

**LAPAROSCOPIC TOTALLY EXTRAPERITONEAL  
INGUINAL HERNIA REPAIR  
WITH AND WITHOUT URETHRAL CATHETERIZATION  
A Prospective Randomized Study  
In Hospital Raja Permaisuri Bainun, Ipoh**

*by*

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Dissertation Submitted In  
Partial Fulfillment Of The  
Requirements For The Degree Of  
Masters of Medicine  
(General Surgery)



2013

## **I. ACKNOWLEDGEMENT**

I would like to acknowledge and extend my heartfelt gratitude for the continuous encouragement, invaluable supervision, timely suggestions and inspired guidance offered by my dissertation supervisors Mr. Yan Yang Wai and Dr. Zaidi Zakaria, in bringing this study to a successful completion.

To the other surgeons involved in this study, Ms. Chan Ching Ping and Mr. Selvan Nallayan, thank you for your endless effort, support, advice and patience provided during the course of the study.

A special thanks to my family. Words cannot express how grateful I am to my parents-in-law, my mother, and father for all of the sacrifices that you have made on my behalf. Above all, I would like to thank to my beloved wife, Dr. Loh Kah Ling. Thank you for supporting me for everything, especially for your great patience and encouragement throughout this experience. To my beloved daughter Isobel, I would like to express my thanks for being such a good girl always cheering me up.

I take this opportunity to also record my sincere thanks to all the faculty members of the Department of Surgery, the Department of Intensive Care and Anesthesiology, my colleagues and friends who have patiently extended their unlimited help in the successful completion of this study. Special thanks to Dr. Ling Li Fan for your invaluable assistance with the data collection.

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## V. LIST OF ABBREVIATIONS

<b>adj.</b>	Adjusted
<b>ANOVA</b>	Analysis of Variance
<b>APIC</b>	Association for Professionals in Infection Control & Epidemiology
<b>ASA</b>	American Society of Anesthesiologists
<b>ASIS</b>	Anterior Superior Iliac Spine
<b>AUA</b>	American Urological Association
<b>BPH</b>	Benign Prostatic Hyperplasia
<b>CAUTI</b>	Catheter-Associated Urinary Tract Infection
<b>CDC</b>	Centers for Disease Control and Prevention
<b>° C</b>	Celsius
<b>Ch</b>	Charrière
<b>CI</b>	Confidence Interval
<b>cm</b>	centimeter
<b>df</b>	degree of freedom
<b>diff.</b>	difference
<b>ed./eds</b>	editor / editors
<b><i>et al.</i></b>	and others

<b>Fr</b>	French
<b>HICPAC</b>	Healthcare Infection Control Practices Advisory Committee
<b>hpf</b>	high power field
<b>IBM</b>	International Business Machines
<b>ID</b>	Identity Document
<b>IDSA</b>	Infectious Diseases Society of America
<b>i.e.</b>	<i>id est</i> ('that is')
<b>IEHS</b>	International Endohernia Society
<b>IPSS</b>	International Prostate Symptom Score
<b>mg</b>	milligram
<b>ml</b>	milliliter
<b>mm</b>	millimeter
<b>MMC</b>	Malaysian Medical Council
<b>mmHg</b>	millimeters of mercury
<b>MPM</b>	Majlis Perubatan Malaysia
<b>n</b>	sample size
<b>NICE</b>	National Institute for Clinical Excellence
<b>NMRR</b>	National Medical Research Register
<b>NHSN</b>	National Healthcare Safety Network

<b>p</b>	p-value
<b>pg.</b>	page
<b>RBC</b>	red blood cells
<b>SD</b>	Standard Deviation
<b>SPSS</b>	Statistical Package for the Social Sciences
<b>stat</b>	Statistics
<b>TAPP</b>	Transabdominal Preperitoneal
<b>TEP</b>	Totally Extraperitoneal
<b>USA</b>	United States of America
<b>USM</b>	Universiti Sains Malaysia
<b>UTI</b>	Urinary Tract Infection

## **VI. ABSTRAK**

### **Latarbelakang**

Penggunaan tiub kencing semasa pembedahan pembaikan hernia inguinal secara laparoscopi masih merupakan amalan pembedahan yang biasa walaupun tidak terdapat bukti kukuh untuk menyokong penggunaannya secara rutin. Tujuan utama kajian ini adalah untuk menilai penggunaan tiub kencing semasa pembedahan laparoscopi pembaikan hernia inguinal secara prospektif.

### **Metodologi**

Pesakit-pesakit yang menjalani pembedahan laparoscopi pembaikan hernia inguinal secara elektif dibahagikan secara rawak menjadi dua kumpulan: Kumpulan dengan tiub kencing dan kumpulan tanpa tiub kencing. Tujuan utama kajian ini adalah untuk menilai kebolehlaksanaan dan keselamatan menjalani pembedahan laparoscopi pembaikan hernia inguinal secara ekstra peritoneum tanpa penggunaan tiub kencing.

### **Hasil**

Seramai 162 pesakit bersetuju menyertai kajian ini dan hanya 148 pesakit menjalani pembedahan tersebut. Pesakit yang lain seramai 14 orang tidak datang untuk pembedahan. Kumpulan tiub mempunyai seramai 72 pesakit manakala kumpulan tanpa tiub mempunyai seramai 76 pesakit ( $p = 0.818$ ). Ciri-ciri dan parameter pembedahan adalah serupa. Tidak terdapat komplikasi pembedahan yang major di dalam kedua-dua

kumpulan dan hanya 3 orang pesakit yang memerlukan penukaran pembedahan laparoscopi kepada cara konvensional. Dua pesakit memerlukan tiub kencing selepas pembedahan, seorang pesakit dari setiap kumpulan ( $p = 0.738$ ). Tiada pesakit daripada kumpulan tanpa tiub kencing yang memerlukan tiub kencing semasa pembedahan. Seramai 19 pesakit (12.8%) dari kumpulan tiub kencing mengalami gejala kencing berbanding 7 orang (4.7%) dari kumpulan tanpa tiub kencing. Perbezaan tersebut adalah ketara secara statistik ( $p = 0.006$ ). Akan tetapi, tiada pesakit yang mengalami 'bacteriuria' atau jangkitan saluran kencing.

### **Kesimpulan**

Pembedahan laparoscopi pembaikan hernia inguinal tanpa penggunaan tiub kencing secara rutin tidak akan menjejaskan keselamatan atau kemudahan menjalankan pembedahan.

***Kata kunci:*** Pembedahan laparoscopi pembaikan hernia inguinal secara ekstra peritoneum, TEP, tiub kencing

## **VII. ABSTRACT**

### **Background**

Urethral catheterization during laparoscopic inguinal hernia repair remains a common surgical practice in spite of the insufficient evidence supporting its routine use. The aim of this study was to prospectively evaluate the utility of urethral catheterization during laparoscopic totally extraperitoneal inguinal hernia repair (TEP).

### **Methods**

Patients undergoing elective laparoscopic totally extraperitoneal inguinal hernia repair were randomized into two groups: catheter and non-catheter groups. The main outcome of the study was to assess the feasibility and safety of performing elective laparoscopic hernia repair (TEP) without urethral catheterization.

### **Results**

A total of 162 patients consented to randomization and 148 patients underwent surgery. The other 14 patients defaulted surgery. The catheter group had 72 patients while the non-catheter group had 76 patients ( $p = 0.818$ ). Patient characteristics and operative parameters were comparable in both groups. There were no major operative complications in both groups and only 3 patients required conversion to open hernia repair. Two patients required postoperative catheterization, 1 patient from each group ( $p = 0.738$ ). No patients from the non-catheter group required intraoperative

catheterization. A total of 19 patients (12.8%) from the catheter group had urinary symptoms compared to 7 patients (4.7%) in the non-catheter group and the difference was statistically significant ( $p = 0.006$ ). However, there were no patients who had bacteriuria or urinary tract infection.

### **Conclusion**

Laparoscopic totally extraperitoneal inguinal hernia repair without the routine use of urethral catheter does not compromise the safety or ease of the surgery.

***Keywords:*** *Laparoscopic totally extraperitoneal inguinal hernia repair, TEP, urethral catheterization*

# **1. INTRODUCTION**

## **1.1 Background of urinary catheters**

The usage of urethral catheters in the modern era can be traced back to the early 11<sup>th</sup> century with the development of malleable catheters by Avicenna (Mattelaer & Billiet 1995; Ramakrishnan & Mold 2005). The use of natural rubber in the catheter was one of the most significant advances in catheter development. This ingenious development in 1930 by a surgeon, Dr Frederic Foley, transpired when he had the C. R. Bard Company make a longitudinally-grooved rubber catheter for him to which he attached an inflating tube and a rubber balloon (Nacey & Delahunt 1993; Mattelaer & Billiet 1995). A catheter is defined as a drainage tube that is inserted into the bladder through the urethra which is left in situ, and is connected to a closed drainage system (Greene, Marx & Oriola 2008). The catheter is also sometimes referred to as a Foley catheter or indwelling urinary catheter.

## **1.2 Complications of Urethral Catheterization**

It has now become common surgical practice to catheterize patients before or during many procedures. This practice is not supported by any evidence based literature but the complications following urethral catheterization is well documented. It has been estimated that up to 25% of hospitalized patients undergo urethral catheterization (Saint & Lipsky 1999). The initial indication for the placement of catheter was reported to be unjustified in 21% of cases while the continued

catheterization was unjustified in 47% of the cases studied (Domingo, Mendoza & Torres 1999).

Urethral catheterization involves the cleaning of the urethral meatus and surrounding structures to achieve a clean environment prior to insertion of a well lubricated catheter. The catheter is then advanced past the sphincters until it is in the trigone area of the bladder. Once the catheter is in place, the balloon at the tip of the catheter is inflated with saline to maintain placement. The open end of the catheter is then connected to a drainage bag. Complications may occur at any point in relation to this multi-step procedure. Introduction of pathogens is one of the many complications that may occur.

The exact infection rate following catheterization is not known but has been estimated to be as high as 14% to 27% per hospital stay with a rate of about 4% to 7% per day a catheter remains in place (Choong et al. 2001). A single in-and-out catheterization is associated with lower than 1% risk of infection (Tang et al. 2005). There are also no data to support the routine use of prophylactic antibiotics for prevention of infection following catheterization (Gould et al. 2009; Fraczyk & Godfrey 2004). In view of this, there is a growing trend towards avoiding routine perioperative catheterization during laparoscopy, caesarean sections, and pelvic surgery. The clinical practices of catheter management vary widely and frequently are not evidence based (Gould et al. 2009).

Catheter-associated urinary tract infection (CAUTI) includes those infections in which a patient had an indwelling urinary catheter at the time or within 48 hours before onset of the event (Nicolle 2005). There is no minimum period of time that the catheter must be in place in order for the UTI to be considered catheter-associated.

### **1.3 Background of Laparoscopic Inguinal Hernia Repair**

Around 98% of inguinal hernias are found in men because of the vulnerability of the male anatomy to the formation of hernias in the inguinal region (NICE 2004). Repair of inguinal hernia is one of the commonest procedures performed by general surgeons worldwide; indeed, it has been stated that ‘the history of hernia repair is the history of surgery’ (Karthikesalingam et al. 2009). Laparoscopic inguinal hernia repair has been increasing in popularity especially in the treatment of bilateral hernias. It was developed based on the preperitoneal synthetic mesh method introduced by Stoppa in 1975 and the Lichtenstein method (Schultz, Baca & Gotzen 2001; Ryberg et al. 1997).

Currently, the two common laparoscopic hernia repair methods are the transabdominal preperitoneal hernia repair (TAPP) and totally extraperitoneal inguinal hernia repair (TEP). The difference is that the TAPP requires an incision into the peritoneum before the access into the preperitoneal space, whereas in TEP, dissection is performed in the preperitoneal space and the peritoneum remains intact. The revolutionary idea of extraperitoneal inguinal hernia repair was established by

Arregui and Dion for TAPP and by Dulucq and McKernan for TEP in 1992 (Chowby 2004).

In our center, the method of choice is the totally extraperitoneal hernia repair method (TEP) using a 3-port midline technique. This procedure would require the patient to be in a supine position. A subumbilical incision is made and the incision is carried down to the anterior rectus sheath. A small incision is then made in the anterior rectus sheath, exposing the rectus abdominis muscle. A 10 mm port is inserted between the rectus muscles anteriorly followed by a 12 mmHg pressure insufflation of carbon dioxide gas to create the preperitoneal space. A 30 degree telescope is then introduced via the port. Under visualization, the telescope is used to further create the preperitoneal space by blunt dissection. Then, a 5 mm port is inserted 3 cm above the symphysis pubis in the midline and another 5 mm port in between the existing ports. The extent of dissection reaches medially 1–2 cm beyond the symphysis pubis to the contralateral side, cranially 3–4 cm above the transversalis arch or any direct defect, laterally to anterior superior iliac spine (ASIS), and caudally minimally 4–5 cm below the ileopubic tract at the level of psoas muscle and 2–3 cm below the Cooper's ligament at the level of superior arch of the pubic bone (Bittner et al. 2011). After reduction of the hernia sac and parietalization of the spermatic cord, a polypropylene mesh is placed over the myopectineal orifice. The mesh is fixed with tackers to the pubis and the musculo-aponeurotic layer above the iliopubic tract. The preperitoneal space is left after desinsufflation.

## **1.4 Complications of Laparoscopic Inguinal Hernia Repair**

In laparoscopic inguinal hernia repair, it is generally perceived that the bladder would be an obstacle due to its close proximity to the surgical field. Urethral catheterization would empty the bladder and would reduce the risk of bladder injury from trocar insertion. It could also prevent the filling bladder from obstructing the operative view. Therefore, urethral catheterization is often performed perioperatively for the ease of the surgery. Despite this precautionary step, injuries to the bladder still occur. The injuries may occur from the insertion of the trocar, the use of balloon dissector or during the laparoscopic procedure itself.

Laparoscopic inguinal hernia repair shares some complications with the open method of repair but also has its own established set of complications. The complication rates for laparoscopic inguinal hernia repair and open hernia repair are comparable (Thanphiphat et al. 1998; Langeveld et al. 2010). In a prospective randomized study which compared Lichtenstein hernioplasty with totally extraperitoneal laparoscopic hernioplasty in recurrent hernia, the prevalence of primary complications were similar in both groups (Kouhia et al. 2009). The complications of laparoscopic inguinal hernia repair maybe divided into intraoperative and postoperative complications (Schultz, Baca & Götzen 2001; Fegade 2008). Intraoperative complications include injuries to the bladder, bowel, vascular and vas deferens. Postoperative complications that commonly occur include hematoma, seroma formation, urinary retention, testicular pain or swelling, wound or mesh infection, neuralgias and recurrence (Fegade 2008).

The majority are postoperative complications. The incidence of urinary retention, which is also a complication of open repair, ranges from 1.3% to 5.8% (Davis & Arregui 2003). The risk of bladder injury in laparoscopic inguinal hernia repair is about 0.1% to 0.8% (Dalessandri, Bhojrul & Mulvihill 2001; Ryberg et al. 1997) while the risk of bowel perforation range from 0.2% to 0.8% (Ryberg et al. 1997). The risk of bleeding from the abdominal wall from trocar insertion is approximately 2.8% (Ryberg et al. 1997) and is due to injury to the inferior epigastric vessels and may be as high as 3.7% in TEP (Langeveld et al. 2010). Testicular complications include pain, swelling, and orchitis, and its prevalence ranges from 0.9% to 1.5% of cases (Davis & Arregui 2003).

## **2. LITERATURE REVIEW**

### **2.1 Guidelines for Urethral Catheterization**

In the *Guideline for the Prevention of Catheter-Associated Urinary Tract Infection 2009* by *Healthcare Infection Control Practices Advisory Committee (HICPAC)*, the indications for catheterization in operative patients are based primarily on expert consensus (Gould et al. 2009).

The *Guide to the Elimination of Catheter-Associated Urinary Tract Infections (CAUTIs)* by the *Association for Professionals in Infection Control and Epidemiology (APIC) 2008* stated that the indications for the use of indwelling urethral catheters are limited and recommended that one of the indications include the perioperative use for selected surgical procedures: surgeries involving the genitourinary tract, anticipated prolonged surgery, operative patients with urinary incontinence, need for intraoperative hemodynamic monitoring, patients anticipated to receive large volume diuretics during surgery. (Greene, Marx & Oriola, 2008)

### **2.2 Guidelines for Laparoscopic Inguinal Hernia Repair**

In the *Guidelines for laparoscopic (TAPP) and endoscopic (TEP) treatment of inguinal Hernia* by the *International Endohernia Society (IEHS)*, the routine use of perioperative urethral catheterization is not suggested.

The recommendations regarding perioperative urethral catheterization include the following:

- (1) patients should void before the operation to empty the urinary bladder
- (2) restriction of preoperative and postoperative intravenous fluid administration, which will reduce the risk of postoperative urinary retention
- (3) When technical difficulties or a prolonged surgical time are expected, urethral catheterization during the procedure should be considered.

However these recommendations are based on Level 4 evidence and were classified under Grade D recommendations (Bittner et al. 2011).

### **2.3 Studies on the utility of Perioperative Urethral Catheterization**

There are few studies that review the necessity for urethral catheterization during surgical procedures. However, these studies were conducted on gynecological surgeries, orthopedic surgeries and even in laparoscopic cholecystectomies.

Tang et al. (2005) performed a randomized controlled trial on women undergoing gynecological laparoscopic surgery where postoperative urinary symptoms and urinary tract infections were the composite outcome. The study recruited 262 women and found that there were statistically significant reduction in postoperative urinary symptoms in the non-catheterized group but urinary tract infections were insignificantly reduced. The postoperative cultures revealed urinary tract infection in 9.9% and 3.8% in the catheterized and non-catheterized groups

respectively. The study also found that operating time longer than 90 minutes was significantly associated with the need for catheterization.

Liu et al (1999) recruited 261 patients undergoing laparoscopic cholecystectomies and they were randomized to either received or not received preoperative urethral catheterization. The endpoint of the study was to evaluate the length of surgery and the intraoperative and perioperative complications such as visceral injury, urinary tract infection and urinary retention. The author found more urinary tract complications in the catheterized group although not statistically significant. There were also no significant difference in the length of surgery and perioperative complications.

Iorio et al. (2000 & 2005) conducted two similar studies to evaluate the necessity of urinary catheterization in patients undergoing total hip arthroplasty and total knee arthroplasty respectively. He recruited 652 patients undergoing total hip arthroplasty in one study and 719 patients undergoing total hip arthroplasty in another. In both studies, the patients were randomized into preoperative indwelling catheter group and observation group who had catheterization as needed. The studies showed that there were no significant differences in urinary tract infection in both groups and the length of hospital stay. However, the preoperative catheterized groups generated greater cost than patients in whom a catheter was inserted when necessary.

A prospective comparative study was carried out in Colombo, Sri Lanka to determine the feasibility and safety of carrying out elective lower segment cesarean section without urethral catheterization (Senanayake 2005). The surgery was carried

out without catheterization on 344 women who had voided within the previous hour. The study showed no difference in the mean surgery time and there were no cases of accidental cystotomy. However, the difference in the urinary tract infection rates was statistically significant, where no woman in the non-catheterized group developed UTI.

Majeed et al. (1998) measured the urine amount in the bladder of 50 patients undergoing laparoscopic cholecystectomies. The patients were not given specific voiding advice before the procedure and all patients were catheterized with a 12-F Foley's catheter after induction of anesthesia. The median amount of urine recorded was 100 ml (range 5 to 500 ml) and the catheters were removed immediately. None of the patients had palpable bladder before catheterization. Only 3 patients developed urinary retention and none had urinary tract infection. They concluded that when the urinary bladder is not palpable after induction of anesthesia, routine catheterization of the patient is unnecessary for laparoscopic surgery as the bladder does not rise more than three fingers breadth above the pubic symphysis even when filled with 500 ml of urine. The risk of injury to the bladder can be minimized by asking the patients to void before the surgery.

In a survey on bladder drainage practices among gynaecologists in the British Isles, up to 93% of the 1229 respondents catheterized the bladder before routine abdominal procedures (Hilton 1998).

## **2.4 Current practices on Urethral Catheterization in Laparoscopic Hernia Repair**

Reported studies and personal experiences by surgeons worldwide on the routine usage of urinary catheterization during laparoscopic hernia repair vary widely. However, laparoscopic inguinal hernia repair, either TAPP or TEP, can be performed safely without the routine use of perioperative urinary catheter.

Oehlenschläger et al. (2010) conducted a retrospective, single institution study in Denmark on patients who underwent laparoscopic inguinal hernia repair (TAPP) for two different time periods: from 1 January 2002 to 31 December 2007 (period I) and 1 January 2008 to 31 December 2009 (period II). The primary endpoint was complications within the first 30 days after surgery. In period II, perioperative indwelling catheter was not routinely used. A total of 684 patients underwent the surgery (78 women and 606 men). The complication risk was calculated on the basis of the number of operations. This study concluded that TAPP may be performed without routine urethral catheterization with less risk of urological complications.

Messarisi, Nicastrì and Dudrick (2010) conducted a prospective study of laparoscopic extraperitoneal inguinal hernia repair between August 2004 and December 2006 in a community teaching hospital in Rhode Island. The procedures were performed by a single surgeon and 286 patients were recruited. In this study, catheterization was not done as all patients were asked to void preoperatively. Only minor complications were noted: two patients developed urinary retention with one of whom required catheterization.

Jongsiri (2009) reported a retrospective review of laparoscopic hernia repair (TEP) done by a single surgeon from March 2000 to October 2008 in a military hospital in Thailand. The surgery was performed successfully in 104 patients with 3 patients requiring conversion to open surgery. The review stated that all patients had urinary decompression by insertion of Foley's catheter preoperatively.

Thill et al. (2008) conducted a non-randomized prospective study in a single center in Belgium from April 1995 to August 2004 in which 839 patients underwent TEP. The purpose of the study was to assess the long-term results of symptomatic hernias treated using the TEP approach. The surgeries were performed with all patients catheterized.

Kriplani, Pachisia and Ghosh (2008) discussed the preparation of patient and the method of performing laparoscopic trans-abdominal pre-peritoneal (TAPP) repair of inguinal hernia and also the perioperative complications. They suggested that the urinary bladder should be emptied before surgery either by self-voiding or by catheterization. They found that a full bladder may interfere with the surgical field during medial dissection and will be prone to injury.

In his book *Laparoscopic Surgery Atlas*, Palanivelu (2008) described in detail regarding the history of laparoscopic hernia repair, the general considerations and preparation of patients and also relates his vast experience and suggestions on the various types laparoscopic hernia repair. He recommended that routine urethral catheterization is not necessary but advised that the patients should void before the surgical procedure.

Wellwood & Tutton (2007) discussed the general considerations, preparation of patient and the operative steps in laparoscopic groin hernia repair. They suggested that patients who are undergoing laparoscopic inguinal hernia repair need to empty their bladder before the surgery. They do not routinely pass a urinary catheter and advised that if the bladder is full during initial laparoscopic assessment, a urinary catheter should be introduced before proceeding further with the surgery.

Molinelli, Tagliavia and Bernstein (2006) conducted a prospective study on 30 patients undergoing laparoscopic TEP inguinal hernia repair by a single surgeon in Connecticut, USA from November 2003 to January 2004 using spinal anesthesia. All patients successfully underwent the laparoscopic surgery under spinal anesthesia and no patients required Foley catheterization perioperatively.

Tanhiphat et al. (1998) performed a randomized controlled trial comparing laparoscopic and open inguinal hernia repair in Chulalongkorn Hospital, Bangkok. A total of 120 patients were recruited for the study. Sixty patients underwent laparoscopic transabdominal preperitoneal mesh repair while the other 60 patients had open repair. In this study, an indwelling bladder catheter was routinely inserted for laparoscopic repair and only selectively for the open repair. The study found that the total number of complications in the two groups were comparable.

## 2.5 Pathogenesis of Bacteriuria

Catheter-associated bacteriuria is mainly caused by the patient's own colonic flora and may also be due to exogenous organisms from the environment (Warren 1996). The various routes of entry to the bladder can be:

- (1) during catheter insertion,
- (2) through the catheter lumen, or
- (3) along the catheter-urethral interface (biofilms).

The latter route is estimated to be the cause of 70% to 80% of episodes of bacteriuria in women and 20% to 30% of episodes in men (Warren 1996). Biofilms are complex structures that include bacteria, host cells and cellular by-products (Greene, Marx & Oriola 2008). Most bacteria strains that enter are able to colonize to a high concentration within a day. The minimum acceptable volume to diagnose bacteriuria is 0.5 to 1 ml of urine (Eisenstadt & Washington 1996).

Bacteriuria in otherwise healthy catheterized patients is often asymptomatic and usually will resolve spontaneously after the catheter is removed (Greene, Marx & Oriola 2008). In older adults, asymptomatic bacteriuria may be present without catheterization or risk of progression to urinary tract infection unless other conditions that predispose the patient to infection are present (Greene, Marx & Oriola 2008).

### **3. OBJECTIVES OF STUDY**

Few high quality evidence based studies have examined the use of urethral catheters during surgical procedures, and urethral catheters are commonly inserted during the perioperative period. In our center, the practice of urethral catheterization prior to laparoscopic hernia repair is based on the operating surgeons' preference.

This study is conducted in order to examine the necessity of Foley's catheters usage with laparoscopic totally extraperitoneal inguinal hernia repair.

#### **3.1 General Objective**

The general objective of this study is to determine the feasibility and safety of carrying out elective laparoscopic totally extraperitoneal inguinal hernia repair without urethral catheterization in Hospital Raja Permaisuri Bainun, Ipoh by 3 of our experienced and laparoscopic-trained surgeons.

#### **3.2 Specific Objectives**

The specific objectives of this study are to evaluate the

1. Urethral catheter related complications:

a. Presence of *urinary symptoms*

(i) dysuria

(ii) frequency

(iii) urgency

b. *urinary tract infection* diagnosed based on

- (i) positive urine culture
- (ii) urinary symptoms
- (iii) fever

2. Laparoscopic surgery related complications

a. Intraoperative Complications

- (i) Peritoneal breach
- (ii) Cord injury
- (iii) Bladder injury
- (iv) Major blood vessel injury

b. Postoperative Complications

- (i) seroma
- (ii) hematoma
- (iii) urinary retention
- (iv) wound infection
- (v) hernia recurrence

3. Surgery duration

4. Surgery conversion rates

5. Requirement for catheterization in the non-catheter group

## **4. RESEARCH METHODOLOGY**

This is a randomized prospective controlled study which was carried out in Hospital Raja Permaisuri Bainun, Ipoh after obtaining approval from the Medical Research and Ethics Committee, Ministry of Health and the university Ethics Committee. From 4 July 2011 to 30 June 2012, all patients aged above 18 years manifesting with inguinal hernia, and fulfilled the inclusion criteria were recruited for this study. The study was registered at [www.nmrr.gov.my](http://www.nmrr.gov.my) with the number NMRR-10-1236-7891.

### **4.1 Patient selection and Randomization**

#### **4.1.1 Inclusion Criteria**

Adult patients with unilateral or bilateral reducible inguinal hernia which require elective surgical repair were considered for enrollment into the study. Patients who presented with hernia that were successfully reduced in the emergency room and could undergo surgery on the next routine operating schedule were also included.

#### **4.1.2 Exclusion Criteria**

Exclusion criteria consist of the following: high risk for general anesthesia, contraindications for laparoscopic hernia repair, previous complicated or multiple lower abdominal or pelvic operations, bacteriuria, urinary tract infection, large or irreducible hernias, and patients with preexisting urinary symptoms.

The urinary symptoms include dysuria (pain during micturition), frequency (increase in the number of times of micturition within a period of less than 2 hours) and urgency (strong and sudden desire to urinate).

An inguinal hernia is a protrusion of a sac of peritoneum (often containing intestine or other abdominal contents) through a weakness in the abdominal wall in the groin (NICE 2004). A large indirect hernia is defined as having a disrupted internal ring that is greater than 4 cm or two fingerbreadths in width, plus it has a long sac with inguino-scrotal presentation. Direct large inguinal hernias are defined as having a complete blowout of the entire direct floor (Zollinger 2003).

Patients with preexisting lower urinary tract symptoms or previously diagnosed to have benign prostatic hyperplasia (BPH) were evaluated with the American Urological Association (AUA) / International Prostate Symptom Score (IPSS) BPH Symptom Score Index Questionnaire whereby only those patients with a mild to moderate symptom score were recruited into the study. Mild symptom score on the AUA/IPSS BPH symptom Score Index Questionnaire ranges from 1 to 7 while the moderate symptom score ranges from 8 to 19.

#### **4.1.3 Informed Consent**

Consents for surgery and study were obtained before randomization and all patients had agreed to undergo the operation and participate in the study. The patients were all admitted into hospital for surgery as had been the custom. Majority of the cases were done on a daycare basis.

#### **4.1.4 Allocation of Patients**

The surgeries were performed by three of our senior surgeons with vast experience in laparoscopic surgery including laparoscopic totally extraperitoneal hernia repair. Simple randomization method was used to divide the patients into two groups: the catheterized group and the non-catheterized group. Each surgeon was allocated with equal number of patients from each group to avoid bias.

The group allocation of patients was done by the use of concealed allotments in opaque sealed envelopes which were opened by the surgeon's assistants only after the patients were anaesthetized. This method of allocation was to blind the patients and the person evaluating and assigning the envelopes to their assigned group. To ensure confidentiality, all patients were provided with a *Study ID* number stated on each envelope which would then be used throughout the study. The master list of the *Study ID* numbers was kept with limited access to only the principal investigator of the study.

The randomized group allocation was also not informed to the operating surgeons. The blinding of the operating surgeons was achieved by cleaning and draping all patients by the surgeon's assistants before the surgeons enter the operating theater.

## 4.2 Operations and Perioperative Care

All patients were fasted for a minimum of 6 hours before surgery. They were also required to void within an hour prior to surgery and would be excluded from the study if circumstances did not allow. The surgeon's assistants then inserted or did not insert a catheter as directed by the randomized envelope and the operation proceeded as normal. The surgeon's assistants were medical officers in the department who were assigned according to the duty schedule.

In the catheterized group, patients had a Idealcare<sup>®</sup> Foley's catheter (Ideal Healthcare, Malaysia) size 14 Ch/Fr inserted after urethral lubrication with 12.5 gram (10 ml) of Cathejell with Lidocaine<sup>®</sup> (Montavit, Austria) under aseptic technique. The balloons of the catheters were inflated with 10 ml of sterile distilled water. In the non-catheterized group, the bladder was catheterized only if bladder filling interfered with the surgery. In both groups, the volume of urine was measured at initial catheterization.

The technique of laparoscopic repair used was the totally extraabdominal preperitoneal inguinal hernia repair with a 3-port midline technique under general anaesthesia. In our center, a single dose intravenous prophylactic antibiotic is routinely given before induction for hernia repair with polypropylene mesh, and the antibiotic of choice is 1.5 gram of Ampicillin-Sulbactam (Easyn<sup>®</sup>, Mustafa Nevzat İlaç Sanayii A. Ş., Turkey). Intravenous fluid was only commenced after anaesthesia and the total fluid given was limited to 200-300 ml per hour.

With the patient in a supine position, a transverse or vertical incision was made at the lower edge of the umbilicus. The incision would be carried down to the anterior rectus sheath. A small incision was then made in the anterior rectus sheath, exposing the rectus abdominis muscle and a 10 mm port would be inserted into the space between rectus abdominis muscle anteriorly. Pneumoextraperitoneum to a pressure of 12 mmHg would be created by insufflating carbon dioxide via the port and maintained under continuous flow. A 30 degrees telescope would be introduced via the same port. Under visualization, the telescope was used to further create the preperitoneal space by blunt dissection. Two 5 mm ports were then introduced: 3 cm above the symphysis pubis in the midline and another in between the existing ports. Blunt and sharp dissection would be performed to expose the pubic ramus and Hesselbach's triangle on the medial aspect and the origin of the inferior epigastric vessels and the iliopubic tract on the lateral aspect. After reduction of the hernia sac and parietalization of the spermatic cord, a 10 x 15 cm Premilene<sup>®</sup> mesh (B Braun, Aesculap, Germany) or a 15 x 15 cm Herniamesh<sup>®</sup> (Herniamesh, Italy) mesh was placed over the myopectineal orifice. The polypropylene mesh was fixed with Autosuture Protack<sup>™</sup> 5 mm tackers (Covidien, USA) to the pubis and the musculo-aponeurotic layer above the iliopubic tract. Carbon dioxide was evacuated from the preperitoneal space and scrotum by manual pressure prior to closure of the abdominal incisions. The skin incisions were closed with absorbable sutures after infiltration of local anesthesia 10 ml of bupivacaine hydrochloride with epinephrine (Marcaine<sup>®</sup> 0.5%, Hospira, Inc., USA) around the port site wounds. The urinary catheters in the catheterized group were removed immediately after the surgery.

Postoperative analgesia used was oral tramadol 50 mg three times a day. The routine postoperative nursing protocol was followed. Postoperatively, if the patient failed to pass urine, catheterization was performed. For daycare patients, they were discharge after voiding.

### **4.3 Measurements**

Patients' demographics, history of urinary tract infection and urinary symptoms were collected using standard data forms (proforma) in the preoperative counseling session after obtaining consent. For both groups, the proforma would be completed after surgery and a preoperative sample of urine and a second one on the first follow-up, at one week postoperatively, were sent for culture.

Symptomatic urinary tract infection is defined as bacteria count  $\geq 10^5$  microorganisms per ml of urine with no more than 2 species of microorganisms and has at least one of the following signs or symptoms with no other recognized cause: fever ( $>38^\circ\text{C}$ ), urgency, frequency, dysuria, or suprapubic tenderness (Horan, Andrus & Dudeck 2008).

Asymptomatic bacteriuria is defined as the isolation of a specified quantitative count of bacteria in an appropriately collected urine specimen obtained from a person without symptoms or signs referable to urinary infection (Nicolle 2005). An asymptomatic bacteriuria must meet at least 1 of the following criterias:

1. Patient has had an indwelling urinary catheter within 7 days before the culture *and* has a positive urine culture, that is,  $\geq 10^5$  microorganisms per ml of urine with no more than 2 species of microorganisms *and* has no fever, urgency, frequency, dysuria, or suprapubic tenderness.
2. Patient has not had an indwelling urinary catheter within 7 days before the first positive culture and has had at least 2 positive urine cultures, that is,  $\geq 10^5$  microorganisms per ml of urine with repeated isolation of the same microorganism and no more than 2 species of microorganisms and patient has no fever, urgency, frequency, dysuria, or suprapubic tenderness (Horan, Andrus & Dudeck 2008).

Operative time was measured from the start of the skin incision to the complete closure of all incisions. The total amount of intravenous fluid given the intraoperative period was recorded.

Complications encountered during the surgery were also recorded. The complications of surgery include peritoneal breach, major blood vessel injuries, visceral injuries and abdominal wall hematoma.

Catheter-related complications would include urinary symptoms, bacteriuria, and urinary tract infection. All the patients were required to participate in the follow-up study. They were evaluated after 1 week and 3 months postoperatively. During the follow-up evaluations, the patients were asked on urinary symptoms based on the proforma and were clinically examined for hematoma, seroma formation, wound healing and recurrence.

#### **4.4 Sample Size Calculation and Statistical Analysis**

From the literature review, studies have shown that the rate of urinary tract infection in the catheterized group ranges from 1.8% to 15% while in the non-catheterized group ranges from 0% to 2.5% (Tang et al. 2005; Iorio et al. 2000 & 2005).

If the rate of urinary tract infection in the catheterized group and non-catheterized group were estimated to be 15% and 2% respectively in this study, and the power of the study is set at 80% to detect such differences with 5% level of statistical significance, the sample size calculated, using PS Power and Sample size Calculations version 3.0, would be 71 patients in each group, or a total of 142 patients. Estimating a drop-out rate of 10%, we recruited a total of 162 patients in order to obtain an equal distribution of patients to the three operating surgeons; i.e. 54 patients randomized to each of the surgeons.