

**EFFECTIVENESS AND SAFETY OF DIFFERENT  
ANAESTHETIC TECHNIQUES CONSIDERATION FOR  
LAPAROSCOPIC TENCKHOFF CATHETER INSERTION IN  
ESRF PATIENTS FROM YEAR 2018 TO 2021**

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## LIST OF SYMBOLS AND ABBREVIATIONS

ASA	American Society of Anaesthesiology
ESRF	End Stage Renal Failure
CAPD	Continuous Ambulatory Peritoneal Dialysis
PD	Peritoneal Dialysis
SAB	Subarachnoid block
RA	Regional Anaesthesia
GA	General Anaesthesia
MAC	Monitored Anaesthesia Care
LA	Local Anaesthesia
IV	Intravenous
IT	Intrathecal
TCI	Target Controlled Infusion
SBP	Systolic Blood Pressure
HR	Heart Rate
PONV	Post Operative Nausea and Vomiting
SPO2	Oxygen Saturation
=	equal to
±	standard deviation
<i>p</i>	<i>p</i> -value
°	degree
%	percent
<	Less than



## **APPENDICES**

APPENDIX A Proforma

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## **ABSTRAK**

### ***Latar Belakang***

Pembedahan secara laparoscopi memberi persepsi bahawa pesakit perlu diberikan bius penuh. Perkara ini melewati pemasangan tiub kateter dialisis sekaligus memberi impak buruk dalam usaha jaya memulakan dialisis peritoneal ambulatori berterusan di Malaysia. Hampir kesemua pesakit renal tahap akhir memiliki pelbagai penyakit kronik yang meletakkan mereka pada risiko yang amat tinggi jika menerima pembiusan secara penuh. Justeru itu, kami akan mengkaji keberkesanan teknik pembiusan selain bius penuh untuk prosedur pemasangan tiub kateter dialisis secara laparoscopi.

### ***Kaedah***

Kami menganalisa 523 pesakit yang menjalani prosedur memasukkan tiub kateter dialisis secara laparoscopi di Hospital Selayang sepanjang tempoh empat tahun yang berlangsung dari tanggal 1 Januari 2018 sehingga 31 Disember 2021. Kaedah pembiusan yang diterima pesakit adalah sedasi terpantau, bius separuh badan atau bius separuh badan bersama sedasi. Bacaan tekanan darah dan nadi pesakit sepanjang tempoh prosedur direkodkan. Sebarang komplikasi seperti tekanan darah rendah, penurunan bacaan oksigen atau loya muntah selepas pembedahan turut direkodkan.

Taburan data yang dikumpulkan adalah 35.2% pesakit menerima bius separuh badan, 41.7% menerima sedasi terpantau dan 22.8% menerima bius separuh badan bersama sedasi. Tiada perbezaan yang ketara di dalam perubahan bacaan nadi atau tekanan darah semasa tempoh prosedur dilaksanakan. Namun, di kumpulan bius separuh badan dengan atau tanpa sedasi mencatatkan penggunaan ubat untuk menaikkan tekanan darah yang lebih tinggi berbanding kumpulan pesakit yang menerima sedasi terpantau sahaja (22.7% vs. 14.7% vs. 9.2%,  $p=0.003$ ). Walaubagaimanapun, tiada perbezaan di antara ketiga-ketiga jenis pembiusan dalam komplikasi penurunan bacaan oksigen atau loya muntah selepas pembedahan.

### ***Kesimpulan***

Pemasangan tiub kateter dialisis secara laparoskopik boleh dilakukan dengan teknik pembiusan lain selain daripada pembiusan penuh. Dengan ini, lebih banyak tiub kateter dialisis berjaya dipasang tanpa membahayakan pesakit, sekaligus dialisis peritoneal ambulatori berterusan lebih banyak dilaksanakan.

### ***Kata Kunci***

*ESRF, Peritoneal Dialysis, Laparoscopic insertion, Tenckhoff, General Anaesthesia, Monitored Anaesthesia Care, Regional Anaesthesia, Subarachnoid Block.*

## **ABSTRACT**

### ***Background***

The general perception of laparoscopic procedure necessitates general anaesthesia (GA) hindered the successful initiation of continuous ambulatory peritoneal dialysis (CAPD) in Malaysia. End-stage renal failure (ESRF) patients possess complex multiple co-morbidities that put them under higher mortality and morbidity with GA. In this study, we will investigate the safety and efficacy of different anaesthetic considerations for laparoscopic tenckhoff catheter insertion.

### ***Material and Method***

The retrospective study included 523 patients who underwent elective laparoscopic tenckhoff catheter insertion in Hospital Selayang for four years between 1 January 2018 and 31 December 2021. The patients received either monitored anaesthesia care (MAC), subarachnoid block (SAB), or SAB+MAC. Their intraoperative haemodynamic parameters like systolic blood pressure (SBP) and heart rate (HR) were recorded. Any haemodynamic fluctuations (hypotension and desaturation) and postoperative nausea and vomiting (PONV) were collected.

## ***Results***

The distribution of anaesthesia was 36.52% under SAB, 41.68% under MAC, and 22.75% under SAB+MAC. No significant differences were observed in haemodynamic (SBP+HR) changes at the time taken among all three groups. However, SAB+MAC and SAB group required boluses of vasopressor intraoperatively more than the MAC group (22.7% vs. 14.7% vs. 9.2%,  $p=0.003$ ). Otherwise, there was no significant difference in PONV and desaturations among the three groups.

## ***Conclusions***

Laparoscopic tenckhoff catheter insertion is feasible to be done in different modes of anaesthesia other than GA. It accommodates many successful tenckhoff insertions and facilitates CAPD initiation without compromising patients' safety and comfort.

## ***Keyword***

*ESRF, Peritoneal Dialysis, Laparoscopic insertion, Tenckhoff, General Anaesthesia, Monitored Anaesthesia Care, Regional Anaesthesia, Subarachnoid Block.*

## **CHAPTER 1 INTRODUCTION**

### **1.1 Background and Significance**

ESRF patients who need long term dialysis may require insertion of permanent peritoneal dialysis catheter insertion (tenckhoff). Peritoneal dialysis (PD) catheter insertion can be done by open surgical dissection or laparoscopic method. However, laparoscopic procedure usually necessitate them for GA.

Most of ESRF patients with concurrent diseases like hypertension, diabetes mellitus and coronary artery disease are at high risk for GA which prevent catheter insertion via laparoscopic. SAB or local infiltration with sedation or known as MAC may be an alternative for this procedure.

In this study, we will investigate different anaesthetic considerations for laparoscopic tenckhoff catheter insertion, their safety and efficacy. To the best of our knowledge the use of LA infiltration with MAC or SAB still very limited even in our country. On top of it, none of previous study reported the use of those alternative anaesthesia in Carbon dioxide (CO<sub>2</sub>) insufflation for laparoscopic tenckhoff catheteter implantation.

Hence our study will provide descriptive data of different anaesthesia modalities for this procedure as in our institution (Hospital Selayang), we have been using different anaesthesia techniques to accommodate high number of laparoscopic tenckhoff catheter insertion using CO<sub>2</sub> insufflation.

By having such data, we able to improve acceptance among anaesthesiologist and surgeon that these procedures can be done under MAC or SAB. By avoiding GA, we able to accommodate

more cases of laparoscopic tenckhoff catheter insertion without compromising patients' safety and comfort and allow them for early discharge after the procedures.

## **1.2 Research Question(s)**

1. What is the trend of anaesthetic considerations for laparoscopic tenckhoff catheter insertion in ESRF patients from year 2018 to 2021?
2. What are the intraoperative haemodynamic responses in ESRF patients towards different anaesthetic technique?
3. What are the complications that may arise from different anaesthetic technique in ESRF patients undergo laparoscopic tenckhoff catheter insertion?

## **1.3 Objective**

### **General:**

- To compares the effectiveness and safety on different anaesthetic consideration for laparoscopic tenckhoff catheter insertion in ESRF patients (Subarachnoid block with or without IV ketamine, TCI Remifentanil+ IV midazolam with or without IV Ketamine).

**Specific:**

- To determine the trend of different anaesthetic modalities for laparoscopic tenckhoff catheter insertion in ESRF patients between year 2018 to 2021
- To compare the effectiveness of different anaesthetic techniques in providing analgesia and sedation, in terms of haemodynamic responses (SBP pre-operation, 10mins intra-operation, and at the end of surgery) with different anaesthetic techniques for laparoscopic tenckhoff catheter insertion in ESRF patients between year 2018 to 2021. (implying the adequacy of anaesthesia given by looking into the trend of SBP whereby in inadequate anaesthesia and analgesia lead to increase sympathetic hyperactivity causing increase SBP)
- To compare the safety in term of complications (hypotension, desaturation, PONV) with different anaesthetic techniques for laparoscopic tenckhoff catheter insertion in ESRF patients between year 2018 to 2021.



## 1.4 Literature review

Laparoscopic insertion of tenckhoff catheter improves immediate functional success rate, lesser wound complication and better perioperative comfort as it allows the operator to have complete visualization of peritoneal cavity.(1) This procedure usually requires general anaesthesia to provide abdominal relaxation and pain control, especially as the need for gas insufflation into abdominal cavity to create pneumoperitoneum will produce peritoneal pain which cause perioperative discomfort to the patients.

However, ESRF patients carry greater risk of complications from general anaesthesia as they have multiple co-morbidities, altered volume status and altered drug metabolism.(2) Exposing them to general anaesthesia means risk of haemodynamic instability perioperatively, prolonging hospital stays and the need of post anaesthesia care units postoperatively. Subsequently limiting the number of procedures to be performed, further reducing the number of tenckhoff penetration.

To avoid risk of general anaesthesia, few research of susceptibility of other methods of anaesthesia for this procedure. Crabtree and Amir Keshvari reported that the insertion of tenckhoff catheter laporoscopically were feasible under LA. (3),(4) Furthermore, a retrospective study had been conducted in Toronto by Liu X et al looking into anaesthesia choice for the laparoscopic tenckhoff catheter insertion from 2008 to 2013 where patients underwent this procedures either under general anaesthesia or sedation with local anaesthesia infiltration. They demonstrated that patients who possessed higher ASA grade and elderly do well under local infiltration with sedation.(5)

The need for sedation as adjunct of LA infiltration is to ensure patients' comfort and pain free throughout the procedure. Usually ESRF patients have concurrent cardiovascular disease like hypertension or coronary artery disease, using LA only may cause catastrophic event in view of labile changes in their blood pressures due to sympathetic hyperactivity intraoperatively hence risking them in getting cardiovascular complication.(6) Hence, providing sedations as adjunct of the LA infiltration or called as MAC is an option to avoid from general anaesthesia for laparoscopic tenckhoff catheter insertion.

MAC is an anaesthesia technique combining local anaesthesia with parental drugs for sedation and analgesia.(7) Anaesthesiologists are responsible for administering adequate dosage of drugs to provide safe sedation without compromising cardiovascular function. With adequate control of pain and safe sedation, allows patient comfort intraoperatively and even postoperatively, allowing them to be discharged early after procedure.

Looking into the ideal sedative/ analgesia technique remains a challenge in this population. Specifically looking into MAC in tenckhoff insertion, there is very limited study in this population. From various studies in different surgical procedures like cataract surgery, ERCP, breast biopsy and laparoscopic oocyte retrieval, there are various combinations of sedatives and analgesics were used like propofol, remifentanyl, ketamine and midazolam.

For sedative purposes, Benzodiazepine group like Midazolam is commonly been used to provide patient comfort and amnesia during the procedure. They are other options like Propofol and Dexmedetomidine, however in ESRF patients who are elderly with or without cardiovascular disease, possible of adverse events like hypotension or bradycardia may occur. Hence, in our study

setting, midazolam is the choice of drug for sedative component of MAC as it provides haemodynamic stability.

In addition of LA infiltration, systemic analgesics are given to relieve the discomfort and pain associated with procedures especially during the tunneling. Remifentanyl, an ultra-short acting opioid with fast onset and offset is an ideal opioid for continuous infusion for this procedure. However, remifentanyl can cause respiratory depression and hypotension.

Other concern regarding laparoscopic tenckhoff catheter insertion is pneumoperitoneum creation by inflating Carbon dioxide gas into peritoneum may cause shoulder tip pain to the patient. This problem can be tackled with a skilful surgeon and anaesthesiologist who readily supplement with other intravenous sedatives or opioids. Agrawal et al 2012 demonstrated that laparoscopic cholecystectomy was successfully done under SAB with only 2 out of 138 patients required conversion to GA, and about 23.8% complained of shoulder tip pain which managed with IV ketamine bolus. (8) Postoperatively, the shoulder tip pain due to peritoneal irritation did not persist with ketamine.

Hence, in our study setting, ketamine, N-methyl-D-aspartate receptor antagonist which has profound properties of analgesic, sedative, and amnesic characteristic has been added for MAC. Low dose ketamine (0.25mg/kg-0.5mg/kg) as analgesic dose does not cause clinically significant respiratory depression or PONV. Besides that, ketamine does not cause hypotension hence useful to counteract the effect of remifentanyl and midazolam.

Other than LA infiltration with MAC, laparoscopic tenckhoff catheter insertion is feasible to be done under regional anaesthesia. R.K Singh et al 2015 studied on regional

anaesthesia in major laparoscopic surgery, whereby subarachnoid block (SAB) / combined spinal epidural (CSE) had advantages over GA where better haemodynamic stability, post op pain control and patient satisfaction. They reported the problems in shoulder tip pain that arised from pneumoperitoneum creation as stretching of diaphragm which supplied by cervical roots are not covered with regional anaesthesia. However, the rate of conversion to GA because of this problem ranged from 0-37% in those patient underwent laparoscopic cholecystectomy. (9) Gautam in 2018 also demonstrated the success of spinal anaesthesia for laparoscopic cholecystectomy in high risk elderly patient with Parkinson and pulmonary dysfunction. (10) This shows that spinal anaesthesia is one of the technique that can be considered for laparoscopic procedure in patients with multiple perioperative risks especially in our study population; ESRF patients.

In our study setting, other modalities of anaesthesia for laparoscopic tenckhoff catheter insertion is subarachnoid block. Parenteral analgesic like fentanyl with or without ketamine is given to tackle pain during tunnelling or the shoulder tip pain from pneumoperitoneum.

Other concerns are the safety of our anaesthesia techniques where ASA analysis showed that 6% of litigation claims in cataract surgery under MAC are associated with respiratory depression (25%) and inadequate anaesthesia and patient mobility during surgery (11%). (11) To determine the adequacy of our anaesthesia, we will look into haemodynamic responses preoperation, 10minutes intraoperation and at the end of surgery as our study was done retrospectively, this will act as surrogate marker of sympathetic hyperactivity that may occur due to inadequate pain control. Increase of SBP > 10% may indicate inadequate anaesthesia, and SBP drop less than 20% suggestive of effects of anaesthesia without causing significant adverse events.(12) Providing effective and safe anaesthesia is main concern where aiming less volatility

of patients haemodynamic changes intraoperatively. Besides that, we will look into the complications that may arise from our anaesthesia drugs like respiratory depression in form of desaturation (SPO2 < 95% or requiring airway manipulation or advanced airway administration) or hypotension that requiring vasopressor or PONV.

Currently, not many anaesthesiologist are convinced to provide MAC or SAB as anaesthesia for laparoscopic tenckhoff catheter due to lack of study on this. To the best of our knowledge, none of such study in Malaysia. The study by Liu et al only mentioned of GA vs LA with sedation. (5) Hence, with our study, it will provide descriptive data on different anaesthesia techniques (MAC and SAB) for laparoscopic tenckhoff catheter insertion . Subsequently able to promote laparoscopic technique which has better advantage compared to open tenckhoff catheter insertion whereby does not necessiate general anaesthesia, without compromising patients' comfort and safety.

Furthermore, through this study, we will not only look into the trend of different anaesthesia techniques but also looking into their efficacy and safety. By the data that we will obtain, we able to improve the acceptance of laparoscopic tenckhoff catheter insertion in Malaysia and break the myth of only GA for this procedure. In addition, adjusting our anaesthesia techniques allowing more tenckhoff catheter implantation hence expedite the rate of peritoneal dialysis (PD) commencement. Although PD has been established since 1980s, it was underutilized as method for renal replacement therapy (RRT) in Malaysia as the national penetration rate of peritoneal dialysis was only 10% of all modes of RRT. (13),(14)

## CHAPTER 2 STUDY PROTOCOL

### 2.1 Research Synopsis

Study title	Effectiveness and Safety of Different Anaesthetic Techniques Consideration for Laparoscopic Tenckhoff Catheter Insertion in ESRF Patients from Year 2018 to 2021
Study Population	ESRF patient underwent elective laparoscopic tenckhoff catheter insertion in general OT in Hospital Selayang between January 2018 to December 2021.
Study Design	Retrospective cohort study using medical records of patients who underwent elective laparoscopic tenckhoff catheter insertion in general OT in Hospital Selayang between 1 January 2018 to 31 December 2021.
General Objective	To compare the effectiveness and safety on different anaesthetic consideration for laparoscopic tenckhoff catheter insertion in ESRF patients (Subarachnoid block with or without IV ketamine, TCI remifentaniol+ IV midazolam with or without IV ketamine).

Specific Objectives	<ul style="list-style-type: none"> <li>a) To determine the trend of different anaesthetic modalities for laparoscopic tenckhoff catheter insertion in ESRF patients between year 2018 to 2021</li> <li>b) To compare the effectiveness of different anaesthetic techniques in providing analgesia and sedation, in terms of haemodynamic responses (SBP pre-operation, 10mins intra-operation, and at the end of surgery) with different anaesthetic techniques for laparoscopic tenckhoff catheter insertion in ESRF patients between year 2018 to 2021.</li> </ul>
Study endpoints/ outcomes	<ul style="list-style-type: none"> <li>a) Frequency and percentage of each anaesthetic modality for each year from 2018 to 2021.</li> <li>b) Adverse events that occurs during anaesthesia for different anaesthetic modalities.</li> </ul>
Sample Size	The corrected sample size for this study is <b>428 patients</b> .
Study Duration	Patients medical records dated from 1 <sup>st</sup> January 2018 until 31 <sup>st</sup> December 2021 will be used.

## 2.2. Methodology

### 2.2.1 Conceptual framework

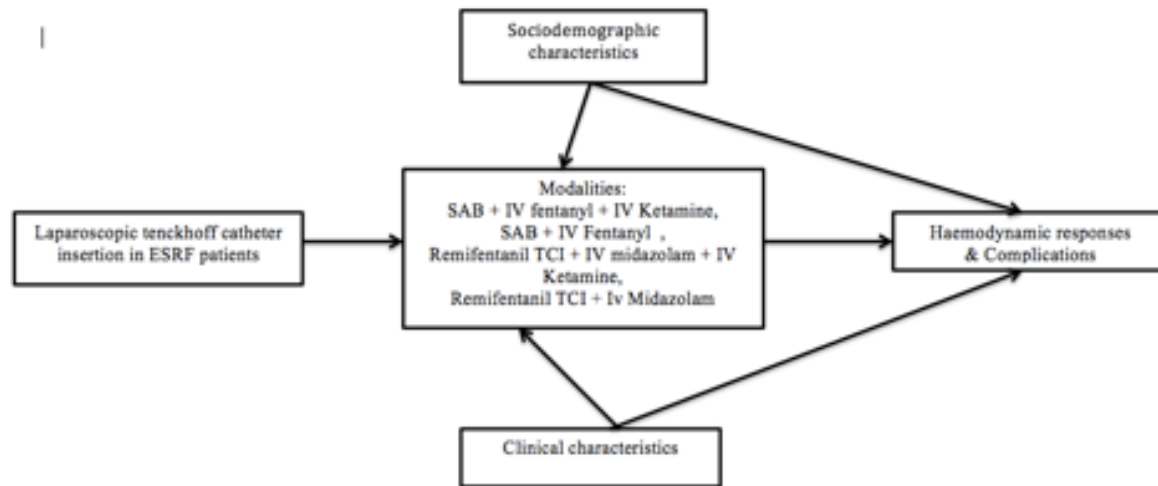


Figure 1: Conceptual framework illustrating relationship between variables and the study outcome

### 2.2.2 Research design

- Retrospective cohort study using medical records of patients who underwent elective laparoscopic tenckhoff catheter insertion in general OT in Hospital Selayang between 1<sup>st</sup> January 2018 to 31<sup>st</sup> December 2021.



### **2.2.3 Study area**

- This study will be conducted in a tertiary hospital, Hospital Selayang.

### **2.2.4 Study population**

- ESRF patient underwent elective laparoscopic tenckhoff catheter insertion in general OT in Hospital Selayang between January 2018 to December 2021.

### **2.2.5 Subject criteria**

- Inclusion criteria
  - Patients aged between 18-65 years old
  - Patients who undergo elective laparoscopic tenckhoff catheter insertion.
- Exclusion criteria
  - Less than 80% of complete medical record related to anaesthetic modalities for laparoscopic tenckhoff catheter insertion, haemodynamic responses, and complications.

### 2.2.6 Sample size estimation

The sample size was calculated for objective 1-4 .

The details are elaborated below.

For objective 1 (different anaesthetic modalities for laparoscopic tenckhoff catheter insertion in ESRF patients), the proportion of each modality for each year will be determined. Four main anaesthetic modalities will be evaluated: SAB + IV fentanyl + IV Ketamine, SAB + IV Fentanyl , Remifentanil TCI + IV midazolam + IV Ketamine, and Remifentanil TCI + Iv Midazolam. The sample size requirement was therefore calculated using formula for estimation of a population's proportion,  $n = \frac{z^2 \cdot p(1-p)}{e^2}$ , where n is the calculated sample size, z is the critical value corresponding to the level of confidence, e is the precision of estimate (also known as the margin of error), and P is the expected population's proportion obtained from previous studies. One previous study by Liu et al reported that the proportion of 42.9% for LA+ sedation and 57.1% for GA. Reference: Liu, X., 2017. Anesthesia Considerations for Insertion of the Peritoneal Dialysis Catheter. *Journal of Clinical Nephrology and Renal Care*, 3(2).

Since the proportion varies between the four different anaesthetic modalities, the proportion of 50% was used to determine the sample size, since the sample size for estimation of proportion will be largest when the proportion is 50%. For an estimation to 95% level of confidence (z=1.96), and 5% precision of estimate, the sample size required for this objective is 385 patients.

For objective 2 (To compare the effectiveness of different anaesthetic modalities for laparoscopic tenckhoff catheter insertion in term of haemodynamic responses), two-way repeated measures ANOVA analysis will be conducted to look into the time-effect: within group changes of SBP

(pre-operative, 10 minutes after induction, and upon completion of surgery), treatment-effect: between group differences based on modalities (SAB + IV fentanyl + IV Ketamine, SAB + IV Fentanyl , Remifentanil TCI + IV midazolam + IV Ketamine, and Remifentanil TCI + Iv Midazolam) and time-treatment interaction effect. The sample size was therefore calculated using sample size calculation for Repeated Measures ANOVA (RM-ANOVA) analysis in G\*power Software version 3.1.9.7. Summary of calculation based on all the three designs of a two-way RM-ANOVA are summarized in table below. For all calculations, medium effect size was used ( $f=0.25$ ), with 5% type I error, 80% power of study, comparison of 4 groups.

The medium effect size value for analysis of variance was based on the recommended value by Cohen J (1992). We use effect size for the calculation of sample size because we could not find similar study which evaluated haemodynamic responses with different anaesthetic modalities for laparoscopic tenckhoff catheter insertion.

*Reference: Cohen J. A power primer. Psychological bulletin. 1992 Jul;112(1):155.*

Design	Option, and parameters used in G*power	Total sample size required
Time-effect	<ul style="list-style-type: none"> <li>· Test family: F tests,</li> <li>· Statistical test: ANOVA, Repeated measures, within factors</li> </ul>	$24*4 = 96$

	<ul style="list-style-type: none"> <li>· Number of measurements: 3</li> <li>· Correlation among rep measurements: 0.5</li> <li>· Nonsphericity correction: 1</li> </ul>	
Treatment effect	<ul style="list-style-type: none"> <li>· Test family: F tests,</li> <li>· Statistical test: ANOVA, Repeated measures, between factors</li> <li>· Number of measurements: 3</li> <li>· Number of groups: 4</li> <li>· Correlation among rep measurements: 0.5</li> <li>· Nonsphericity correction: 1</li> </ul>	124
Time-treatment interaction effect	<ul style="list-style-type: none"> <li>· Test family: F tests,</li> <li>· Statistical test: ANOVA, Repeated measures, within-between interaction</li> <li>· Number of measurements: 3</li> </ul>	40

	<ul style="list-style-type: none"> <li>· Number of groups: 4</li> <li>· Correlation among rep measurements: 0.5</li> <li>· Nonsphericity correction: 1</li> </ul>	
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For the third objective (To compare the complications of hypotension, desaturation and PONV with different anaesthetic techniques for laparoscopic tenckhoff catheter insertion), Chi2 test of association will be conducted to determine if there is any association between complications and different anaesthetic techniques. We could not calculate the sample size requirement for this objective as there is no previous study reported the complications associated with these four types of anaesthetic techniques for laparoscopic tenckhoff catheter insertion.

**The largest sample size was obtained from the calculation for objective 1 (385 patients). Taking into account 10% dropout rate due to anticipated missing information from the medical records, the corrected sample size for this study is 428 patients.**

### **2.2.7 Sampling method and subject recruitment**

- The elective laparoscopic tenckhoff catheter insertion cases from Jan 2018 to December 2021 will be identified using anaesthesiology operating room census.
- No sampling method will be applied in this study as we believe that the number of eligible patients between 2018 and 2021 will be almost similar to the required sample size.

### **2.2.8 Research tool**

Two research tools will be used in this study: 1) medical records of patients and 2) proforma for data collection.

#### **1) Medical records**

Patients who received treatments in Hospital Selayang, all of their medical history including their blood investigations will be charted in their electronic medical records. This record only can be assessed by the medical staffs who are permitted by Hospital Selayang administrations. Every departments have their own categorized record where other unable to modify once the data has been submitted. The electronic medical records are are stored in powerchart software that are managed by IT department.

The nephrology team will send the list of patients for laparoscopic tenckhoff catheter insertion to the anaesthesiology team, 3 days prior the operation date for early preoperative assessment.

The anaesthesiology team will chart their preoperative assessment in standardized Ministry of Health general anaesthesia form. This records are available physically where during the day of operation, all the patient intraoperative drugs, vital signs and events will be recorded in this hardcopy by anaesthesia medical officer. This records will be kept in the store under (unit rekod)

On top of that, the medical officer from anaesthesiology team who incharges of the laparoscopic tenckhoff catheter insertion on that day will chart all the relevant datas intraoperatively like mode of anaesthesia, duration of surgery, members of anaesthesia and surgical team involved, the drugs that given to patient and any significant perioperative events into anaesthesia intraoperative notes in electronic medical records. This electronic medical record is useful as easier for others to access and review in the next future hence allowing better and easier anaesthesia planning in the future.

## **2) Proforma for data collection. Refer appendix A**

With the context of my research, I have defined a proforma as form or document designed by myself to be unilaterally applied as method of data collection for analysing data.

The primary use of this proforma has been to analyse the data and access to essential record significant to this study. The creation of this form allows me to have an organised and systematic approach to analyse the collected data.

Data collected in the proforma includes patients sociodemographic, comorbidity and intraoperative procedures, vital signs and events. Sociodemographic data that will be recorded like age, gender, height, weight and bmi.

The types of anaesthesia given and the dose of anaesthesia drugs will be recorded according to the groups ie; SAB + IV fentanyl + IV Ketamine, SAB + IV Fentanyl , Remifentanil TCI + IV midazolam + IV Ketamine, and Remifentanil TCI + Iv Midazolam. Any other analgesia given will be recorded too with the dose to look for adequacy of our analgesic in our anaesthesia recipe.

As we are looking for the safety of our choice of anaesthesia on the patient, patients premorbid and preoperative investigations will be recorded too. The premorbid investigations that will be significant in affecting the drugs pharmacokinetic and pharmacodynamic and our choice of anaesthesia like Full Blood Count (FBC), Coagulation Profile, Renal Profile, Albumin and Echocardiograph (ECHO) are recorded. The baseline investigations that will be collected are any latest results that available before the operation done.



Intraoperatively, patient's vital signs like blood pressure (BP) , heart rate (HR), respiratory rate (RR) and oxygen saturation (SpO2) will be recorded. In the event of desaturation, any airway manipulation or adjunct will be recorded. For looking into post operative nausea vomiting (PONV) event, the intraoperative antiemetic prophylaxis will be recorded. If PONV occurs, the rescue antiemetic treatment will be recorded.

The location of patient discharged postoperatively will be recorded to look any correlation of intraoperative events with their postoperative care.

The data collection will be done by me from patient's medical record from the electronic medical record (EMR) and the hardcopy of general anaesthesia form that will be retrieved from unit record. Any missing data that not available for the proforma above, will be recorded as not available (NA) . The proforma records will be kept by me and can be accessed by research members only .

### **2.2.9 Operational definition**

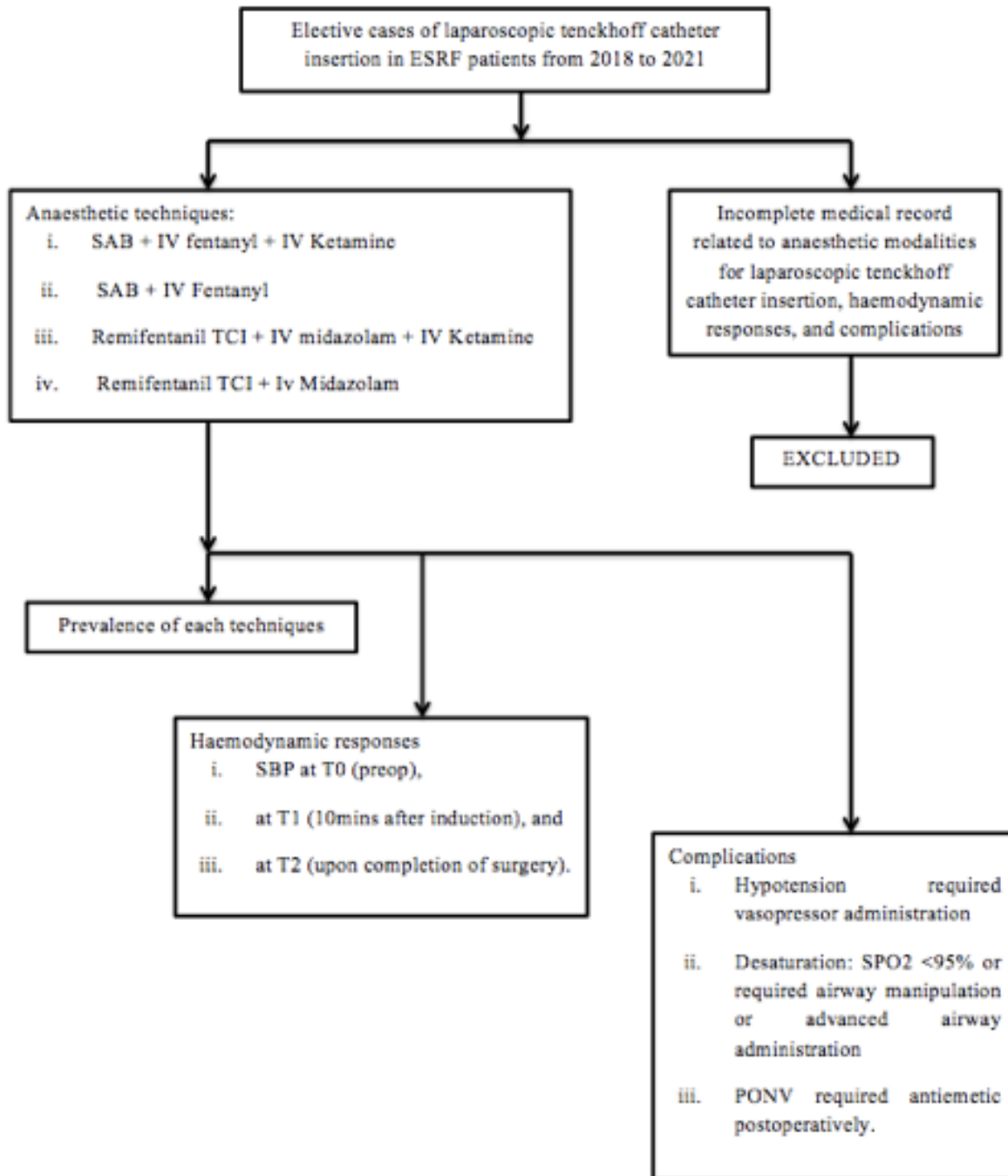
- I. Haemodynamic responses of different anaesthetic techniques: SBP at T0 (preop), at T1 (10mins after induction) and at T2 (upon completion of surgery).
- II. Hypotension required vasopressor administration (given IV ephedrine or IV phenylephrine)
- III. Desaturation  $SPO_2 < 95\%$  or required airway manipulation or advanced airway administration.
- IV. PONV required antiemetic postoperatively.

### 2.2.10 Data collection method

- The elective laparoscopic tenckhoff catheter insertion cases from Jan 2018 to December 2021 were identified using anaesthesiology operating room census.
- Analysed medical records of all the enrolled patients via electronic medical record.
- Based on these records, we obtained patients' basic demographic information, age, gender, race, height and weight.
- From these records obtained
  - i. Sociodemographic details of patients (age, gender, height, weight, race)
  - ii. Baseline investigations and premorbid status
  - iii. Anaesthetic techniques
    - i. SAB + IV fentanyl + IV Ketamine
    - ii. SAB + IV Fentanyl
    - iii. Remifentanil TCI + IV midazolam + IV Ketamine
    - iv. Remifentanil TCI + Iv Midazolam
  - iv. Haemodynamic responses of different anaesthetic techniques:
    - i. SBP at T0 (preop),

- ii. at T1 (10mins after induction), and
  - iii. at T2 (upon completion of surgery).
- v. Complications of different anaesthetic techniques.
  - i. Hypotension required vasopressor administration
  - ii. Desaturation: SPO2 <95% or required airway manipulation or advanced airway administration
  - iii. PONV required antiemetic postoperatively.
- vi. Duration of surgery

## 2.2.11 Study flowchart



### **2.2.12 Data analysis**

Data entry and analysis will be conducted in IBM SPSS version 26. Descriptive statistics will be used to summarise the socio-demographic characteristics of subjects. Numerical data will be presented as mean and standard deviation (SD) or median and interquartile range (IQR) based on their normality distribution. Categorical data will be presented as frequency and percentage (%).

For objective 1 (trend of different anaesthetic modalities for laparoscopic tenckhoff catheter insertion in ESRF patients), the proportion of each modality for each year will be determined. Four main anaesthetic modalities will be evaluated: SAB + IV fentanyl + IV Ketamine, SAB + IV Fentanyl, Remifentanil TCI + IV midazolam + IV Ketamine, and Remifentanil TCI + Iv Midazolam. The results will be presented as frequency and percentage of each modality for each year from 2018 to 2021.

For objective 2 (To compare the effectiveness of different anaesthetic modalities in providing sedation and analgesia for laparoscopic tenckhoff catheter insertion in term of haemodynamic responses), two-way repeated measures ANOVA analysis will be conducted to look into the time-effect: within group changes of SBP (pre-operative, 10 minutes after induction, and upon completion of surgery), treatment-effect: between group differences based on modalities (SAB + IV fentanyl + IV Ketamine, SAB + IV Fentanyl, Remifentanil TCI + IV midazolam + IV Ketamine, and Remifentanil TCI + Iv Midazolam) and time-treatment interaction effect. Assumption of compound symmetry will be assessed using Mauchly's test of sphericity. Greenhouse-Geisser epsilon correction will be applied if the sphericity assumption is violated. For all the three designs of the two-way RM-ANOVA, post-hoc test for multiple comparisons using Bonferroni's method will be when the overall F-test result is significant.