reaction triggered by this material. Host reaction leads to encapsulation by fibrous connective tissue.

Synthetic non-absorbable sutures include; nylon - this is a polyamide polymer suture material available in monofilament and braided forms. Nylon is quite pliable, especially when moist. Nylon has 81% tensile strength at 1 year, 72% at 2 years, and 66% at 11 years. The material is stronger than silk suture and elicits minimal acute inflammatory reaction. Nylon is hydrolyzed slowly, but remaining suture material is stable at 2 years, due to gradual encapsulation by fibrous connective tissue. Polypropylene (Prolene) - this monofilament suture is an isostatic crystalline stereoisomer of a linear propylene polymer, permitting little or no saturation. The material does not adhere to tissues and is useful as a pull-out suture (eg, subcuticular closure). Prolene is not subject to degradation or weakening and maintains tensile strength for up to 2 years.

1.4 Selection of technique and suture material

The notion that non-absorbable sutures in fascial closure are better than slowly absorbable ones is partially a myth, because tension will gradually cause remodeling of the connective tissue around the suture. If fascial strength has not developed adequately in the repair process, the suture material will not have an influence on outcome. In general, when proven infection or contamination is a concern, monofilament, non-absorbable, non-braided suture is preferred. For abdominal wall closure in debilitated, malnourished cancer patients, permanent closure with non-absorbable suture seems prudent. In cirrhotic patients with established ascites or a patient with potential for development of postoperative ascites, the abdomen is closed with continuous suture, and a multilayer, watertight closure must be achieved.[8]

Selection of surgical technique and suture material has been an important consideration for surgeons which is a science rather than an art. For those artisans the selection is usually the matter of habit, guesswork or tradition. In the past selection of suture material was based on testimonials and anecdotal experience from senior surgeons. Today, surgeons select sutures on the basis of well-controlled, randomized clinical and experimental trials.[4]

CHAPTER TWO

LITERATURE REVIEW

High technology has lead to tremendous advances in surgical techniques and materials. However despite that being the case, abdominal fascial closure has remained a procedure that often reflects a surgeon's personal preference with reliance on traditional and anecdotal experience. None of the treatments for abdominal wall closure (except skin closure in the midline group) is performed on a consensus level.[9] There is still controversy about the best strategy for abdominal wall closure due to inconsistent and incomplete evidence provided by several randomized controlled trials.

Complications which may arise following fascial closure include wound dehiscence, wound infection, incisional hernia, stitch sinus formation, persistent irritating knot and wound pain. They may arise partly as a result of poor technique or faulty selection of suture material or patient's factors; however the most important causes are poor surgical technique, persistent increased intra-abdominal pressure and local necrosis due to infection. Other patient's factors associated with increased risk of wound dehiscence include male sex, advanced age, malignant diseases, obesity, malnutrition, treatment with steroids and uraemia.[4,5] The risk of wound dehiscence should be less than 1% and usually occurs within 2 weeks post operative. Incisional hernia occurs approximately in 25% of cases.[4,10,11]

Incisional hernia remains a major problem for the surgeon. Most published studies have followed up patients for 6-12 months after operation. In one study, 363 patients, known not to have an incisional hernia at 1 year, were reviewed between 2.5 and 5.5 years after operation. Twenty-one patients (5.8%) were found to have developed incisional hernias.[12] Other studies have suggested that most incisional hernias develop between the first post operative month and the first year after surgery, yet many patients do not develop signs and symptoms until several years later.[13,14,15,16]

An experimental study was conducted to assess relationship between synergistic wound sepsis and suture materials. An inoculums of 6 x 10 (S) of Escherichia coli and of Bacteriodes

fragilis produced a frank infection rate of 27%. Addition of a catgut or a braided nylon tie significantly increased the rate to 56 and 48% respectively. Proline and silk produced much smaller non-significant rises. The rate with polyglycolic acid was 18% which, though not statistically significant, suggests the possibility that this material produces conditions unfavourable to multiplication of bacterial that produces this type of infection.[17]

A multi-centric study[9] conducted in Germany in 2008 included 85 patients who underwent midline laparotomy of which fascia closure was performed with a continuous suture in 55 patients (65%), interrupted sutures in 16 patients (19%), in 13 patients (15%) a combination of both techniques was applied. Monofilament sutures were applied for fascia closure in 51 patients (60%), braided sutures in 32 patients (38%), non-absorbable sutures in four cases (5%), slowly absorbable sutures in 47 patients (55%), and moderately rapid absorbable sutures in 33 patients (39%). Sutures with size number 0 were used in two patients (2%), with size number 1 in 48 patients (57%), and with size number 2 in 31 patients (36%).[9] It concluded there was lack of consensus regarding the strategy for fascial closure following midline laparotomy. It demonstrates persistent uncertainty within the surgical community. Hence, the ideal closure strategy is still to be determined; moreover no clinical guidelines are available for abdominal fascial closure after any incision.

The meta-analysis by Hodgson et al.[18] reported significantly less incisional hernias after closure with continuous non-absorbable sutures but also found significantly more suture sinuses and wound pain requiring further interventions.

In meta-analysis conducted in Netherlands by van‘t Riet M et al[19] fifteen studies were identified with a total of 6566 patients. Closure by continuous rapidly absorbable suture was followed by significantly more incisional hernias than closure by continuous slowly absorbable suture ($P < 0.009$) or non-absorbable suture ($P = 0.001$). No difference in incisional hernia incidence was found between slowly absorbable and non-absorbable sutures ($P = 0.75$), but more wound pain ($P < 0.005$) and more suture sinuses ($P = 0.02$) occurred after the use of non-absorbable suture. Similar outcomes were observed with continuous and interrupted sutures, but continuous sutures took less time to insert. Hence, to reduce the incidence of

incisional hernia without increasing wound pain or suture sinus frequency, slowly absorbable continuous sutures appear to be the optimal method of fascial closure.

Diener MK et al[20] conducted a meta-analysis comparing slowly absorbable suture and rapidly absorbable suture in which the latter was significantly associated with incisional hernia. Similar results were obtained by Wissing J et al.[21]

Anderson ER, and Gates S[22] conducted a survey of techniques used in caesarean section operation by obstetricians following lower midline laparotomy in UK, found that the majority of operations (73%) used a continuous non-locking suture, 21% used a continuous non-locking suture with a single central lock, and remainder used continuous locking suture (5%), while 1% used interrupted suture or more than one technique. Vicryl was the most commonly used suture material (87%), with small numbers using chromic catgut, plain cutgut, dexon, monocryl or other suture materials.

The value of a particular abdominal fascial closure technique may be measured by the incidence of early and late wound complications, and the best technique should have low incidence of these complications. Ceydeli A et al[23] conducted a study to address the closure of vertical midline laparotomy. All articles related to abdominal fascial closure published from 1966 to 2003 were included in the review. It was concluded that the optimal technique to be mass closure in continuous manner using number 1 or 2 absorbable monofilament suture material.

Dynamic process of wound healing consists of three phases.[19,24] Exudative phase: days 1 - 4, it is characterized by vascular, cellular and enzymatic processes. It does not provide any holding strength to the wound. Proliferative phase: days 5 – 20, it is dominated by epithelialisation, wound contraction and connective tissue repair. Tissue regains approximately 15% – 30% of its original strength. The process can be delayed by wound infection or inflammation. Most rapidly absorbable sutures loose their tensile strength between 14 – 21 days; thus the likelihood of incisional hernia is high in the settings of infection. Remodelling phase: days 21 to several years, it is dominated by rearrangement and cross-linking of collagen fibres. Tissue

regains up to 80% of its original strength. Slowly absorbable and non absorbable sutures retain their tensile strength up to this phase.

In summary a good technique should meet the following criteria[3,25]; continuous suture, use number 1 or 2 delayed absorbable monofilament suture, mass closure, take wide tissue bites, a short stitch interval, non-strangulating tension on the suture and use a suture length to wound length ratio of 4 to 1.

PROBLEM STATEMENT

Development of wound dehiscence, incisional hernia, stitch sinuses and long standing pain following midline fascial closure pose challenges to surgeons worldwide. There is still controversy about the techniques used in fascial closure as well as selection of suture material. In reducing incisional hernia risk, non-absorbable suture material is recommended while risking the patient to developing stitch sinuses and wound pain. On the other hand, fear of developing the latter complications absorbable suture material is used while risking the patient to develop incisional hernia. However, there is inconsistent and incomplete evidence provided by several randomized controlled trials.[18,19]

A pilot study conducted by the author at MNH found that between May 2010 and February 2011 there were 197 elective midline laparotomies done in general surgery, urology and gynaecology. Being the commonly used approach for laparotomy, no known studies have been launched to assess the practice of midline fascial closure and its related complications at MNH.

RATIONALE

Lack of guidelines for abdominal fascial closure leaves surgeons uncertain about the optimal technique and suture material to be used worldwide. Thus, practices of abdominal fascial closure differs greatly from one centre to another, differences also exists even among surgeons themselves in the same centre.

Complications arising following fascial closure are fairly common. Hence, it was important to understand the practices and related complications of fascial closure at MNH in order to improve surgical outcomes.

This study is also done as a partial fulfillment of the requirements for the degree of Masters of Medicine in Surgery of MUHAS.

OBJECTIVES

2.3.1 Broad Objective

To determine the practices and related complications of abdominal fascial closure following elective midline laparotomy at MNH in 2011.

2.3.2 Specific objectives

1. To describe demographic characteristics of the study participants
2. To determine techniques of fascial closure
3. To determine suture materials used for fascial closure
4. To demonstrate the prevalence of post operative complications;

    4.1 Wound dehiscence

    4.2 Wound sepsis

    4.3 Stitch sinus formation

    4.4 Persistent wound pain

    4.5 Incisional hernia

CHAPTER THREE

METHODOLOGY

3.1 Study design

Hospital-based descriptive prospective study.

3.2 Study area

The study was conducted at MNH – surgery and gynaecology departments. MNH receives patients mainly from the three municipal hospitals (within Dar es Salaam) and from other referral hospitals across the country. Other patients are self referable while some of them are under IPPM.

3.3 Study population

Patients admitted in general surgical, urological and gynaecological wards who underwent midline laparotomy in elective settings.

3.4 Study sample

Patients who underwent elective midline laparotomy in general surgical, urological and gynaecological wards from April to November 2011.

3.5 Study duration

The study was conducted from April 2011 to January 2012

3.6 Randomization

There was no randomization in choosing technique, suture material and in recruiting the study participants.

3.7 Sampling procedure

Comprehensive sampling – all eligible patients for the study were recruited during the study period totaling **166**, of which **148** patients were available for analysis.

3.8 Inclusion criteria

Patients undergoing elective midline laparotomy in general surgery, urology and gynaecology units during the study period consenting to participate in the study were included.

3.9 Exclusion criteria

- Those with previous abdominal incisions
- Patients with advanced malignancies (inoperable malignancies)
- Patients who underwent obstetric procedures
- Patients whose information on the technique and/or suture material used was not known

3.10 Data collection

Information about patients was retrieved using a structured questionnaire which needed interviewing the patient, checking operation notes and carrying physical examinations. Demographic characteristics were established, hospital registration numbers, wards to which they were admitted, date of surgery and duration of hospital stay were also enquired. Procedures were done by surgeons and residents; the latter being supervised by the former. Operation notes were inspected for the type of surgery done, technique of fascial closure and suture material used. In case these were not documented properly, communication with the surgical team was made to accomplish this task. Patients were evaluated in the wards before being discharged and during follow up visits at outpatient clinics. All patients were seen at least once during follow up period; for those who were not able to attend clinic more than once, on phone interview was conducted.

Parting of the layers of surgical wound either superficial layers only or the whole wound splits open was described as wound dehiscence. Wound sepsis was considered in all patients who developed discharge at the surgical site. Evidence for sinus formation at the surgical site was also looked for. Patients who had wound pain which was causing any degree of limitation to activities beyond one month were considered to have persistent wound pain. Incisional hernia

was diagnosed clinically by inspection or palpation of a mass protruding through the abdominal wall or a defect at the site of a surgical scar.

3.11 Confounding factors

Some complications, such as wound sepsis, are not solely due to suturing technique and/or suture material used alone; other factors such as poor adherence to aseptic technique may contribute. To control for that, all patients received prophylactic intravenous antibiotics as per MNH guidelines and aseptic techniques adhered to throughout the surgery and during wound dressing.

3.12 Data analysis

In the analysis, suture material was categorized as moderately absorbable (vicryl), slowly absorbable (PDSII) and non-absorbable (prolene). Surgical techniques were categorized as continous or interrupted; and mass closure or layered closure. Information from the questionnaires was entered into the computer by using SPSS version 16 programme. Frequency tables and tests for significance were used for analysis.

3.13 Ethical consideration

The study was ethically cleared by MUHAS research and publication committee. Informed consent was obtained from the patients who agreed to participate after reading the information in the form. Patients who developed complications were treated accordingly. Questionnaires contained names of patients and their phone numbers; thus in order to maintain confidentiality they were kept in safety boxes and to be discarded safely after the completion of this study.

3.14 Study limitations

Inadequate time for follow up; usually a minimum of six months was needed for follow up to ascertain development of some post operative complications such as incisional hernias. Due to this shortage of time some patients were followed up for less than 6 months.

Loss to follow up; some patients died during follow up period while others were untraceable – did not show up at outpatient clinic, furthermore their phone numbers were not reachable.

Incomplete documentation on the technique and/or suture material used during surgery lead to exclusion of that particular study participant, particularly so if communication with the surgical team was futile; thus reducing sample size.

CHAPTER FOUR

RESULTS

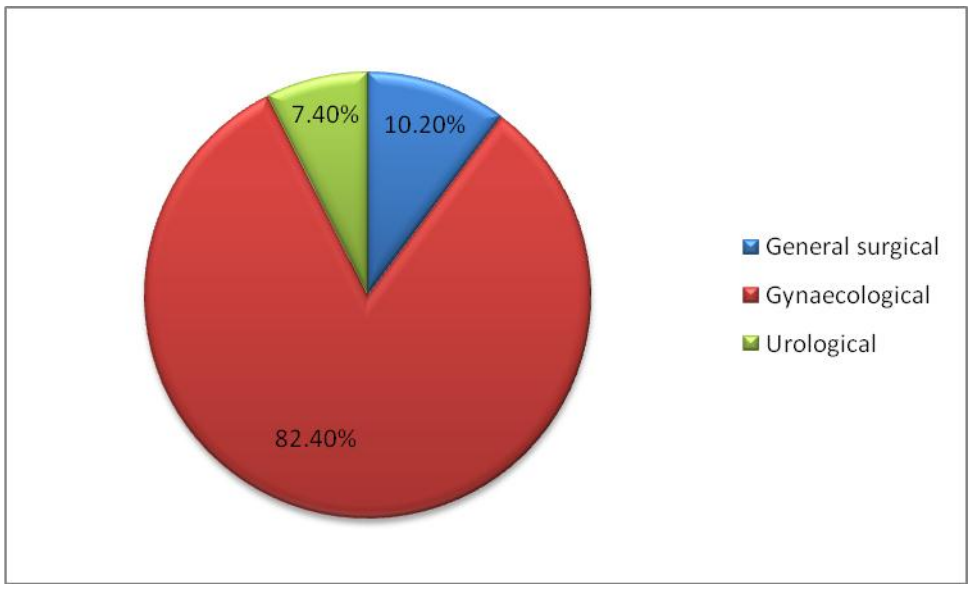
A total of 166 patients were recruited from April to November 2011. However, 8 patients died during the course of follow up and 10 patients were lost to follow up; thus remaining with 148 patients for analysis. Among these, 130 (87.8%) were females and 18 (12.2%) were males. The overall average age was 44.7 (SD 13.9) years and ranged from 15 to 90 years. Majority of the study participants were in the age group 35 – 44 constituting 52 (35.1%).

Table 1: Demographic characteristics of study participants

	Characteristics	Frequency	Percentage (%)
Sex			
	Male	18	12.2
	Female	130	87.8
Age			
	<25	7	4.7
	25 – 34	20	13.5
	35 – 44	52	35.1
	45 – 54	45	30.4
	55 – 64	10	6.8
	>64	14	9.5
	Total	148	100.0

Majority of laparotomies in the studied population were performed due to gynaecological conditions; accounting to 122 (82.4%), general surgical procedures were 15 (10.2%) and urological procedures were 11 (7.4%) as summarized in the figure below.

Figure 1: Type of surgery



After midline incisions fascia closure was performed with continous sutures in 147 (99.3%) patients while in one patient it was closed with interrupted sutures. Preference to mass closure was shown in 147 patients (99.3%) as compared to layered closure.

Sutures used for fascial closure were vicryl 78 (52.7%), prolene 46 (31.1%) and PDSII 24 (16.2%); as summarized in the table below. Those with size number 1 were used in 147 (99.3%) of patients and with number 0 was used in one patient.

Table 2: Suture material used

Suture	Frequency	Percentage (%)
Vicryl	78	52.7
Prolene	46	31.1
PDSII	24	16.4
Total	148	100.0

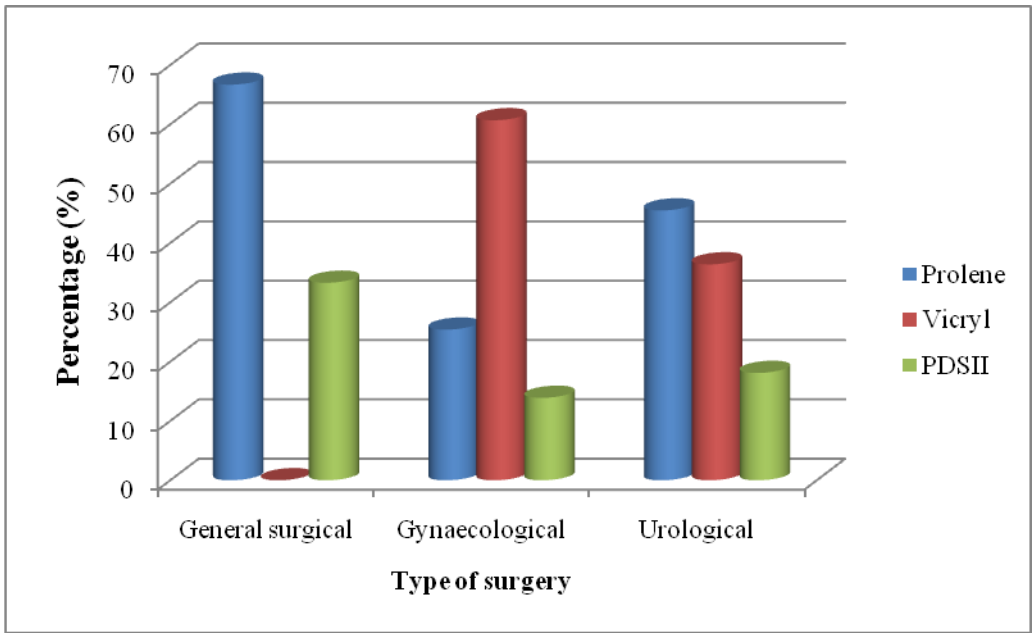
Vicryl was the commonest used suture in gynaecological procedures (60.7%); in contrary to general surgery where it was never used, prolene being the commonest suture (66.7%). The table below summarises the use of different suture materials in the three surgical units.

Table 3: Type of surgery in relation with suture material used

Type of procedure	Suture material used			Total
	Prolene	Vicryl	PDSII	
General surgical	10 (66.7%)	0 (0)	5 (33.3%)	15 (100%)
Gynaecological	31 (25.4%)	74 (60.7%)	17 (13.9%)	122 (100%)
Urological	5 (45.5%)	4 (36.4%)	2 (18.1%)	11 (100%)
Total	46	78	24	148

The information from the above table has been represented in the figure below

Figure 2: Type of surgery in relation with suture material used



Duration of follow up after surgery varied from 2 months to 9 months; mean duration being 5.8 months (SD 2.0 months). Eight three patients (56%) were followed for at least 6 months. The table below illustrates follow up duration.

Table 4: Duration of follow up after surgery

Months	Frequency	Percentage (%)
2	5	3.4
3	20	13.5
4	17	11.5
5	23	15.5
6	25	16.9
7	16	10.8
8	29	19.6
9	13	8.8

Twelve patients (8.1%) encountered complications during follow up; of which eleven patients had one complication each while one patient had two complications, namely stitch sinus and wound sepsis. Wound sepsis and persistent wound pain occurred in patients whose fascial closure was performed using prolene and vicryl; while stitch sinus developed in patients whose closure was done using prolene.

None of the study participants developed wound dehiscence or incisional hernia during the study period.

The tables below summarise complications encountered.

Table 5: Complications score

Suture material	Complications		
	No	Yes	Total
Vicryl	75 (92.2)	3 (3.8)	78 (100)
Prolene	37 (80.4)	9 (19.6)	46 (100)
PDSII	24 (100.0)	0	24 (100)
Total	136 (91.9)	12 (8.1)	148 (100)

Using Fisher's exact test; p-value = 0.002

The observed difference was statistically significant.

Table 6: Numbers of complications encountered

Suture material	Complications			Total
	Wound sepsis	Stitch sinus	Wound pain	
Vicryl	2	0	1	3
Prolene	3	2	5	10
PDSII	0	0	0	0
Total	5	2	6	13

Complications rates were higher in prolene group, 9 out of 46 (19.6%) than in vicryl group - 3 out of 78 (3.8%); p-value = 0.002. Five out of 46 patients (10.9%) whose fascial closure was performed using prolene complained of persistent wound pain as opposed to 1.3% who were repaired using vicryl. Likewise wound sepsis, prevalence was higher in prolene group (6.5%) than in vicryl group (2.6%). Two patients (4.3%) whose repair was done using prolene developed stitch sinus. None in the PDSII group developed any of the complications.

Table 7: Comparing wound sepsis in prolene and vicryl

Suture material	Wound sepsis		
	Yes	No	Total
Prolene	3	43	46
Vicryl	2	76	78

Using Fisher's exact test; p-value = 0.265

The difference observed was not statistically significant.

Table 8: Comparing persistent wound pain in prolene and vicryl

Suture material	Persistent wound pain		
	Yes	No	Total
Prolene	5	41	46
Vicryl	1	77	78

Using Fisher's exact test; p-value = 0.026, 95% confidence interval of 1.02 to 70.34

The observed difference was statistically significant.

CHAPTER FIVE

DISCUSSION

This is the first study to investigate practices of abdominal fascial closure after midline laparotomy at MNH. Larger numbers of females in this study reflect larger numbers of gynaecological operations.

The ideal suture method should aim at preventing incisional hernia and wound dehiscence without increasing wound infection, wound pain or formation of stitch sinus.[19,25] Continous mass closure of the fascia is the ideal technique. In this study surgeons performed continous suture in all patients except one (99.3%). Likewise, all patients except one had mass closure. This shows surgeons at MNH conform to this technique, thus contributing to higher prevalence of the technique compared to any other centres studied so far. A multicentric study conducted in Germany by Rahbari et al[9] demonstrated the prevalence of continous closure to be 65% while that of interrupted closure was 19%. The increasing tendency for use of continuous sutures was also reported by several other studies.[28,29,30,31]

Vicryl was the most commonly used suture material (52.7%); the same findings as in the study conducted in UK by Anderson et al[21] where vicryl was used in 87% of patients. However, Rahbari et al[9] showed the use of slowly absorbable suture like PDSII was higher (55%) followed by moderately absorbable suture like vicryl (39%) and non absorbable suture was used in only 5% of patients. In this study the use of prolene was relatively higher compared to other studies (31.1%); while the use of PDSII was alarmingly lower (16.2%)

Lack of consensus on use of sutures has been plainly revealed in this study; vicryl being the most commonly used suture in gynaecology unit (60.7%), it was never used in general surgery unit where the preference was on prolene (66.7%). Surprisingly, both units were located in the same centre. These findings are in accordance with several other studies.[9,13,14,17,19] This discrepancy may explain selection of the sutures might be based on experience from senior surgeons, which might be just a matter of habits.

The use of suture with size number 1 or 2 was recommended for the best outcome.[22] In this study suture with size number 1 was used in 99.3% of patients; whereas in one patients (0.7%) suture with size number 0 was used. However suture with size number 2 was never used by any surgeon among study participants. Likewise in a study by Rahbari et al [9] suture with size number 1 was commonly used (57%), but also demonstrated the use of suture with size number 2 (36%). Suture with size number 0 was used in 2% of study participants, the prevalence which is relatively higher compared to the current study.

Factors influencing selection of a particular suture material were beyond the scope of this study, however generally the selection is governed by availability, cost and knowledge on sutures.

Duration of follow up varied from one patient to another due to limited study period. This period was crucial to ascertain occurrence of complications, thus being an important factor. All study participants had quite adequate duration of follow up, with a mean of 5.8 months, to assess development of complications such as wound sepsis, wound dehiscence, stitch sinus and persistent wound pain. However, development of incisional hernia requires longer duration of follow up. Most studies have demonstrated the need to assess patients up to 6 – 12 months after surgery. Bloemen A et al[11] showed the peak incidence of incisional hernia occuring 13 to 18 months after surgery for both prolene and PDS. In this study 83 patients (56%) had a minimum follow up period of 6 months. Moreover, some studies have demonstrated development of incisional hernia up to 5.5 years after operation.[12] Thus, although none of the study participants developed incisional hernia so far, it cannot be ruled out completely.

The type of incision is an important factor influencing occurrence of incisional hernia. There is lower incidence of incisional hernia after paramedian incision than after the more commonly used midline incision.[25] For this reason, this study included only patients who underwent vertical midline incision.

The incidence of persistent wound pain was higher in prolene group (10.9%) than in vicryl group (1.3%), p-value 0.026, 95% CI 1.02 to 70.34. Thus, the difference observed is statistically significant although its precision is questionable. This is consistent with the meta-analysis which compiled 15 studies conducted by van't Riet M et al[19] indicating the incidence of 13.4% in proline group; however in vicryl group the incidence was relatively higher (6.6%) compared with the current study. Forty six patients (3.5%) whose closure was achieved using slowly absorbable suture developed persistent wound pain; the findings are contrary to the current study where none of study participants developed persistent wound pain.

Stitch sinus occurred in 4.3% in prolene group, nearly correlating with the incidence of 6.2% in a study by van't Riet et al[19] While it was not encountered in vicryl and PDSII group, stitch sinus was also seen among rapidly absorbable suture group (1.1%) in the above study. The incidence of wound sepsis was higher in prolene group (6.5%) than in vicryl group (2.6%); however no statistical significance was established. Also van't Riet et al found the incidences were almost equal, with no statistical difference between 8.4% in vicryl and 7.3% in prolene. Both findings contradict with the fact that vicryl being a multifilament poses higher chances of developing wound sepsis than prolene which is a monofilament.[2]

No study participants developed wound dehiscence, and in fact the risk of wound dehiscence should be less than 1%[4]. A study by Wissing J et al showed higher incidence of wound dehiscence, which was 2.3%.[32]

Non absorbable sutures are known to be associated with increased incidence of prolonged wound pain and stitch sinus; slowly absorbable sutures should be used in preference.[14,17,20] The use of vicryl for fascial closure needs critical attention as its strength is 65% at 14 days; and completely absorbed between 56 and 70 days.[2] This may be too short a time for the abdominal wall to recover enough structural integrity; as the abdominal fascia regains only 51 to 59% of its original tensile strength after 42 days.[21,22]

The two groups, that is prolene and vicryl, were not comparable at baseline in terms of number of participants; however, the established significant test picked up the characteristic in a group with fewer participants.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

Uniformity on the techniques of fascial closure after elective midline laparotomy does exist among surgeons in MNH; however the use of different sutures to serve this purpose reflects lack of consensus. The use of prolene for fascial closure is associated with persistent post operative wound pain. Factors influencing selection of suture material at MNH should be well addressed. Long term follow up is crucial for patients who undergo midline laparotomy to assess the occurrence of incisional hernia.

REFERENCES

1. Johnstone JIMS, Rintour RF; Abdominal operations. Farquahrson's Textbook of Operative Surgery, 7th edition
2. Lai SY, Becker DG, Edlich RF; Sutures and needles. eMedicine Clinical Procedures. March 31, 2010
3. Meeks GR, Trenhaile T, Turnage R, Collins KA; Principles of abdominal wall incisions
4. Lin KY, Long WB; Scientific basis for the selection of abdominal fascial suture closure. March 2005
5. Parks RW; Practical procedures and patient investigation, post operative care and complications, in Principles and practice of Surgery, pages 141, 167
6. Nygaard IE, Squatrio RC; Abdominal incision from creation to closure. Obstet Gynecol Surv 1996 Jul; 51(7):429 - 436
7. Sullivan SR, Engrav LH, Klein MB; Acute wound care in ACS Surgery; Principles and practice, 2007 edition, chapter 7
8. Neumayer L, Vargo D; Principles of pre operative and operative surgery in Sabiston textbook of surgery 18th edition, chapter 12
9. Rahbari N, Knebel P, Diener M, Seiler C; Current practice of abdominal wall closure in elective surgery – Is there any consensus? Ann Surg.2009;249: 576 – 582
10. Franz MG; The biology of hernia formation. Surg Clin North Am 2008;88: 1 – 15
11. Yahchouchy-Chouillard E, Aura T, Picone O, Etienne JC, Fingerhut A; Incisional hernias. I. Related risk factors. Dig Surg 2003;20: 3 - 9
12. Ellis H, Gajraj H, George CD; Incisional hernias – when do they occur? Br J Surg 1983 May; 70(5): 290 – 291

13. Bloemen A, van Doreen P, Huizinga B, F, Hoofwijk A.G; Randomized clinical trial comparing polypylene or polydioxanone for midline abdominal wall closure. Br J Surg 2011 May; 98(5): 633 – 639

14. Playforth MJ, Saunen PD, Evans M, Pollock AV; The prediction of incisional hernias by radio-opaque markers. Ann R Coll Surg Engl 1986;68:82 – 84

15. Pollock AV, Evans M; Early prediction of late incisional hernias. Br J Surg 1989; 76: 953 – 954

16. Burger JW, Lange JF, Halm JA, Kleinrensink GJ, Jeckel H; Incisional hernia: early complications of abdominal surgery. World J Surg 2005;29(12): 1608 - 1613

17. McGeen D, Hunt D, Chaudhuri A, Rutter P; An experimental study of the relationship between synergistic wound sepsis and suture materials. Br J Surg 1980 Sep; 67(9):636 - 638

18. Hodgson NC, Malthaber RA, Ostbye T; Current practice of abdominal fascial closure: a survey of Ontario general surgery. Can J. Surg. 2001;44:366 – 370

19. Van't Riet M, Steyerberg EW, Nellensteyn J, Bonier HJ, Jeekel J; Meta-analysis of techniques for closure of midline abdominal incisions. Br J Surg 2002;89: 1350 – 1356

20. Diener MK, Voss S, Jensen K, Buchler MW, Seiler CM; Elective midline laparotomy closure: the INLINE systematic review and meta-analysis. Ann Surg 2010; 251: 843 – 856

21. Anderson ER, Gates S; Techniques and materials for closure of the abdominal wall in caesarean section (Review). The Cochrane collaboration 2007

22. Ceydeli A, Rucinski J, Wise L; Finding the best abdominal closure: an evidence-based review of the literature. Curr Surg 2005 Mar – Apr; 62(2)220 – 225

23. Rath AM; The healing of laparotomies, a review of the literature. Part I. Physiologic and pathologic aspects. Hernia. 1998; 2: 145 – 149

24. Weiland DE, Bay RC, Del Sordi S; Choosing the best abdominal closure by meta-analysis. Am J Surg 1998; 176: 666 - 670

25. Kendall SW, Brennan TG, Guillon PJ. Suture length to wound length ratio and the integrity of midline and paramedian incisions. Br J Surg 1991; 78:705 – 707

26. Corman ML, Verdenheimer MC, Coller JA. Controlled clinical trial of three suture materials for abdominal wall closure after bowel perforations. Ann J Surg 1981; 141: 510 – 513

27. Douglas DM. The healing of aponeurotic incisions. Br J Surg 1952; 40: 79 – 84

28. Sloop RD. Running synthetic absorbable suture in abdominal wound closure. Am J Surg 1981; 141:572-573

29. Archie JP, Feldtman RW. Primary abdominal wound closure with permanent continuous monofilament sutures. Surg Gynecol Obstet 1981;153:721-722

30. Wasiljew BK, Winchester DP. Experience with continuous absorbable suture in the closure of abdominal incisions. Surg Gynecol Obstet 1982; 154:378-380

31. Richards PC, Balch ChM, Aldrete JS. Abdominal wound closure. A randomized prospective study of 571 patients comparing continuous versus interrupted suture techniques. Ann Surg 1983; 197:238-243.

32. Wissing J, van Vroonhoven TJ, Schattenkerk ME, Veen HF, Ponsen RJ, Jeekel J. Fascial closure after midline laparotomy-results of a randomized trial. Br J Surg 1987;74:738-741

APPENDICES

Appendix A: Questionnaire

Serial number: _____ Ward/Clinic_____ File number: _____

Name of a patient: _____

Age: _____ Sex: 1. Male 2. Female

Phone number _____

Diagnosis: _____

Type of surgery performed: _____

Date of surgery:_____

Technique of fascial closure:

1. Continuous
    a) Mass closure
    b) Layered closure
2. Interrupted
    a) Mass closure
    b) Layered closure

Suture material used:

1. Name: _____
2. Size: [ ]

Duration of hospital stay: _____

Re-admission due to complication: [ ]

1. Yes, duration _____
2. No

Follow up after surgery:

1. First visit (date)_____; duration after surgery_____
2. Second visit (date)_____; duration after surgery_____
3. Third visit (date)_____; duration after surgery_____
4. Others _____; _____; _____

Complication(s) encountered and time of onset - duration after surgery

1. Wound dehiscence _____
2. Wound sepsis _____
3. Stitch sinus formation _____
4. Persistent wound pain _____
5. Incisional hernia _____

Appendix B: Informed consent (English Version)
ID number _____

Consent to participate in the study on current practices of abdominal fascial closure following midline laparotomy and related complications in MNH from April to December 2011.

Greetings!

My name is Dr Charles Komba, I am a postgraduate student at MUHAS, studying the current practices of abdominal fascial closure following midline laparotomy and related complications in MNH

The purpose of the study;

To determine the current technique and suture material used and related complications

What participation involves;

On agreeing to participate in this study, you will be required to answer some questions and you will be examined physically.

Confidentiality;

All information collected on questionnaires will be entered into computer with identification number. The questionnaires will be handled with greater secrecy in order to maintain confidentiality.

Risks;

There is no risk which might be encountered by participating in this study

Right to withdraw;

Taking part in this study is completely voluntary choice. If you choose not to participate in the study, you will continue to receive all services that you would normally get from the hospital.

Benefits;

By participating in this study you will be followed for a long period, thus monitoring your progress adequately; hence early intervention should the need arise.

Who to contact;

If you have any question about the study, you should contact Dr. Charles Komba 0714236066. If you have questions about your rights as a participant, you may contact Prof M. Abood, Chairman of MUHAS Research and Publications Committee, P. O. Box 65001 Dar es Salaam. Tel 2150302-6

I _____ have read the content of this form. My questions have been answered. I agree to participate in this study.

Signature of participant _____

Signature of witness _____

Date of signed consent _____

Appendix C: Informed consent (Swahili Version)
Namba ya utambulisho _____

Idhini ya kushiriki katika utafiti unaochunguza namna ya ufungaji wa tumbo na matatizo yatokanayo baada ya kufanyiwa upasuaji wa tumbo wa kupangwa katika hospitali ya taifa ya Muhimbili kuanzia Aprili mpaka Desemba 2011.

Salamu!

Naitwa Dr. Charles O. Komba, mwanafunzi wa stashahada ya juu ya upasuaji wa jumla; nafanya utafiti unaochunguza namna ya ufungaji wa tumbo na matatizo yatokanayo baada ya kufanyiwa upasuaji wa tumbo wa kupangwa katika hospitali ya taifa ya Muhimbili.

Dhumuni la utafiti

Kujua aina ya ufungaji wa tumbo, nyuzi zitumikazo na matatizo yatokanayo.

Ushiriki una maana gani

Kushiriki kwako katika utafiti huu itakupasa kuwa tayari kujibu maswali na kupimwa mwili

Utunzaji wa siri

Taarifa zote zitatunzwa kwa siri na mwendesha utafiti.

Madhara yatokanayo

Hakuna madhara yoyote yale ambayo mshiriki wa utafiti huu ataupata kwa kushiriki kwako

Uhuru wa kushiriki

Ni hiari kushiriki katika utafiti huu, pia unaweza kujitoa wakati wowote. Hata hivyo kushiriki au kutoshiriki katika utafiti huu hakukunyimi haki zako za kupata huduma ya tiba katika hospitali hii.

Faida za kushiriki

Kushiriki kwako katika utafiti huu utapata fursa ya kufuatiliwa kwa muda mrefu na kujua maendeleo yako; na iwapo utaonekana umepata matatizo yatokanayo na upasuaji uliofanyiwa utapewa tiba inayoendana na hilo tatizo lako.

Taarifa

Iwapo utakuwa una swali lolote kuhusu utafiti huu wasiliana na Dr. Charles O. Komba – mwanafunzi wa udhamili chuo cha sayansi za tiba Muhimbili, 0714 236066; na endapo utakuwa na swali kuhusu haki yako ya kushiriki katika utafiti huu wasiliana na Prof. M. Abood - mwenyekiti wa kamati ya utafiti, S.L.P 65001, Dar es Salaam. Tel:2150302-6.

Mimi _____ nimesoma nakuelewa maelezo hapo juu, pia maswali yangu yamejibiwa, nakubali kushiriki katika utafiti huu.

Sahihi ya mshiriki _____

Sahihi ya shahidi _____

Tarehe _____