A RANDOMISED CONTROL TRIAL COMPARING MERIL'S 2ROWS WITH 3ROWS STAPLER FOR PROCEDURE OF PROLAPSED HAEMORRHOIDS

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2020

STATEMENT OF SUPERVISORS

We declare that we have read this thesis and in our opinion this thesis is sufficient in terms of scope and quality for the award of the degree of

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DECLARATION

I Soma Balaganapati a/l Chandra Kanthan hereby declare that this thesis entitled "A Randomised Control Trial Comparing Meril's 2rows With 3rows Stapler For Procedure Of Prolapsed Haemorrhoids' is based on my original work except for quotations and citations which have been duly acknowledged. I also declare that it has not been previously or concurrently submitted for any other degree at KPJ Healthcare University College or other institutions.

Date : 5 MAY 2020

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Dr Soma Balaganapati a/l Chandra Kanthan

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DEDICATION

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ABSTRACT

A RANDOMISED CONTROL TRIAL COMPARING MERIL'S 2ROWS WITH 3ROWS STAPLER FOR PROCEDURE OF PROLAPSED HAEMORRHOIDS

Background

Haemorrhoidal disease remains as a common benign anorectal disease worldwide. Irregular bowel habits, hard stools and straining leads to the prolapse increase the risk of haemorrhoids. When haemorrhoids become symptomatic, they may include bright red bleeding, itchiness post defecation, mucous discharge post defecation and a protruding mass per anus. Severe pain can occur, when haemorrhoids are prolapsed and irreducible, therefore requiring urgent surgical intervention. Symptomatic haemorrhoids is indicated for conventional haemorrhoidectomy, however post-operative outcomes may be unfavourable. Hence newer treatment modalities such stapled haemorrhoidectomy is currently widely practised.

Materials and Methods

The objective of this study was to compare two hemorrhoidopexy staplers (MERIL'S 2 - rows with 3 - rows stapler). Stapled hemorrhoidopexy is a treatment option for patients with symptomatic internal haemorrhoids who have failed more conservative measures. Patients (n=51) from two private hospitals in Johor Bahru ages between 20 and 69 years with symptomatic grade 3 internal haemorrhoids were enrolled in this 3-month study. The primary end point was to see the difference of early postoperative complications which includes postoperative bleeding, recurrence, postoperative pain and early anal stenosis between 2 staplers. Participants were considered to be enrolled after signing an informed consent, meeting the eligibility criteria, and receiving randomization assignment. The patients were subsequently assessed at 2, 4 and 12week intervals postoperatively in the surgical clinic.

Results

The incidence of postoperative pain was similar with the use of 2 and 3 row staplers at 2 weeks, 4 weeks and 12 weeks. Statistical analysis using pearson correlation showed a weak relationship between the 2 variables and no significant difference were reported. The incidence of postoperative bleeding was also similar, not showing a positive correlation. There was no difference in early recurrence of haemorrhoidal disease with the use of either stapler. The incidence of early anal stenosis on the other hand was also similar in both groups at the end of 3 months and no significant difference were reported.

Conclusion

There is no significant difference of early postoperative complications with the use of either 2 or 3 row staplers.

Key Words: Haemorrhoidal disease, haemostasis, postoperative pain, early anal stenosis, recurrence rate

TABLE OF CONTENTS

LIST OF FIGURES

No table of figures entries found.No table of figures entries found.

LIST OF TABLES

CHAPTER 1: INTRODUCTION

Background of Study

Haemorrhoids were well known by mankind for centuries. The literature was found in Egyptian papyrus (1700 BC) and there were documents that stated Hippocrates (460 BC) had attempted treatment procedures. The modern change in the treatment for haemorrhoids was led by Fredrick Salmon; in 1888 he proposed a combination of ligation and excision of haemorrhoids. Later, Ferguson and Milligan-Morgan have modified his treatment approach. Milligan and Morgan introduced (Open) Haemorrhoidectomy in 1937 in the UK. It includes excision of haemorrhoidal tissue along with its vessels with placement of a suture at the haemorrhoid pedicle. Care is taken during the excision to preserve adequate skin bridges to avoid strictures. Once haemostasis has been secured, secondary healing is encouraged by leaving the wound open using a classical clover method. Ferguson proposed a Closed Haemorrhoidectomy in 1952 in US. It is the same as Milligan-Morgan's Haemorrhoidectomy but the mucosal wound and skin are completely closed with a continuous suture. Since then several treatment approaches were modified till the late 1990's when stapled haemorrhoidectomy was introduced. Its ease of u and short learning curve lead the procedure to be widely accepted by both surgeons and patient's as it significantly reduced postoperative pain and promoted quick recovery.

Treatment for haemorrhoids is principally aimed at improving quality of life. The selection of treatment is based only partly on the evidence and partly on personal experience and expertise. Treatment options are vast and include outpatient management and operative interventions. The use of bulk laxatives have long been practiced in the initial symptomatic management of haemorrhoidal disease but clearly lack evidence. Topical remedies which include local anaesthetics or steroids are frequently practiced for symptomatic relief to aid in the control of inflammation however suffer a lack of evidence to support their use. The use of dietary fibre and osmotic laxatives to regulate consistency or frequency of stools has also been practiced along with the use of analgesics to control pain.

In the past the use of phenol in oil as injection sclerosant therapy was practiced, but had resulted in poor outcomes and complications which include intraprostatic administration resulting in chemical prostatitis and rarely impotence in the males and reported anovaginal fistula in the females. Sclerotheraphy aims to initiate proximal haemorrhoidal plexus thrombosis and encourage fibrosis which results in thrombosis of the proximal haemorrhoidal plexus and promotes localized fibrosis which leads to mucosal retraction and tethering. Results were rather successful in grades I and II disease but showed a larger relapse rate in grade III and IV diseases which has been observed within a period of 6 months after administration. Patients usually require 2 to 3 injections to complete the treatment.

The most popular outpatient therapy in practice is rubber band ligation. This procedure usually requires suctioning and application of a rubber band over the haemorrhoid, as a result the haemorrhoid is strangled and falls off by around 14 days. This technique has shown better results as compared with injection sclerotheraphy. However, this method has been proven to be less effective than surgery, especially if it involves larger prolapsed haemorrhoids.

Operative management in the treatment of haemorrhoidal disease was impacted by Lockhart-Mummeryin the 1930'sand has since gained a vast interest, debate and evolvement(Lockhart- Mummery, 1936). Haemorrhoidectomy involves excision of both internal and external components. During surgery care is to be taken not to damage the internal sphincter and adequate mucosal bridges are left between excised areas of the anoderm to ensure that the tissues do not succumb to circumferential scarring or subsequent anal stenosis. Postoperatively the wounds are left open to heal via secondary intention. The use of energy devices in the excision of haemorrhoids has been proven to minimize initial post-operative pain and promote early return to work.

Traditionally, surgical excision of haemorrhoidal disease remain to be Miligan Morgan Haemorrhoidectomy which was widely practiced in the 1940s(Shalaby & Desoky, 2001). It involves excision of the haemorrhoidal tissue radially at discrete or multiple locations of a haemorrhoidal complex. The development of anal stenosis during the healing process is prevented by ensuring sufficient mucosal bridging at the excision site. This procedure obtained a vast interest however was feared among the

patient's due dreadful postoperative pain and a prolonged recovery. Furthermore, the perilous complication of anal stenosis along with its prolonged treatment course was a concern. Several modifications have been implied, namely Closed Ferguson haemorrhoidectomy vastly practiced in the states in the 1950's whereby upon the end of the procedure, absorbable sutures are used to approximate mucosa and skin. Another method was improvised by Park where a linear incision is made over the haemorrhoid and the plexus is subsequently resected from below the anoderm, wherein the wound is closed without any epithelium excision. Other options for surgical excision of haemorrhoids is whitehead haemorrhoidectomy which was used for circumferential excision of haemorrhoidal disease by developing a new mucosa-anoderm junction. This procedure did not gain popularity due to massive blood loss, poor control of continence, ectropion formation and poor healing with resultant anal strictures. These conventional surgical procedures were combated with the introduction of stapled haemorrhoidopexy. The fundamental principle of SH was first introduced in the 1980's by Kobeldin. However, several significant modifications in technique and the stapler itself was later re-illustrated by Antonio Longo in the late 1990's and gained vast interest and global acceptance by the year 2000.Significant reduction in postoperative pain and quick recovery has enabled stapled haemorrhoidopexy to gain popularity and acceptance.

Problem statement

The Longo stapled haemorrhoidopexy technique has established its role in significant reduction in operative time, bleeding, postoperative pain and a significantly reduced length of hospital stay. In spite literature reporting more benefits with the use of stapled hemorrhoidopexy, higher relapse rates were observed when compared to conventional haemorrhoidectomy. This study aims to examine clinical outcomes of 2 different types of staplers for procedure for prolapsed haemorrhoids comparing the incidences of early complications. This research has not been done in the Malaysian context and will serve as a platform for future research.

Research objectives

General objectives

This study general objectives is to examine the difference in outcome post stapled hemorrhoidopexy, comparing the use of 2 row circular stapler compared to 3 row circular stapler.

Specific objectives

The specific objective assessments of this research include the following:

a) Primary objective: To analyse the difference in recurrence rates, haemostasis (ascertained with post-operative gauze staining), assessment of postoperative pain by utilizing the visual analog scale (VAS) and the incidence of anal stenosis (assessed using digital rectal examination with gentle or limited proctoscopy), with the use of 3 row circular stapler compared to 2 row circular staplers.
b) Secondary objective: To analyse the difference in anal incontinence, pelvic infection and staple dehiscence with the use of 3 row circular stapler compared to 2 row circular staplers.

Hypothesis

The following hypothesis was proposed based both on previous research and in theory: There is a difference in recurrence rates, haemostasis, postoperative pain and incidence of anal stenosis with the use of 2 row circular stapler compared to 3 row circular stapler in stapled haemorrhoidopexy.

Significance of study

Stapled haemorrhoidopexy, is a well-recognized treatment option for haemorrhoidal disease. Although the surgical technique may not be very demanding and has a short learning curve; it does require proper surgical training and competency with a decent amount of surgical experience to ensure performance of a safe surgery. The postoperative outcomes from this study is not determined entirely on the stapler selected but also from application of safe and detailed surgical technique. Hence, this study will serve as a body of knowledge for future research. For each surgery performed, the surgeon's skill and experience affects the performed stapled haemorrhoidopexy, whether its 2 row or 3 row staplers, can give satisfying results. These results are explained to contribute to the existing literature about stapled haemorrhoidopexy. On the basis of this study, the researcher believes that stapled haemorrhoidopexy still has its place in selected cases.

Chapter 2: REVIEW OF LITERATURE

Introduction

Worldwide, haemorrhoidal disease remains as a common benign anorectal disease. In maintaining continence, it is important for the presence of anal cushions anatomically. Hard stools, irregular bowel habits, and straining lead to the prolapse of these supportive anal cushions. The formation of haemorrhoidal disease with or without bleeding per rectum is caused the prolapse of the lax anal cushions when the muscle wall is detached by enlarged vascular plexuses. When haemorrhoids become symptomatic, they may comprise itchiness post defecation, mucous, discharge post defecation, a distended mass per anus, bright red bleeding, and some redness or swelling around the anus. They may cause severe pain when they are prolapsed and irreducible requiring urgent surgical intervention

Haemorrhoidal disease

The anal canal is illustrated as the last 4cm of the alimentary tract and is typically shorter in females. It is a muscular tube of primarily circular muscle fibres forming the internal and external anal sphincters which are composed of visceral and skeletal muscle fibres respectively. Their role is to keep the anal canal continuously closed except for the momentary passage of faeces and flatus(Festen, Van Geloven, & Gerhards, 2009). The mucous membranes in the upper third of the anal canal has 6 to 10 longitudinal ridges called the 'anal columns' which are joint together by small horizontal folds in their lower end called the 'anal valves'. Just above these valves, there are several pockets called the anal sinuses containing several anal glands where mucous is secreted. This mucous preserve the moisture within the anal canal. The level at which the anal valve's end defines the formation of the 'dentate line' is avital landmark in the anatomy dividing the anal canal into its upper and lower parts. Below to the dentate line, the anal canal is composed of a pale and smooth area called 'pecten', which is lined by non-keratinizing stratified squamous epithelium(Giordano, 2009).It extends till the intersphincteric groove and further continues as the buttock

skin which is lined by keratinized stratified squamous epithelium, hair follicles, sweat glands and sebaceous glands. Several small submucous masses, composed mostly of fibroelastic connective tissues and smooth muscles which are intervened by dilated venous spaces and arteriovenous anastomosis form the anal cushions. They usually are prominently seen at the left lateral, right posterior and right anterior positions in the upper anal canal; lying at 3, 7 and 11 o'clock positions most of the time which aid in watertight closure of the anal canal(Giordano, 2009).

Classification of Haemorrhoids

Haemorrhoids can be classified into several grades according to Goligher (Figure 2.1), where by grade I is purely internal, grade II prolapses at defecation but shows spontaneous reduction(Goligher, 1980). Grade III prolapses require the need of manual replacement and grade IV disease does not allow manual reduction(Ray-Offor & Amadi, 2019). Haemorrhoidal disease may present with an external component which is usually lined by squamous epithelium. It may cause immense pain when thrombosed resulting in the need of emergency evacuation under anaesthesia.

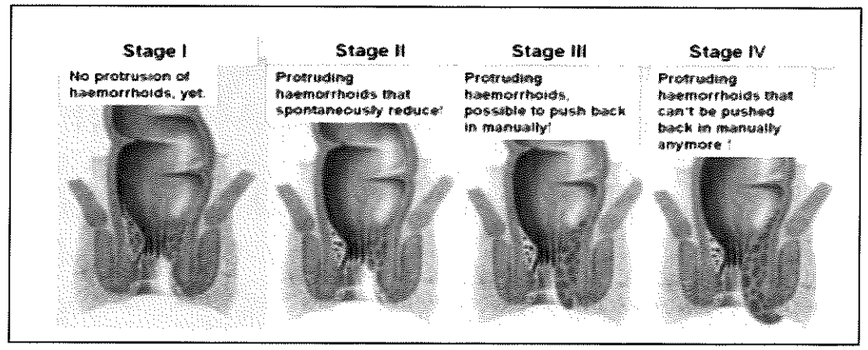

Figure 2.1: Grading of Haemorrhoids

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Office management for haemorrhoidal disease

Treatment for haemorrhoidal disease is aimed at improving one's quality of life. Initial approaches are usually office management, however recalcitrant or persistent symptoms usually resort to invasive procedures. In the past, the use of bulk laxatives have long been practiced as initial symptomatic management of this disease but clearly lack evidence (Yamana, 2017). Evidence has suggested that that many topical agents are used for symptomatic control in haemorrhoids such lignocaine with steroids and keratolytic agents (Yamana, 2017). These are commonly used but studies has proven they are not favourable and their use should be discouraged (Davis, Lee-Kong, Migaly, Feingold, & Steele, 2018). Studies have suggested that lifestyle habits which includes dietary and behavioural practices remain the mainstay prevention and treatment options for haemorrhoids (Davis et al., 2018). In addition, a higher content of fibre and minimal straining during defecation are also recommended. Literature has also recommended the application of sitz baths in individuals suffering with symptomatic anorectal disease (Picchio, Palimento, Attanasio, & Renda, 2006).The use of dietary fiber combined with osmotic laxatives along with analgesics aid in regulating the consistency and frequency of stools during defecation especially reducing the pain during its passage (Alonso-Coello et al., 2005).

Further, micronized purified flavonoids have been used widely in symptomatic haemorrhoids which have enhanced the venous tone, increase the lymphatic flow and reduce inflammation. These materials comprises of venotropic agents which is useful in many venous diseases. In addition, these venotropic agents has been proven to theoretically reduce symptoms associated with haemorrhoid (Sagap & Remzi, 2006). Nevertheless, the use of these medications are still not sufficient to avoid surgical based treatments for haemorrhoids. A topical anti-inflammatory preparation Pileseptine-e with strong osmotic properties has been used with good outcome. It is applied as a film layer that reduced the size by fluid exudation though controlling the symptoms (Shrivastava, da Silva Borges, & Shrivastava, 2018).

In the past the use of phenol in oil as sclerosant therapy was practiced. Thrombosis and fibrosis of haemorrhoidal which results in retraction of the anal mucosa is seen with the use of sclerotherapy. Reported results were rather successful in grades I and

II disease but a high recurrence rate in grade III and IV diseases was reported within 6 months after administration (Al-Ghnaniem, Leather, & Rennie, 2001). Patients may need up to 3 injections to complete the treatment. However several dreaded complications sequelae to the injection such as chemical prostatis due to intraprostatic administration discouraged its use (Al-Ghnaniem et al., 2001). There also have been several reports of impotence in the males and anovaginal fistulation in the females with its use.

The most popular and favoured office therapy in practice since the 1960's till date is rubber band ligation. In a single session, multiple or single ligations can be performed. More frequently encountered minor complications are mild bleeding, pain, vaso-vagal symptoms, slippage of bands, priapism, difficulty in urination, anal fissure, and chronic longitudinal ulcers (Acheson & Scholefield, 2008). Uncommon major complications are massive bleeding, thrombosed haemorrhoids, severe pain, urinary retention needing catheterization, pelvic sepsis and death Several infectious complications have also been reported including pelvic sepsis, Fournier's gangrene, liver abscesses, tetanus and bacterial endocarditis (Albuquerque, 2016).

This procedure requires a suctioning device called the suction elastic band ligator. The rubber band is delivered when the haemorrhoidal tissue is suctioned via the apparatus. Rubber banding can also be done using a forward or retroflexed endoscope .The contained mucosa and vascular plexus are retracted and strangulated leading to fibrosis and fixation of the anal cushions .This technique has shown better results as compared with injection sclerotherapy and is well liked due to its cost effectiveness (Sagap & Remzi, 2006). However, this method has been proven to be less effective than surgery, especially in eradicating larger prolapsed haemorrhoids.

Although injection sclerosant is a convenient form of therapy, it is not as effective compared to RBL (Agbo, 2011). This is because the use of sclerosant is recommended for patients primarily presenting with bleeding as the main symptoms, failure of conservative interventions, increased risk of secondary bleeding and

immunocompromised patients. In the event sclerosant therapy is administered too deeply, complications such as pain, haemorrhage and prostatic symptoms may occur (Tomiki et al., 2015).

Infrared photocoagulation is an efficient treatment for outpatients with 1st and 2nd degree haemorrhoids. Gami (2011) reports that the infrared probe should be applied to the base of the haemorrhoids through a proctoscope to produce a circular burn 2 mm deep where the exposure is for 1 second at each site. The results are comparable to those of banding and sclerotherapy, however the procedure is less painful (Gami Bharat, 2011).

Amongst other options stated in the literature is radiofrequency ablation and suture fixation of haemorrhoids is an innovative procedure designed in 1998 by Gupta for haemorrhoids of grades III and IV (Gupta, 2014). The procedure involves the use of an Ellman dual-frequency, 4-MHz radiofrequency generator for ablation of haemorrhoids. The alternating current generates changes in the direction of ions inside the tissue fluid. This produces ionic agitation and frictional heating, leading to coagulative necrosis of tissue. Subsequently, the haemorrhoids are plicated using resilient absorbable sutures. The plication begins from the most distal end of the haemorrhoid at the anal verge and is carried towards the pedicle in a continuous locking manner and knotted at the pedicle, thereby fixing the haemorrhoidal mass. It gives better results in terms of postoperative pain and bleeding than stapled haemorrhoidectomy and Doppler- guided haemorrhoidal artery ligation (Picchio et al., 2006).

Cryosurgery creates water crystals inside the cells resulting in annihilation of the cell membrane and finally the tissue, using very low temperature. Cryosurgery was expected to lead to less pain by freezing the sensory nerve endings and causing an instant anaesthetic effect, however clinical results have proved the opposite. Other disadvantages include profuse discharge, prolonged recovery, late return to work and in addition to being a lengthy procedure. Thus, compared to other treatments cryosurgery does not seem offer the patient with haemorrhoidal disease any advantages (Sakr, 2014; Trompetto et al., 2015)

For the minimally invasive treatment of haemorrhoids, laser ablation has unlocked new possibilities. Tissue shrinkage and degeneration at different depths depending on the laser power (irradiance) and the duration of laser light application is caused by the laser beam. Recent evidence has supported this modality treatment for symptomatic haemorrhoids,(Naderan et al., 2017). Many studies reported that the application of laser technique in the treatment of haemorrhoids was safe, effective, and painless, and resulted in partial to complete resolution within a short time (Hoyuela et al., 2016; Nikshoar, Maleki, & Honar, 2018).

Operative management

Operative management in the treatment of haemorrhoidal disease was impacted by Lockhart-Mummery, 1936 in the 1930'sand has since gained a vast interest, debate and evolvement (Lockhart- Mummery, 1936). Open haemorrhoidectomy involves excision of both internal and external components. During surgery, care is taken not to damage the internal sphincter and adequate mucosal bridges are left between excised areas of the anoderm to ensure that the tissues do not succumb to circumferential scarring or subsequent anal stenosis. Postoperatively, the wounds are left to heal via secondary intention.

In the 1940s, the most widely practices gold standard procedure for surgical resection of haemorrhoidal disease is 'Miligan Morgan haemorrhoidectomy' (Miller, 2007). This procedure is still practiced in the current era. It involves excision of the haemorrhoidal tissue radially at one or more sites which includes the external skin as a complex. Adequate bridges of mucosa are usually left intact in between the excisions to prevent anal stenosis developing later once it has healed. This procedure obtained a vast interest and several modifications have been implied, namely 'closed ferguson haemorrhoidectomy', and vastly practiced in the states in the 1950s whereby upon completion of the operation, the mucosa and skin are closed with absorbable sutures.

This method obtained good results with low recurrence rates however perioperative bleeding and postoperative pain remained a main concern to both practitioner and patient.

Another method was improvised by Park, Submucosal hemorrhoidectomy known as Parks procedure is in 1956 aimed to reduce postoperative pain besides avoiding anal and rectal stenosis (Wang et al., 2007). This technique requires a linear incision over the haemorrhoid and the plexus is then dissected out from beneath the anoderm. Here no epithelium is excised and the surgical wounds are closed(Miller, 2007).Park's procedure preserves the anal canal mucosa, decreasing the surgical wound dimensions .Furthermore, it requires a shorter healing time, as well as lower stenosis index than those with conventional techniques. The mucosa is not included in the ligation and leads to reduce postoperative pain. However, the operational surgical time is longer, the recurrence rate is higher and it involves greater risk of bleeding during the surgery and postoperatively (Wang et al., 2007).

Other options of surgical excision include 'Whitehead-Rand' haemorrhoidectomy which was used for circumferential excision of haemorrhoidal disease with fashioning of a new mucosa-anoderm junction (Miller, 2007). It fully excises the piles and the associated rectal internal mucosal prolapse and reconstructs the anal canal by suturing skin flaps to the rectal mucosa. Whitehead-Rand operation is a relatively complex procedure, prone to suture dehiscence and for that reason it requires tags excision(Arezzo, Podzemny, & Pescatori, 2011).This procedure did not gain popularity due to massive blood loss, poor control of continence, ectropion formation and poor healing with resultant anal strictures (Miller, 2007).

Chugh et al (2014) study discussed about occurrence of coagulation at temperatures higher than 150 °C with diathermy hemorrhoidectomy, which results in the formation of an eschar that seals the bleeding area (Chugh, Singh, & Agarwal, 2014). Diathermy hemorrhoidectomy is associated with less bleeding, shorter operating time and lower postoperative analgesic requirement, but with similar post-operative pain in comparison to conventional hemorrhoidectomy.

For excellent hemostatic control and avoiding the need to ligate the pedicles , the The Ligasure haemorrhoidectomy proves to provide an answer (Chen & You, 2010).Improved haemostasis may also offer better visibility and therefore a more accurate dissection. Ligasure hemorrhoidectomyis superior to conventional hemorrhoidectomy in terms of operation time, postoperative pain, urinary retention and time to return to normal activity. A long-term follow-up of patients is necessary, although early functional and symptomatic outcomes have been satisfactory (Heng & Tan, 2016).

Studies show that there have been numerous randomized trials comparing harmonic scalpel hemorrhoidectomy (HSH) with other various open and closed techniques but the results were inconstant (Agbo, 2011; Picchio et al., 2006; Sakr, 2014). Some studies displayed clear-cut benefit of HSH for operative time, blood loss, postoperative pain, length of hospital stay, and return to normal activity, while others indicated no advantages, with even increased cost.

Haemorrhoidal artery ligation is another treatment modality thatinterrupts the blood supply to the haemorrhoids through multiple ligations of the branches of the inferior haemorrhoidal arteries recognized by a Doppler device fixed on an operating proctoscope. Since no surgical wound and sutures are applied above the dentate line, pain is theoretically reduced and recovery is heightened. Pain is inclined to be moderate and recedes in the first few days after surgery such that there is minimal to no pain by 1–3 weeks. Complications include mild bleeding, urinary retention, and thrombosis and fissure formation (Charles & Evans, 2008).

Stapled Haemorrhoidopexy

The use of these conventional surgical procedures was reduced when stapled haemorrhoidopexy was first introduced in the 1990s. This method was further refined by Antonio Longo in 1998 which incorporates the use of a disposable stapling device requiring either general or spinal anesthesia (Longo, 1988).

This procedure aims to restore the haemorrhoidal tissues back to their anatomic position; interrupts the superior haemorrhoidal vessels; preserves anal cushions for continence; and simultaneously avoids a painful anal wound in the anal canal. It has

since gained much enthusiasm in view of its shorter learning curve, less operative time, reduced blood loss and a significant reduction in postoperative pain. This technique emphasizes on the principle of stapling the feeder branches of the superior haemorrhoidal arteries above the base of the haemorrhoids. The surgery requires the patient to be placed in Llyod Davis position. It concentrates on the use of a circular anal dilator, a purse string suture anoscope, a suture threader and a haemorrhoidal circular stapler of 32-34mm.

Firstly, the anal canal is dilated using a circular dilatoras shown in Figure 2.2. Then a circumferential submucosal purse string using a polypropylene suture is placed 3-5cm above the dentate line with the aid of a suture anoscope. This suture should incorporate the mucosa and submucosa at the same level each time a bite is taken. Care is taken to avoid the muscular tissue during the bites. Tightening of this purse string suture will draw the mucosa and submucosa into the stapler. Next the PPH stapler anvil is then introduced beyond the purse string and is tightened. This forms a doughnut that is composed of anal mucosa, submucosa and haemorrhoidal plexus which will be drawn into the resection circumference of the stapler. The stapler wheel is then approximated and this closes the stapler until a desired level of firing range is attained which is marked on the stapler. The device is then held in place for about 30 seconds to ensure tissue compression and is subsequently fired. A ring of staples is delivered and a 'doughnut' of mucosa and submucosal tissue is concurrently excised with resultant stapling of the proximal arterial inflow. This causes a reduction in vascularity and the retraction of the prolapsed mucosa back into the anal canal. The stapler anvil is then manipulated out, removing the resected tissue doughnut and examining its completeness. A suture anoscope is then reintroduced to inspect the stapled line integrity and bleeding. Hemostatic sutures are placed to ensure haemostasis, usually using polyglactin sutures. The patients are usually discharged back to the ward for further observation once deemed suitable.

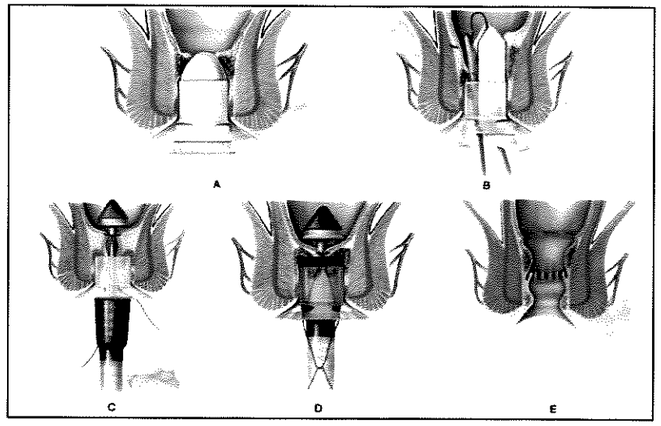

Figure 2.2:Steps of stapled haemorrhoidopexy

Complications of stapled haemorrhoidectomy

Postoperative complications of stapled haemorrhoidectomy encompass immediate, early and delayed complications. Immediate complications include stapled line bleeding which usually can be limited using haemostatic suture ligatures. Another dreaded immediate complication is anastomotic dehiscence or incomplete firing of the stapler due to device failure resulting in profuse bleeding requiring the need of salvage suture ligatures

Early complications of these procedure usually arise once the patient is discharged back to the ward which include acute urinary retention and anal pain which may arise from numerous causes such as a result of submucosal hematomas, thrombosis of the external haemorrhoidal component, staple lines which are closer to the anal sphincter and inclusion of muscle fibers in the resected mucosal doughnut (Oughriss, Yver, & Faucheron, 2005). These complications of pain may induce fecal urgency, constipation and incontinence in the early postoperative period and may cause pruritis and erythema later (Porrett, Porrett, & Ho, 2015).

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Late complications usually occur after postoperative day 7, which include persistent bleeding, anal strictures, anal fissures, deep intramural abscesses with possible anal fistulization which predispose to anal or pelvic sepsis (Ng, Ho, Ooi, Tang, & Eu, 2006). Anal or pelvic sepsis post stapled haemorrhoidectomy may need prolonged antibiotic therapy and needs consideration of a diverting colostomy to aid healing (Porrett et al., 2015).Recurrent disease has been constantly reported as a known complication after stapled haemorrhoidectomy and has been reported to occur as early as 3 month postoperatively (Brown, 2017).

However, majority of disease recurrence has been observed to present after 12 months. Later recurrences have been reported to be noticed after 6 years (Tjandra & Chan, 2007; Voigtsberger et al., 2016) .

Chapter 3: METHODOLOGY

Materials and Methods

This chapter presents the methodology used in this study to answer the research objectives. The research framework, instrumentation, data collection (sampling and procedures) and methods of data analysis are explained. This study obtained ethical clearance from Research Ethics Committee KPJ Healthcare University College (KPJUC), reference number: KPJUC/RMC/SOM/MOGS/EC/2018/166 (as shown in Appendix)

Research framework

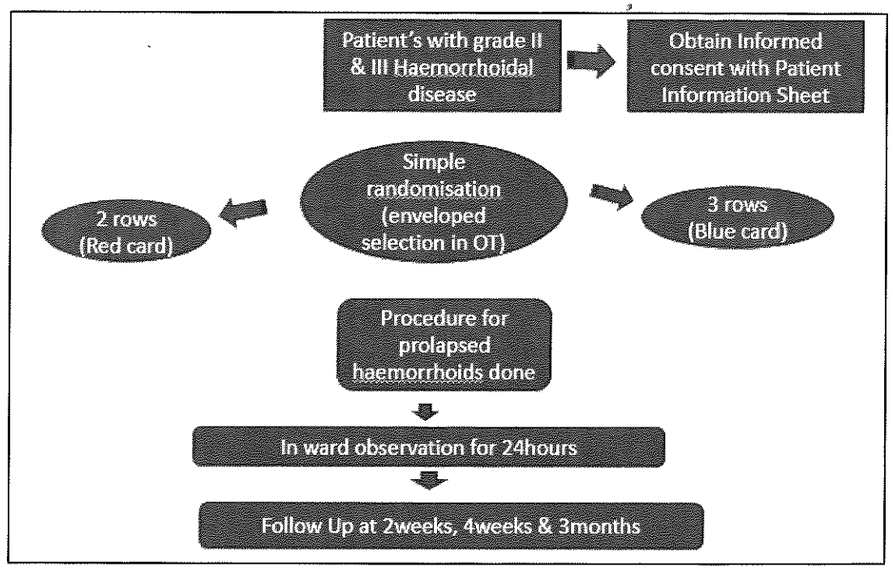

Figure 3.1: Research framework

Patient proforma

Patient proforma was used to collect postoperative information from patients who underwent 2 row and 3 row stapled haemorrhoidopexy, to assess recurrence rates(patient's symptoms with demonstrable clinical sign (straining), haemostasis (gauze staining), postoperative pain using visual analog scale (VAS) and anal stenosis by performing digital rectal examination (DRE)with gentle/limited proctoscopy.

Operational Definition

Haemostasis in stapled haemorrhoidopexy,

Haemostasis is the arrest of bleeding, whether it be by normal vasoconstriction (the vessel walls closing temporarily), by an abnormal obstruction (such as a plaque) or by coagulation or surgical means (such as ligation).

Stapled haemorrhoidopexy

A stapled hemorrhoidopexy is well accepted treatment option for haemorhoidal disease. It is also called as stapled hemorrhoidectomy, or procedure for prolapse of haemorrhoids. A prolapsed hemorrhoid is a hemorrhoid that extends out of the anus.

Early anal stenosis

When a tubular or muscular hollow becomes excessively narrow in the lumen; disallowing the passage of bodily fluid or stools, so that it can no longer perform as nature intended, it is a condition referred to by physicians as stenosis. Anal stenosis, also known as an anal stricture, is the narrowing of the anal canal, located just before the anal sphincter. Most commonly at the stapled line anastomosis in patients who have underwent SH.

Study Instrument

Haemorrhoidal Circular Stapler by Meril Endo-Surgery

This study was on an improvised haemorrhoidal circular stapler as shown in Figure 3.2 by Meril Endo-Surgery Pvt Ltd which has attained its CE certification (Cert No. :245505-2017-CE-IND-NA-PS Rev 0.0) valid till August 2020. The study incorporated the use of the 34mm diameter stapler only for the purposes of this research. These staplers come both in 2 and 3 row circular staples. The vendors ensures optimal tension free tissue compression and accurate B shape staple formation. The device delivers adjustable height staple pins upon firing. This ultimately ensures a proper staple line formation with optimal closed height staples which ensures a leak proof anastomosis with the use of these staplers.

The stapler comes as a whole unit which includes a non-detachable stainless-steel anvil attached to an adjustable steel shaft which closes into a voluminous internal housing of 14 cc. The anvil is controlled by a wing nut at the stapler's end to be opened and closed. The wing nut is attached to the body of the stapler which has a tissue compression indicator display which shows an acceptable firing range once adequate tissue compression is achieved. Attached to the body is the firing lever which is guarded by a safety lock, which needs to be released before firing the stapler.

The internal housing mounts a sharp stainless-steel circular cutting blade which cuts the compressed tissue onto the inferior surface of the anvil once the stapler is fired. Concurrently the staples are deployed during the stapler firing. The circular razor blade comes in 2 sizes depending on the stapler used. The 2 row stapler houses a 25.6mm blade whereas the 3 row stapler houses a 23 mm blade. The 2 row stapler consists of 32 staples pins in total whereas the 3 row stapler consists of 48 staples pins in total. All the staple pins are made of titanium and have a 3.5 mm open leg length. Upon deployment they have an adjustable height depending on tissue thickness and are 0.75 to 1.5mm in length.

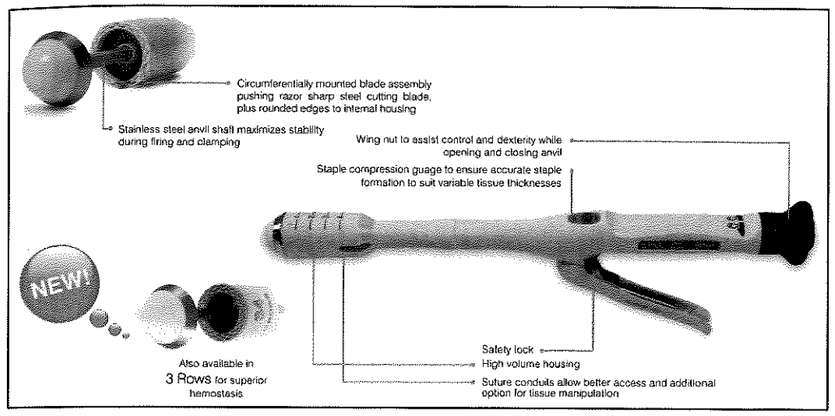

Figure 3.2: Meril's haemorrhoidal circular stapler

Data collection

The objective of the study was to compare two hemorrhoidopexy staplers in the treatment of symptomatic grades 3 haemorrhoids. Randomization was conducted via random number and sealed envelopes in the study site. Meril's 2 row stapler and 3 row stapler were employed per the manufacturer's instructions and local practice techniques, similar to prior publications. Haemostasis, postoperative pain, early anal stenosis, bleeding rates, and recurrence rate were recorded through a patient proforma. The patients were observed first at 2 weeks after the surgery. The observation of the patients were followed up at two weeks, four weeks and at 3 months after the operation.

Sampling Method

Convenience sampling is a type of nonprobability or non-random sampling where members of the target population that meet certain practical criteria, such as easy accessibility, geographical proximity, availability at a given time, or the willingness to participate are included for the purpose of the research (Palinkas et al., 2015). It is also denoted to the researching subjects of the population that are readily reachable to the researcher. With numbers derive from convenience sampling, one can make only weak statement about some characteristic of the sample itself rather than a formal inductive inference concerning the population of interest. Further explains that, the patients in the researcher's own institution are main examples of convenience sampling.

Moreover, according to Viswanathan (2005) (Viswanathan, 2005), convenience sampling is suitable for this study rather than probabilistic sampling because the aim is not to establish population estimates, but rather to use correlational analysis to examine relationships between items and measures.

Data Analysis

Data were managed on an Excel spreadsheet. Descriptive analysis of demographic data, clinical parameters and post-operative complications were carried out. Quantitative variables were summarised by mean and standard deviation or median and categorical variables were summarised by frequency (percentage). Statistical analysis was done using SPSS 21 software. Data are presented as the mean ± SD. Pearson correlation and a P-value < 0.05 was taken as statistically significant. Categorical data was analysed using Chi-Square test, continuous data was analysed using Independent T-test.

Chapter 4: RESULTS

Characteristic of subjects

There were 8 female patients and 16 male patients who underwent stapled haemorrhoidopexy in the 2-row arm. The 3-row stapler arm on the other hand had 13 male and 14 female patients. With regards to ethnicity, the 2-row stapler arm had 7 Malays, 13 Chinese and 4 Indian patients, in comparison to the 3-row stapler arm that had 6 Malays, 13 Chinese, 4 Indians and 4 patients from other races.

The patients who underwent 2-row stapled haemorrhoidopexy had a mean age of 41 years. The minimum age included was 19 years and the maximum age was 61 years. In contrast with the 3-row arm, the mean operating age was 44 years. The minimum age operated on was 25 years and the maximum were 65 years. There is no significant difference in baseline characteristics of patients in 2 and 3- row stapled haemorrhoidopexy as statistical analysis displayed a p value of > 0.05. The distribution of participant's demographics and baseline characteristics who underwent 2 and 3-row staplers is shown in Table 4.1.

Table 4.1: Characteristic of subjects

Variables (n=51)		2-Rows N (%)	3-Rows N (%)	P-value
Gender	Male	16(67)	13(48)	0.259[a]
	Female	8(33)	14(52)	
Ethnicity	Malay	7(29)	6 (22)	0.271[a]
	Chinese	13(54)	13(48)	
	Indian	4(17)	4(15)	
	Others	0 (0.0)	4(15)	
Age group (years) mean (SD)		41.3(13.4)	44.1 (13.6)	0.460[b]

Note. [a] Pearson Chi square; [b] Independent T-test

Primary objective: Post-operative pain, bleeding, early Anal Stenosis and early recurrence

The incidence of postoperative pain at 2, 4 and 12 weeks illustrates no significant difference with the use of either stapler (p value = >0.05) at all intervals. All subjects were found to be completely relieved from pain before their review at 12 weeks.

The incidence of postoperative bleeding was most marked during the first review at 2 weeks with most subjects categorized to have mild bleeding. Bleeding had significantly subsided before the 2nd interval review at 4 weeks. No subjects were reported to have moderate or severe bleeding. Two subjects (4%) developed secondary haemorrhage within 2 weeks and required a formal arrest in theatre. The differences in post-operative bleeding from either stapler were not significant with p value > 0.05 and had a weak correlation from statistical analysis.

The incidence for early recurrence showed no difference in the variables tested. Hence, the correlation was not significant. The incidence of anal stenosis was most marked during the 2nd interval assessment at 4 weeks revealing 8.3% from 2-row stapler arm and 18% from the 3-row stapler arm (mild stenosis) with p value > 0.05 and was not significant from statistical analysis. A correlation analysis done showed no significant difference from either stapler arm. Table 4.2 describes the correlation and level of significant of post-operative pain, bleeding, early anal stenosis and early recurrence between participants in the 2 and 3 – rows stapler

Table 4.2: Comparison of clinical operative outcomes

Clinical outcomes	2-Rows N (%)	3-Rows N (%)	P-value	(r)
Post-operative Pain				
2 weeks				
Mild	9 (37.5)	9 (33.3)	0.760	-0.66
Moderate	1 (4.2)	2 (7.4)		
Severe	0	0		
4 weeks				
Mild	1(4.2)	2(7.4)	0.385	-0.063
Moderate	0	0		
Severe	0	0		
12 weeks				
Mild	0	0		
Moderate	0	0		
Severe	0	0		
Post-operative Bleeding				
2 weeks				
Mild	4 (16.7)	3 (11)	0.430	-0.169
Moderate	0	0		
Severe	0	0		
4 weeks				
Mild	1 (4.2)	1 (3.7)	0.840	-0.043
Moderate	0	0		
Severe	0	0		
12 weeks				
Mild	0	0		
Moderate	0	0		
Severe	0	0		

Note.(r), Pearson's correlation.

Clinical outcomes	2-Rows N (%)	3-Rows N (%)	P-value	(r)
Early Anal Stenosis				
2 weeks				
Mild	1 (4.2)	0		
Moderate	0	0		
Severe	0	0		
4 weeks				
Mild	2 (8.3)	5(18.6)	0.530	-0.135
Moderate	0	0		
Severe	0	0		
12 weeks				
Mild	1 (4.2)	2 (7.4)	0.770	-0.063
Moderate	0	1 (3.7)		
Severe	0	0		
Early Recurrence				
2 weeks	0	0		
4 weeks	0	0		
12 weeks	0	0		

Note. Table 4.2 cont. (r), Pearson's correlation.

Table 4.3 below depicts the difference in hemostatic stitches required with the use of either 2 or 3-row stapler. The results reveal P value of > 0.05 and illustrates no apparent difference in statistical analysis.

Table 4.3: Comparison of Haemostatic Stitches between 2 and 3- row stapler

No. of Stitches	2-Row N (%)	3-Row N (%)	P value
0	8 (29.6)	14 (51.9)	0.305[a]
1	5 (18.5)	8 (29.6)	
2	8 (29.6)	4 (14.8)	
3	2 (7.4)	1 (3.7)	
4	0	0	
>5	1 (3.7)	0	

Note.[a] Pearson Chi square.

Secondary objectives: Anal incontinence, pelvic infection and staple dehiscence

There is no significant difference with regards to developing anal incontinence, pelvic infection and staple dehiscence with the use of either stapler in both arms (p value > 0.05) as shown in Table 4.4.

Table 4.4: Post-operative complication between 2 and 3-row stapled haemorrhoidopexy

Complication		2-Rows N (%)	3-Rows N (%)	P-value
Anal incontinence	Yes	0	0	
	No	24 (100)	27 (100)	
Pelvic infection	Yes	0	0	
	No	24 (100)	27 (100)	
Staple dehiscence	Yes	0	1 (4)	0.341[a]
	No	23 (96)	26 (96)	

Note.[a] Pearson Chi square.

Chapter 5: DISCUSSION

Discussion on study findings

Stapled haemorrhoidopexy has been a well-recognized and commonly practiced modality for the treatment of haemorrhoidal disease. From its first use, much attention has been given to stapler design and this has led to much research and development in stapler architecture. Invariably, this has given birth to the global acceptance and use of a specific and detailed stapler for the procedure for prolapsed haemorrhoids (PPH). This has encouraged product manufacturers to further research on stapler development and has resulted in bringing about a stapler with 3 stapled line formation. In particular, by the R&D unit of Meril Endo Stapler Pvt Ltd.

In this research, we have incorporated the expertise of 3 different surgeons in comparing the use of two staplers which have 2 and 3 stapled row formation respectively. They are both products from of the same manufacturer (Meril Endo Stapler Pvt Ltd) and have obtained CE certification. This study has applied the use of these staplers to 51 patients from 2 centres which were randomised to the use of these 2 and 3 row staplers respectively. In total, 24 patients were randomised to the 2-row stapler group and 27 patients were randomised into the 3-row stapler group. Early post-operative complications were objectively assessed for these patients and tabulated using a patient proforma sheet. They were reviewed at 2 weeks, 4 weeks and 12 weeks postoperatively in the surgical clinic. This research studies on the rates of early complications which include bleeding, pain, early recurrence and early anal stenosis.

The rates of early bleeding at 2 weeks for 2 and 3-rows were 16.7% and 11.1% respectively. At 4 weeks, they were 4.2% and 3.7% respectively. At 3 months, there were no cases reported to have bleeding in either groups. Early bleeding appears to be in descriptive terms only lower among the recipients of the 3-row stapler compared to the 2-row stapler group. Hence, the p value for early bleeding was >0.05 and statistical analysis revealed a weak relationship comparing both groups. All bleeding was quantified as mild bleeding and did not require any intervention. This concludes that

the differences encountered were not significant, and were consistent with an earlier study done by Peeters et al (Peeters, Bronckaers, & Hendrickx, 2016), which reported early post-operative bleeding rates ranging from 2-4%. A systematic review by Porrett et al reported that early bleeding was the most common complication and may range up to 68% (Porrett et al., 2015).

In the assessment of early postoperative pain, the 2 row stapler reported incidence of mild pain at 37.5% and 4.2% for moderate pain at 2 weeks. No patients were found to have severe pain and 58.3% of patients were reported to have experienced no pain at all. In comparison with the 3 row stapler; 33.3% patients were found to have mild pain and 7.4% were experiencing moderate pain at 2 weeks. 59.2% of the patients using the 3-row stapler had no pain. There were no reports of severe pain at 2 weeks from either group. At 4 weeks, 4.2% of patients from the 2-row stapler group experienced mild pain in comparison with 7.4% from the 3-row stapler group. There were no reports of moderate or severe pain from both groups at 4 weeks. 92% of patients from the 3-row stapler group experienced no pain at 4 weeks. At 12 weeks, patients from both groups did not any experience any pain. Statistical analysis revealed a non-significant p- value and a correlation analysis between both groups showed a weak relationship paving the results as no significant difference. This is consistent with the findings from Porrett et al (Porrett et al., 2015). The literature also states that the accepted incidences for persistent anal pain is about 2% (Sturiale et al., 2018).

On the other hand, there were no patients reported to have recurrence with the use of both staplers at 2 weeks, 4 weeks and 12 weeks. Hence, there were no difference with the use of either 2 or 3-row stapler in assessing early recurrence during the stipulated follow up. Literature states that the recurrence rates for stapled haemorrhoidectomy are about 40%. However, most recurrences were noticed at longer follow up periods with a mean period of 5 years (Sturiale et al., 2018).

The incidence of early anal stenosis at 2 weeks for the 2 row stapler was reported at 4.2% as opposed to no patients from the 3-row stapler group. At 4 weeks, the reported stenosis rate for the 2 row stapler was 8.3% whereas the 3 row stapler reported an 18.6% incidence. At 3 months, the 2 row stapler group showed mild stenosis rates at 3.7% and 7.4% of moderate stenosis. In comparison the 3 row stapler

group the incidence of mild anal stenosis rates at 4.2%. There were no reports of moderate or severe stenosis at 3 months in the 3-row stapler group. This research reports 7 (13.7%) patients to have anal stenosis noticed at the 4-week interval review, of which 2 (3.9%) patients from the 2-row stapler group and 5 (9.8%) patients from the 3-row stapler group. This results were consistent with the rates for early anal stenosis post stapled haemorrhoidopexy from literature at about 10% (Peeters et al., 2016). The p value for either group was >0.05 and comparative statistical analysis done did not reveal a significance difference comparing the use of either stapler. All patients noted to have mild anal stenosis were subjected for gentle finger anal dilatation. Almost all patients responded to self-anal dilatation but one (4.1%) from the 2 row stapler group was found to have persistent mild anal stenosis at 12 weeks. It was found that the patient did not succumb to treatment measures and required repeated reassurance for treatment compliance. From the 3-row stapler group, 2 (7.4%) out of five patients was found to have to progressive stenosis throughout their clinic visits, with one of them having pain and bleeding during defecation. Both these patients had gone on to receive a formal anal dilatation under anaesthesia in theatre.

Of all 51 patients, only 21 patients had their specimen sent for histology. The remaining specimen was discarded due to misinformation from the theatre staff. The mean volume of resected tissue was 42 x 35 x 7mm. There no reports of muscle tissue seen on histology in all resected tissue specimens sent for histological review. All the histological reports concluded tissue with presence of inflammatory cells which were consistent with internal haemorrhoids.

This research encountered one (1.9%) patient which had a device failure during the surgery which required the surgeon to salvage the operative procedure using manual circumferential stitches along with completing the submucosal excision using 'ligasure' energy device. The mentioned patient had an uneventful recovery thereafter with no reports of bleeding, persistent pain or anal stenosis.

This study also found one (1.9%) patient from the 3-row stapler group to have developed secondary haemorrhage, noticed on the 10th postoperative day and went on to receive a formal arrest of haemorrhage in the theatre. The subsequent recovery of the mentioned patient was uneventful.

Twenty-nine (56%) of 51 patients required the application of hemostatic sutures to the stapled line post firing. Of the 29 patients; 16 (31.3%) patients were from the 2-row group and 13 (25.4%) from the 3-row group. All patients had a mean operating time of 43minutes. No patients were reported to have reactionary bleeding within 24 hours of the procedure and all patients were discharge home with a mean postoperative hospital stay of 2 days.

There were no reported cases of anal incontinence or pelvic infection from all patients enrolled in this study. This study also did not encounter any other severe complications like rectal perforation or acute post-operative rectal hematomas requiring evacuation.

Strengths and Limitations

To date this is the first study that had looked into the post operative complication among patients in Malaysia who were treated with a 2 and 3- row circular stapler haemorrhoidopexy.

Among the limitation of this study was, due to the short duration of the study, convenience sampling technique was followed. A possible bias might be present due to the small study population of only 51 patients in total from both groups. In addition, both hospitals had different assessors throughout the study which might have further contributed to bias. The duration of data collection for each patient was determined at 3 months which may not enable proper evaluation of early complications.

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CHAPTER 6: CONCLUSION AND RECOMMENDATIONS

Conclusion

The use of stapler haemorrhoidectomy is still a relevant treatment option in this current era. However, this research concludes that there is no significant difference in the incidence of early postoperative complications comparing both staplers. Meticulous tissue handling with prompt use of standardised operating procedural steps is mandatory in maintaining a safe and reproducible outcome.

Early postoperative pain was maximally noticed during the review in the 1st clinical review at 2 weeks with the use of both staplers and gradually declined with no pain noticed during the 3-monthly review. Early postoperative bleeding was found to be of similar incidence with the use of either stapler. There was no significant difference in initial haemostasis post stapler firing with the use of either stapler.

The incidence of early postoperative anal stenosis was also found to be more apparently noticed during the 2nd clinical review assessment at 4 weeks and did not show to have a significant difference with the use of either stapler at 3 months. There was no difference in the incidence of early recurrence comparing both staplers.

This research aids as a platform to future comparative studies which should include bigger study population to achieve more diverse results.

Recommendation

Similar studies should be conducted with larger sample size to attain more diverse results. This will help debate the outcome measures that are being assessed. Adding a 3rd row to the stapler device was thought to have a positive impact in the outcome of stapled haemorrhoidopexy. However, this research did not discover any added advantage to this advancement. Henceforth, this research suggests that the added cost of a 3-row stapler may not be necessary.

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APPENDIX A: Ethical Approval

KPJ HEALTHCARE UNIVERSITY COLLEGE
(A Member of KPJ Healthcare Berhad Group)

RESEARCH ETHICS COMMITTEE
KPJ HEALTHCARE UNIVERSITY COLLEGE
Lot PT 17010, Persiaran Seriemas Kota Seriemas, 71800 Nilai, Negeri Sembilan Malaysia. Tel: +606-798 4485/4431/4437 Fax:+606-794 2669

Reference No: KPJUC/RMC/SOM/MOGS/EC/2018/166	
Date: 6th December 2018	
Principal Investigator: Dr. Soma Balaganapati	**Designation :** Postgraduate
Title: A Randomized Control Trial Comparing Meril's 2 And 3 Row Stapler For Procedure Of Prolapsed Haemorrhoids	
School: School of Medicine	
Co-Researchers: Mr Ballan Kannan, KPJ Johor Specialist Hospital Prof Datuk Ismail Sagap, University Kebangsaan Malaysia Medical Centre Mr Mohammad Ismail, KPJ Johor Specialist Hospital Mr Shanmugam Subbiah, KPJ Puteri Specialist Hospital Dato Dr Abdul Kadir Mohd Salleh, KPJ Puteri Specialist Hospital	

Dear Dr Soma,

SUB: ETHICAL CLEARANCE AND APPROVAL (HUMAN STUDY)

This served to certify that your research proposal titled "A Randomized Control Trial Comparing Meril's 2 And 3 Row Stapler for Procedure of Prolapsed Haemorrhoids" was presented before the Institutional Research and Ethics Committee of KPJ Healthcare University College on the 9th November 2018. After the review and discussion of the proposal, the committee had approved the project to be conducted in the present form.

The study is approved for the duration of 2 years from **6th December 2018** to **6th December 2020.** This project shall be conducted according to KPJUC Research Policy, and other guidelines, to ensure ethical research practice. The Research Ethics Committee expects to be informed on the progress of your study from time to time.

Kindly be advised that any changes of the content or design to your proposal will have to be notified to us otherwise your approval will be null and void.
Wishing you all the best.

Yours sincerely,

Prof. (C) Dato' Dr. Shahrudin Mohd Dun
Chairman, Research Ethics Committee
KPJ Healthcare University College

Cc:

Prof Dato' Dr Lokman Saim, Dean School of Medicine, KPJUC
Prof. (C) Dr. Wan Hazmy Che Hon , Chairman, Research Committee, KPJUC
Dr Faizah Safina Bakrin,Director, Research Management Centre, KPJUC
Dr. Mohd Fauze Md Jais,Research Coordinator, KPJUC

APPENDIX B: Patient information sheet (English)

KPJ HEALTHCARE UNIVERSITY COLLEGE
(A Member of KPJ Healthcare Berhad Group)

RESEARCH MANAGEMENT CENTRE

PATIENT INFORMATION SHEET

You are hereby invited to participate in the research study carried out by Dr Soma Balaganapati as part of postgraduate studies at **KPJ HEATLHCARE UNIVERSITY COLLEGE** for the award of Masters in General Surgery.

TITLE OF THE RESEARCH: A Randomised Controlled Trial of Meril's Circular Stapler for Procedure for Prolapsed Haemorrhoids

BRIEF DESCRIPTION OF THE RESEARCH STUDY:

This study serves as a preliminary study for future research for procedure for prolapsed haemorrhoids in patients with symptomatic haemorrhoids in KPJ Johor Specialist and Putri Specialist Hospitals, Johor Bahru, Malaysia. This study has been approved by Research & Ethics Committee of KPJ Healthcare University College (Ethical approval number :_____).

A total number of 60 patients or more as yourself will be participating in this study from both the above hospitals. This study will last about 10 months from the 1st of September 2018 till 30th June 2019; and your participation will be about 3 months from the date of your surgery. Once you are deemed suitable, you will be assigned to one of two groups where this surgery will be performed in a standard operative protocol using the standard operative equipment. Postoperatively, you will be monitored for a minimum of 24hours in our hospital till you are fit to be discharged. You will then be followed up at 2weeks, 4weeks and 3 months from the date of your surgery at our clinic. Once you have read and understood this information sheet; you will be required to sign the informed consent form to participate in this study.

OBJECTIVE(S) OF THE STUDY:

This study aims to assess early postoperative bleeding, postoperative pain, recurrent disease and the incidences of early anal stenosis in patients with symptomatic haemorrhoid disease subjected for stapled haemorrhoidectomy.

POTENTIAL BENEFITS OF THE STUDY:

There may or may not be any benefits to you. Information obtained from this study will help improve the treatment or management of other patients with the same disease or condition .

RISKS OF THE STUDY:

Procedure for prolapsed haemorrhoids has been a well established technique in the treatment for prolapsed haemorrhoids. Complications from this procedure may be divided into early and delayed. The former which include bleeding, infection and postoperative pain; and the latter

which include faecal incontinence, anastomotic dehiscence, reccurrence and stapled line stenosis. You will be followed up in our clinic to ensure your well being.

PROTECTION OF CONFIDENTIALITY:

All your information obtained in this study will be kept and handled in a confidential manner, in accordance with applicable laws and/or regulations. When publishing or presenting the study results, your identity will not be revealed without your expressed consent. Individuals involved in this study and in your medical care, qualified monitors and auditors, governmental or regulatory authorities may inspect your medical records, where appropriate and necessary. Your biospecimens will be sent to local laboratories for testing. Data from the study may be archived and may be transmitted outside the country for the purpose of analysis.

PARTICIPATION AND RESPONSIBILITY:

Your participation is entirely voluntary and refusal to participate will not affect any form of your treatment.However once enrolled we humbly request your utmost cooperation in complying to and answering all questions from our doctors and staff honestly and completely and cooperate for physical examination during your clinic reviews. It is very important that your study doctor be informed very rapidly of any eventual changes to your health during your participation in the study. For your own security, it is important that you follow your doctor's instructions throughout the entire duration of the study.

OTHER TREATMENT OPTIONS

The other treatment options for prolapsed haemorrhoids available in this hospital include conventional traditional surgery (open or close), and other conservative approaches such as rubber band ligation and sclerotheraphy. However stapled haemorrhoidectomy has an established role in the treatment of haemorrhoidal disease and has a proven shorter hospital stay, reduced postoperative pain and morbidity and a significant reduction in postoperative bleeding.

WHOM SHOULD I CALL?:

If you have any questions about the study and you want information about treatment, please contact the study doctor, [Dr Soma Balaganapati] at telephone number [+60164151084]. If you have any questions about your rights as a participant in this study, please contact: Research Management Centre, Research & Ethics Committee, KPJ Healthcare University College at telephone number [+06 7984431]The Secretary, Medical Researcher will provide the full contact information such as address. Phone number, and email of the researcher so that if the participants have any queries they may contact the researcher

APPENDIX C: Patient information sheet (Bahasa Melayu)

KPJ HEALTHCARE UNIVERSITY COLLEGE
(A Member of KPJ Healthcare Berhad Group)

LEMBARAN MAKLUMAT PESAKIT
Anda dengan ini dijemput untuk mengambil bahagian dalam kajian penyelidikan yang dijalankan oleh Dr Soma Balaganapati sebagai sebahagian daripada kajian pascasiswazah di **KPJ HEATLHCARE UNIVERSITY COLLEGE** untuk penganugerahan Master dalam bidang Pembedahan Umum.

TAJUK PENYELIDIKAN: Ujian Terkawal Rawak Stapler Meril untuk 'Prosedur' Prolapsed Buasir

KETERANGAN RINGKAS KAJIAN PENYELIDIKAN:

Kajian ini berfungsi sebagai kajian awal untuk penyelidikan masa depan bagi buasir 'prolapsed' pada pesakit-pesakit yang mengalami gejala buasir di 'KPJ Johor Specialist' di 'KPJ Putri Specialist'n Hospital Specialist Hospitals, Johor Bahru, Malaysia. Kajian ini telah diluluskan oleh Jawatankuasa Penyelidikan & Etika KPJ Healthcare University College (Nombor kelulusan etika: _____).

Sejumlah 60 pesakit atau lebih diri termasuk diri anda akan mengambil bahagian dalam kajian ini di kedua-dua hospital di atas. Kajian ini akan berlangsung selama 10 bulan dari 1 September 2018hingga 30 Jun 2019; dan penyertaan anda akan dikira 3 bulan dari tarikh pembedahan anda. Sebaik sahaja anda dianggap sesuai, anda akan disenaraikan kepada salah satu daripada dua kumpulan di mana pembedahan ini akan dilakukan dalam protokol piawai standard menggunakan peralatan pengendalian standard. Selepas beroperasi, anda akan dipantau selama sekurang-kurangnya 24 jam di hospital kami sehingga anda layak untuk discaj. Anda akan dinilai pada 2 minggu, 4 minggu dan 3 bulan dari tarikh pembedahan anda di klinik kami. Sebaik sahaja anda membaca dan memahami kunci maklumat ini; anda dikehendaki menandatangani borang persetujuan anda untuk mengambil bahagian dalam kajian ini.

OBJEKTIF (S) KAJIAN:
Kajian ini bertujuan untuk menilai pendarahan 'postoperative' awal, sakit 'postoperative', penyakit berulang dan kejadian stenosis dubur awal pada pesakit-peakit dengan penyakit buasir simtomatik yang tertakluk kepada prosedur 'stapled hemorrhoidectomy'.

MANFAAT POTENSI KAJIAN:

Mungkin ada atau tiada manfaat kepada anda. Maklumat yang diperoleh dari kajian ini akan membantu meningkatkan rawatan atau pengurusan pesakit lain dengan penyakit atau keadaan yang sama.

RISIKO KAJIAN:
Prosedur untuk buasir prolapsed telah menjadi teknik yang mantap dalam rawatan untuk buasir prolapsed sejak dekad yang lalu. Komplikasi daripada prosedur ini boleh dibahagikan kepada komplikasi awal dan tertunda. Antara komplikasi yang boleh berlaku adalah; pendarahan, jangkitan dan sakit postoperative; dan juga 'faecal incontinence' atau dehiscence anastomosis, reccurrence dan stenosis garis stapled. Anda akan dinilai dalam rawatan susulan di klinik kami untuk memastikan kesejahteraan anda.

PERLINDUNGAN SELESAI:
Semua maklumat anda yang diperoleh dalam kajian ini akan disimpan dan dikendalikan secara rahsia, mengikut undang-undang dan / atau peraturan yang berkenaan. Apabila menerbitkan atau membentangkan hasil kajian, identiti anda tidak akan diturunkan tanpa kebenaran anda. Individu-individu yang terlibat dalam kajian ini dan dalam penjagaan kesihatan anda adalah pemantau yang berkelayakan. Pihak berkuasa kerajaan atau pengawal selia boleh memeriksa rekod perubatan anda, jika perlu. Setiap 'biospecimen' anda akan dihantar ke makmal tempatan untuk analisa lanjutan. Data dari kajian ini boleh diarkibkan dan boleh dihantar di luar negara untuk tujuan analisis.

PENYERTAAN DAN TANGGUNGJAWAB:

Penyertaan anda adalah secara sukarela dan keengganan untuk menyertai tidak akan memberi apa-apa kesan kepada apa-apa bentuk rawatan anda. Namun begitu sekali didaftar; kami dengan rendah diri meminta kerjasama anda sepenuhnya dalam mematuhi dan menjawab semua soalan doctor kami dan kakitangan kami dengan jujur dan sepenuhnya serta member kerjasama untuk pemeriksaan fizikal semasa rawatan susulan klinik anda. Adalah sangat penting bahawa doktor kajian anda dimaklumkan dengan segera berkenaan apa-apa perubahan kepada kesihatan anda semasa penyertaan anda dalam kajian ini. Untuk keselamatan diri anda, adalah penting untuk mengikuti arahan doktor anda sepanjang tempoh pengajian/rawatan.

PILIHAN RAWATAN LAIN

Pilihan rawatan lain untuk buasir prolapsed yang terdapat di hospital ini termasuk pembedahan tradisional konvensional (terbuka atau tertutup), dan pendekatan konservatif lain seperti 'banding' dan 'sclerotherapy'. Walau bagaimanapun, 'stapled haemorrhoidectomy' terbukti mempunyai peranan yang mantap dalam rawatan penyakit ini serta menyumbang kepada jangkamasa duduk di hospital yang lebih pendek. Prosedur ini juga dapat mengurangkan kesakitan dan morbiditi selepas pembedahan dan pengurangan pendarahan yang signifikan.

SIAPAKAH YANG PERLU SAYA HUBUNGI?
Sekiranya anda mempunyai sebarang soalan mengenai kajian ini dan anda mahukan maklumat lanjutan mengenai rawatan, sila hubungi doktor kajian, [Dr Soma Balaganapati] di nombor telefon [+60164151084]. Sekiranya anda mempunyai sebarang soalan mengenai hak anda sebagai peserta/pesakit dalam kajian ini, sila hubungi: Pusat Pengurusan Penyelidikan, Jawatankuasa Etika Penyelidikan & Etika, Kolej Universiti KPJ Healthcare di nombor telefon [+06 7984431]. Setiausaha Kajian Perubatan akan menyampaikan maklumat hubungan penuh seperti sebagai alamat; nombor telefon dan e-mel penyelidik agar pertanyaan peserta/pesakit akan dijawab serta mereka boleh menghubungi penyelidik

APPENDIX D: Informed consent

KPJ HEALTHCARE
UNIVERSITY COLLEGE
(A Member of KPJ Healthcare Berhad Group)

INFORMED CONSENT FORM

***Study Title** : A Randomised Controlled Trial of Meril's Circular Stapler for Procedure for Prolapsed Haemorrhoid*

By signing below, I _____ confirm the following:

- I have been given oral and written information for the above study and have read and understood the information given.
- I have had sufficient time to consider participation in the study and have had the opportunity to ask questions and all my questions have been answered satisfactorily.
- I understand that my participation is voluntary, and I can at any time freely withdraw from the study without giving a reason and this will in no way affect my future treatment. I am not taking part in any other research study at this time. I understand the risks and benefits, and I freely give my informed consent to participate under the conditions stated. I understand that I must follow the study doctor's/staffs instructions related to my participation in the study.
- I understand that study staff, doctors and healthcare workers, and governmental or regulatory authorities, have direct access to my medical record in order to make sure that the study is conducted correctly, and the data are recorded correctly. All personal details will be treated as STRICTLY CONFIDENTIAL.
- I will receive a copy of this subject information/informed consent form signed and dated to bring home.
- I expect no financial or other benefits from my participation in the study

Subject: *(change to parent's subject for minor respondent / participant)*

Signature: I/C number:

Name: Date:

Investigator conducting informed consent:

Signature: I/C number:

Name: Date:

Impartial witness: *(Required if subject is illiterate and contents of participant information sheet is orally communicated to subject)*

Signature: I/C number:

Name: Date:

Research Management Centre (RMC)
KPJ HEALTHCARE UNIVERSITY COLLEGE
Lot PT 17010, Persiaran Seriemas, Kota Seriemas,
71800 Nilai, Negeri Sembilan Darul Khusus,
Tel: 606-794 2692:6067984437
Fax: 606-794 2662
Web Site: http://www.kpjuc.edu.my

Pain scoring uses Visual Analog Scale (VAS)
Categorized into
Score 1-4 : ***mild***
Score 5-7 : ***moderate***
Score 8-10 : ***severe***

Bleeding per rectum (post stapling)
Min stains post defaecation : ***mild***
Staining per rectum requiring pad : ***moderate***
Bleeding per rectum requiring change of pad/pampers : ***severe***

Anal stenosis
Able to admit index finger with difficulty : ***mild***
Able to admit index finger after forcefull dilatation : ***moderate***
Unable to admit little finger unless forcefull dilatation done : ***severe***