MASTERS IN INTERNAL MEDICINE

UNIVERSITI KEBANGSAAN MALAYSIA

DISSERTATION:

SAFETY AND EFFICACY OF 8 HOURLY NORMAL SALINE FLUSHING WITH AND WITHOUT HEPARIN LOCK IN MAINTAINING SMALL BORE INTERCOSTAL CHEST CATHETER (ICC) PATENCY ; A PROSPECTIVE PILOT STUDY

ETHICS NO : FF-2024-043

[SENSHIP TRIAL]

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LIST OF ABBREVIATION

ICC : Intercostal Chest Catheter

INR : International Normalised Ratio

PT : Prothrombin Time

aPTT : Activated Partial Thrombin Time

SBICC : Small Bore Intercostal Chest Catheter

BTS : British Thoracic Guidelines

CHAPTER 1

INTRODUCTION

1.1 Research Background

Pleural diseases are among the most common clinical problems encountered in healthcare settings in Malaysia and even worldwide. Most patients presented in a hospital setting with pleural diseases will need pleural aspirations or thoracentesis and chest drains for a variety of reasons. Healthcare providers will often be exposed to patients requiring pleural drainage hence it is important to be aware of safe techniques and procedures of insertion and also maintaining the pleural drainage systems to yield beneficial results.

Most often, smaller catheters were deemed to be less effective in view of slower drainage rates and associated with high risk of blockage. However presently , in tertiary hospital settings small bore intercostal chest catheters (SBICC) have become an alternative to large bore intercostal catheters (LBICC). SBICC has been found to be equally effective, less painful and easily tolerated by patients. [1] Hence, proper maintenance of SBICC should be undertaken to reduce rates of occlusion and to yield most benefits from the pleural aspirations procedures.

British Thoracic Society in their latest guidelines recommends the use of small bore intercostal chest drain as the first choice in draining pleural effusions.[2] However, the success of draining pleural effusions with a SBICC has shown variable rates of success among different studies conducted. [3] Most common issues faced are drain blockage and drain dislodgement.[4] Davies et al in their study suggests regular flushing with normal saline 0.9% showed remarkable reduction rates of drain blockage across the study.[5]

However, there is limited data comparing the use of normal saline flushing versus fibrinolytic drug lock in maintaining patency of small bore intercostal chest drains in draining pleural effusions. This has lead us in conducting this research to compare the rates of partial or complete occlusions among normal saline flush with and without heparin saline lock in maintaining the patency of small bore intercostal chest catheter among patients with pleural diseases in Hospital Canselor Tuanku Muhriz, UKM requiring chest drains.

CHAPTER 2

LITERATURE REVIEW

According to statistics released by Department of Statistics Malaysia, for the past 3 years, pneumonia has been on the top 3 as the leading cause of deaths among Malaysians. [6] Covid-19 infections being the majority cause of deaths reported in 2022 while Pneumonia was reported as the third cause of deaths in 2022 among others.[6] This data again shows the importance of managing pleural infections and pleural diseases to improve patient's general outcome and well-being. Pleural effusions may arise from various systemic, inflammatory, infectious, or malignant etiologies.[7] Pleural infections are among most common causes of pleural effusions that lead patients to seek medical attention in tertiary health care centers.

British Thoracic Society in their latest guideline insisted on prompt diagnosis of pleural effusions and adequate drainage of pleural fluids in symptomatic patients in order to reduce rates of morbidity and mortality among patients with parapneumonic effusions. [8] In order to achieve the best outcome in lowering mortality and morbidity, adequate drainage of pleural fluid from pleural space is the cornerstone of management. British Thoracic Society in their guideline again recommends initial drainage of pleural fluid to be undertaken with small bore intercostal chest drain. [8]

Through many literature reviews, there is no exact definition to separate between small and large bore intercostal chest catheters. However, SBICC generally referred to chest tubes with sizes <16 F and LBICC refers to sizes > 20 F.[10]

The ideal size of chest tube for management of pleural diseases still remains controversial to this day. Many recent researches conducted shows inclination of respiratory physician to use SBICC as opposed to LBICC as there are non-inferior to the outcome of LBICC. [9] Sumit M. et al , in their study showed comparable success rate in small bore and large bore groups respectively in draining pleural effusions. [10] Small bore chest tubes were found to be better tolerated by patients when compared to large bore chest tubes, in a study conducted by Sumit M. et al observed the mean duration of analgesia administered in a patient with small bore chest tubes were much less than in patients with large bore chest tubes. [10] However, SBICC were associated with higher rates of complications such as blockage, kinking of tubes and also accidental removal. Collop NA, et al in their study suggested blockage rate

of 8.1% in small bore group and 5.2% in large bore group were observed in this prospective (non-randomized) study. [11]

Growing trends in using small bore chest tubes and drainage systems among health care providers and pulmonary physicians warrants further research and studies as to minimising failures of drainage reported with the use of small bore chest tubes. The British Thoracic Society Guidelines recommends frequent and regular flushing of the tubes if small bore chest tubes are used. The guideline recommends flushing of the tube by instilling 20-30ml of Normal Saline flush every 6 to 8 hours by a three way stopcock. [8] Most tertiary health care centres follow this guideline in maintaining the patency of small bore chest tubes. However, this guideline only recommends the use of normal saline as a flush. No research has been conducted to compare the outcome of effusions drainage and rates of blockage in small bore chest tubes with different techniques of flushing.

A study done by Candice L. et al on the Safety and Efficacy of Fibrinolytics Therapy on Restoring Functions of an Obstructed Tunnelled Pleural Catheter, the study concluded that instillation of fibrinolytics through a tunnelled pleural catheter into the intrapleural space is safe and effective in restoring functions of and obstructed catheter. [12] Flushing and locking of catheter tubes has always been a practice strongly associated with catheter blockages prevention commonly practices in central venous catheter (CVC). [13] By applying the similar principle of using fibrinolytics to maintain patency of SBICC we would like to study the safety and efficacy of using heparin saline as locking solution, our aim with this study is to compare the safety and efficacy of regular 8 hourly Normal Saline flushing of SBICC with heparin saline lock versus without heparin saline lock in maintaining SBICC patency. To the best of our knowledge there is no similar study that has been conducted with head to head comparison between flushing with heparin saline lock and without heparin saline lock. This study is aptly named as SENSHIP Trial , the acronym comes from the title of the research itself - *Safety And Efficacy Of 8 Hourly Normal Saline Flushing With And Without* H*eparin Lock In Maintaining Small Bore Intercostal Chest Catheter (ICC) Patency.* We will refer to the study as SENSHIP Trial throughout the period of study and data collection.

CHAPTER 3

RESEARCH OBJECTIVES

3.1 Objectives

3.1.1 Primary

1. To compare the rate (in percentage) of partial and complete occlusions of ICC between 2 groups

3.1.2 Secondary

1. To determine the onset of ICC occlusions (in hours) from the time ICC is inserted.
2. To determine the change of blood parameters (FBC and Coagulation profile) at baseline and at 48 hours post ICC insertion.
3. To determine the associated factors of partial and complete occlusions of small-bore cathether. (Eg : Serum LDH level, exudative effusions, different sizes of ICC)
4. To determine the adverse effects of heparin saline lock.
5. To assess the number of fenestrations occluded with fibrin or blood clots after the removal of ICC.

3.1.3 Hypothesis

1. Rate of occlusion is less in group with Heparin Saline lock.
2. Rate of occlusions is higher in patients with exudative effusions.
   - Ie : Empyema, raised pleural fluid LDH, low pleural pH, positive pleural cultures.
3. Onset of ICC occlusions is lower in group with Heparin Saline lock.
4. There is no difference in blood parameters between 2 groups.
5. There are no apparent adverse effects between 2 groups.
6. Patients in group with Heparin Saline lock have lower numbers of fenestration occluded.

3.2 Significance of Research

Pleural diseases are among the most common diseases encountered in tertiary hospitals in Malaysia. Healthcare providers will need to provide adequate drainage of pleural fluids to improve the treatment outcome of patients. One of the mainstays of treatment is to ensure adequate drainage by reducing the rate of blockage of chest drains. This study is a pilot study to determine the efficacy as well as to ascertain the safety profile of using normal saline vs heparin saline lock for small bore intercostal catheters among pleural disease patients.

CHAPTER 4

RESEARCH METHODOLOGY

4.1 Type of Study

Study on the Safety and Efficacy of 8 Hourly Flushing of ICC with and without Heparin Saline Lock in Maintaining Patency of ICC (SENSHIP Trial) is a prospective open label randomized controlled trial , a pilot study of patients admitted with pleural diseases in need of small bore intercostal catheters in Hospital Canselor Tuanku Muhriz, HUKM.

4.2 Standard Of Care

Current Standard of Care in managing ICC in pleural diseases follows the recommendation of British Thoracic Society Guidelines where it suggests for regular flushing of ICC. The guideline recommends flushing of the tube by instilling 20-30ml of Normal Saline flush every 6 to 8 hours by a three way stopcock. [8] However, this guideline only recommends regular flushing with Normal Saline and no research has been conducted to compare the outcome of effusions drainage and rates of blockage in small bore chest tubes with different techniques of flushing. Despite regular flushing with Normal Saline solutions as recommended, the rate of blockages in ICC still remains high. Hence, by adapting the concept of Heparin Saline Lock in IJC to maintain the patency of the tubing, we would like to study the difference of regular 8 hourly Normal Saline flushing with and without Heparin Saline Lock in maintaining ICC. Participants in this study who are chosen into Heparin Saline Lock arm will be receiving approximately 2ml of Heparin Saline as locking solution in attempt to maintain the ICC tube.

4.3 Study Design

4.3.1 Period of Study

July 2023 until November 2026

4.3.2 Study Setting

This study will be conducted in all medical wards of Hospital Canselor Tuanku Muhriz., HUKM.

4.3.3 Sampling Population

This study will be conducted among inpatients in medical wards with pleural effusions requiring small bore intercostal chest catheters who had been screened and consented to be involved in this study. All patients will be randomly allocated into 2 groups :

a. Group without Heparin Saline Lock
b. Group with Heparin Saline Lock

The group with heparin saline lock will receive approximately 2mls Heparin Saline as a locking solution. The amount of Heparin Saline lock to be instilled will depends on the estimated catheter volume. After flushing, the catheter will be clamped for 1 hour and then unclamped after 1 hour. Data will then be collected from 2 different groups to be analysed.

4.3.4 Inclusion criteria

All patients admitted in medical wards for pleural effusion who had small bore intercostal catheters inserted.

4.3.5 Exclusion Criteria

1. Patients with hydropneumothorax with small bore intercostal catheters
2. Patients with septated effusion planned for intrapleural fibrinolysis
3. Patients with severe coagulopathy
    a. INR ε 1.5
    b. PT > 37s
    c. aPTT > 100s
4. Patients with thrombocytopenia of less than 50 x 10^9/L
5. Patients who has not consented to be involved in the study
6. Patients with indwelling pleural catheters
7. Unconscious patients will be excluded from this study
8. Patients with poor GCS score will be excluded from this study

4.3.6 Drop Out Criteria

1. Patients who had severe coagulopathy after enrollment into the study.
    a. INR ε 1.5
    b. PT > 37s
    c. aPTT > 100s

2. Patients who had developed thrombocytopenia of less than 50 x 10^9/L after enrollment into the study.
3. Patients refused to participate further into the study after enrollment.
4. Patients who develop severe bleeding due to other causes after enrollment.

4.3.7 Stop Criteria

1. Data collection will stop once ICC is removed.

4.4 Study Protocol and Data Acquisition

This is a prospective open label randomized controlled trial study of patients admitted with pleural diseases in need of small-bore intercostal catheters in Hospital Canselor Tuanku Muhriz, HUKM. This study is conducted under the Respiratory Unit, Department of Internal Medicine, HUKM. In this study, we would like to compare the rate (in percentage) of partial and complete occlusions of small bore intercostal chest catheters (SBICC) between 2 groups of patients.

All patients admitted with intercostal chest tubes will be identified. Among these patients, ones that fulfilled the inclusion criteria of this study will be recruited to participate. Those patients who had been selected to participate in the study will then be randomly allocated into 2 groups of patients. Randomization of patients into respective groups will be conducted through block randomization technique.

Informed, written consent will be taken from the patient, himself, or herself or their next of kin once they are agreeable to participate in the study. Written consent for this study will be taken prior to the insertion of the ICC for every patients. Once consented, data collection on the patient's details, demographic backgrounds will be recorded. Then, the primary team of the patients will be informed to facilitate the data collections as per protocol designed.

4.5 Operational Terms and Definition

4.5.1 Small-bore Intercostal Catheters (SBICC)

For the purpose of this study, small-bore ICC will be defined as drain size <20 F. Generally, to date, there is no fixed consensus as to differentiate between small-bore ICC and also large-bore ICC as well.

4.5.2 Large-bore Intercostal Catheters (LBICC)

Large bore Intercostal Catheter is defined as chest drain sizes >20F. Chest tubes with sizes of >20F will not be included in this study.

4.5.2 Partial Occlusions of ICC

Partial occlusions of the ICC is defined as :

- Drainage less than 150cc over 24 hours with radiological evidence of persistent pleural effusion.
- Needed manoeuvring to effectively aspirate the effusion via the ICC.

4.5.3 Complete Occlusions of ICC

Complete occlusions of ICC is defined as :

- Nil drainage of ICC over 24 hours with radiological evidence of persistent pleural effusion.
- Inability to flush the ICC

4.5.4 Change of Blood Parameters

This study is also designed to determine the outcome and side effects of heparin saline as opposed to normal saline flush with regards to change in blood parameters. Some of the blood parameters that will be paid attention in this study are :

4.5.4.1 Thrombocytopenia

Heparin is well known to cause thrombocytopenia in some patients. Sudden drop of platelets counts by 50% from baseline after 48 hours or reduction in platelet counts from baseline to less than 50×10^3 /L after 48 hours with complete resolution of platelets counts once heparin saline flush is withheld, is significant and will be taken into accounts as side effects of heparin flush. [13]

4.5.4.2 PT and aPTT Derangement

Activated partial thromboplastin time (aPTT) and prothrombin time (PT) are 2 major methods of screening patients for bleeding tendency. Heparin is an anticoagulant commonly used for various clinical conditions and will thus affect the coagulation profile. Changes in the level of PT and aPTT at the beginning of study and after 48 hours will be taken to determine the side effects of heparin and normal saline flush on the 2 different parameters.

4.6 Sample Size

Sample size is calculated using ***'Select Statistical Online Calculator'***; using 2 sample comparisons of percentages. There were no previous study comparing the efficacy and safety of Heparin Saline Lock vs Normal Saline Lock in maintaining the patency of small-bore ICC, thus the sample size calculated using the study conducted by Claire EH et al. [13] The study reported a 32% reduction in pleural fluid volume on CT over 3 days in the irrigation group compared to a 15% reduction in patients treated with chest-tube drainage alone ($p<0.04$).

Estimated sample size for two-sample comparison of percentages
Assumptions:

Alpha	=	5% (two-sided)
Power	=	80%
Intervention (Heparin)	=	32%
Standard (NS)	=	15%

Estimated sample size:

n1 (Heparin)	= 96
n2 (NS)	= 96

Missing data estimated to be 10%, therefore minimum total sample required is 212 (Intervention = 106 , Standard = 106)

However, as this is a pilot study, the estimated sample size taken for this study is 20% from the calculated sample size with missing data estimated to be 10%.
Estimated sample size :

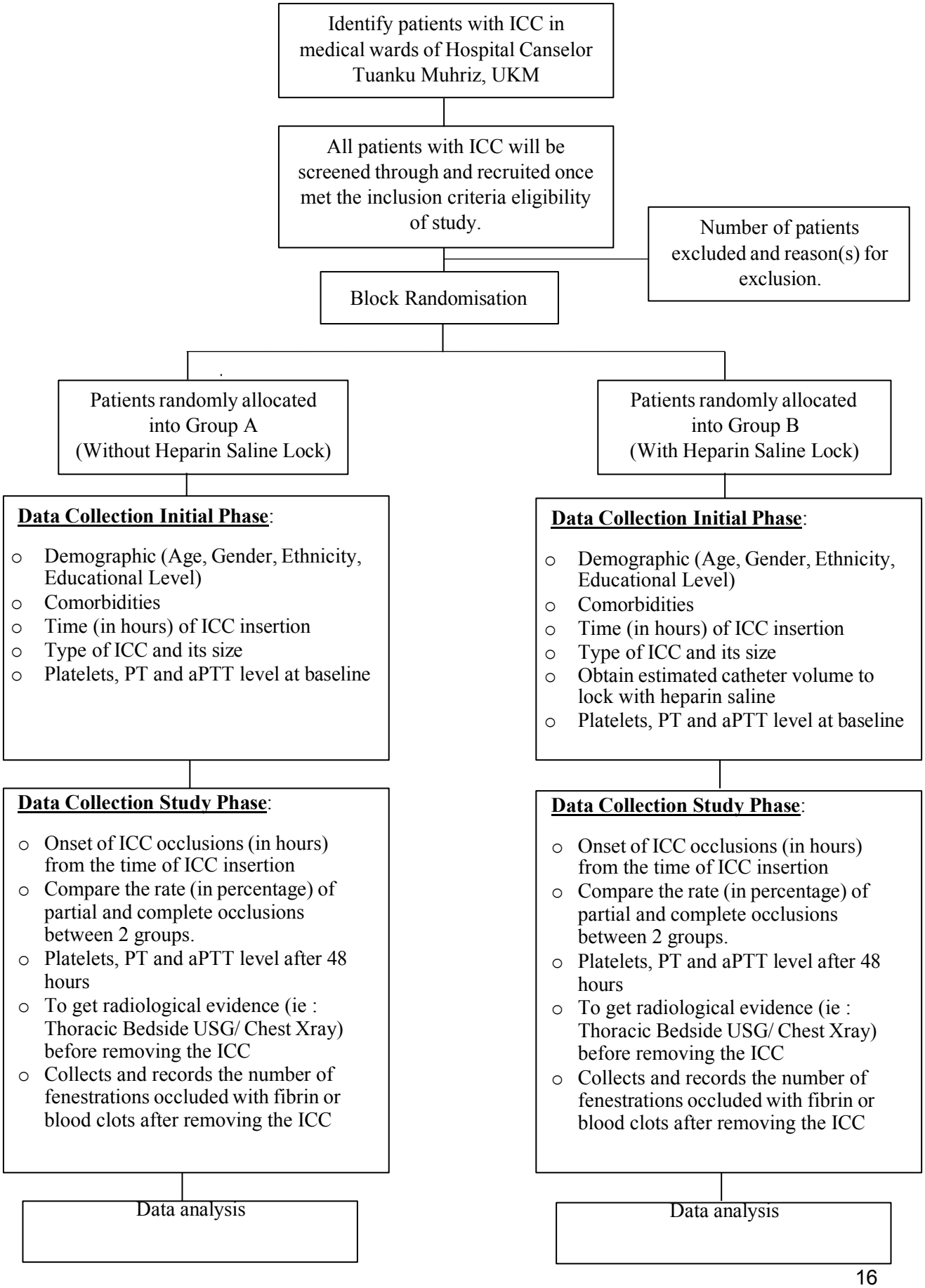
n1 (Heparin)	: 20
n2 (NS)	20

Therefore, minimum total sample needed is 40

4.5.1 Statistical Analysis

Statistical analyses will be performed with SPSS v23 software. Descriptive statistics, such as the frequency (n), arithmetic mean (x), and standard deviation (SD), are presented for normally distributed variables. A 2- sample independent test for mean and proportions will be used to calculate the statistical significance value between the 2 independent groups. Statistical significance was defined as $p<0.05$.

4.7 Data Collection Pathway



4.8 Dummy Table

Table 1: Baseline demographic data

Characteristic	Subcategory	Heparin Saline		Without Heparin Saline	
		N	%	N	%
Gender	Male				
	Female				
Ethnicity	Malay				
	Chinese				
	Indian				
	Others				
Comorbidities	Diabetes				
	Hypertension				
	IHD				
	Stroke				
	Heart failure				
	OSA				

Table 2 : Pleural Fluid Analysis

Characteristic	Heparin Saline				Without Heparin Saline			
	N	%	N	%	N	%	N	%
Exudative								
Transudative								

Table 3: Blood Parameters

Characteristic	Heparin Saline				Without Heparin Saline			
	0 hours		48 hours		0 hours		48 hours	
	N	%	N	%	N	%	N	%
Platelets								
aPTT								
PT								

Table 4: Outcome Post Removal of ICC

Characteristic	Heparin Saline		Without Heparin	
	N	%	N	%
Time of ICC Insertion				
Time of ICC Occluded : 1) Partial Occlusion				
2) Total Occlusion				
Number of fenestrations with fibrin/blood Clots				

CHAPTER 5

RESEARCH ETHICS

Approval from the Research and Ethics Committee National University of Malaysia granted with code **FF-2024-043**

CHAPTER 6

FINANCIAL PLANS

Description	Allocation per unit (RM)	Total allocation (RM)
Printing	0.2 x 10 x 110	220
Heparin Saline	*Flow Stock Items	*No extra charges applied
Total		220

CHAPTER 7

RESEARCH INFORMATION

INFORMATION SHEET FOR PATIENTS (ENGLISH VERSION)

Research title:

SAFETY AND EFFICACY OF 8 HOURLY NORMAL SALINE FLUSHING WITH AND WITHOUT HEPARIN LOCK IN MAINTAINING SMALL BORE INTERCOSTAL CHEST CATHETER (ICC) PATENCY ; A PROSPECTIVE PILOT STUDY

[SENSHIP TRIAL]

Researcher's name:

Dr Yusra binti Hashim / Associate Prof Dr Mohamed Faisal Abdul Hamid/ Dr Mas Fazlin binti Mohamad Jailaini

Place of Conduct:

Hospital Canselor Tuanku Muhriz, HUKM.

Introduction:

Pleural diseases are among the most common clinical problems encountered in healthcare settings in Malaysia and even worldwide. Most patients presented in a hospital setting with pleural diseases will need pleural aspirations or thoracentesis and chest drains for a variety of reasons. British Thoracic Society in their latest guidelines recommends the use of small bore intercostal chest drain as the first choice in draining pleural effusions. However, there is limited data comparing the use of regular 8 hourly normal saline flushing with and without heparin saline lock in maintaining patency of small bore intercostal chest drains

Purpose of study:

The main purpose of this study is to compare the rate of incomplete and complete occlusions of catheter between 2 groups. Apart from that, this study is also designed to determine the safety of using heparin saline to maintain the patency of the catheter.

Study conduct:

You will be given written consent to take part in this study. The data needed for this study will be documented and provided by ward staff and monitored directly under supervision of the doctor in charge. If you are chosen to receive the non-standard of care therapy (ie : heparin saline) , your treatment will slightly deviate from standard of care practiced in the hospital because approximately 2ml of Heparin Saline will be use as a locking solution to the catheter after each flushing.

Benefit:

Your participation in this study may assist physicians in further improvement of medical care and techniques in maintaining small bore ICC patency.

Risk:

Some side effects of regular flushing of Small Bore Intercostal Chest Catheters are mild discomfort during the procedure and some may experience slight pain while flushing. Apart from that, there is also risk of introducing infection, increment in bleeding risk and also mild shortness of breath as fluid was instilled into the pleural cavity

Participation in this study is entirely voluntary. It is your choice to participate (or allow patients to participate). Regardless of your choice, the standard quality of care and treatment remains the same. All data obtained will be recorded and will be used for analysis.

Confidentiality:

Information collected during this study will be kept confidential. Access to the data is only by the research team and Research Ethic Committee of Hospital Canselor Tuanku Muhriz, HUKM. No specific reference to any individuals will be reported in this study. Participants have the right to know the outcome of this study.

Reimbursements:

Participants do not have to pay additional cost in hospital bills. Participants will not be paid for participating in this study.

Right to Refuse or Withdraw:

This study is a voluntary basis, patients or his/her next of kin have the right to withdraw from this study. The choice is yours and all your rights will be respected.

Disclaimer :

Insertion of ICC in every patients involved in this study are for treatment purposes and not for the benefit of this research only.

Who to contact:

Dr Yusra binti Hashim (+60122838157)

Respiratory Unit, Department of Internal Medicine, Hospital Canselor Tunku Muhriz, UKM.

MAKLUMAT PENYELIDIKAN KEPADA PESAKIT (BAHASA MALAYSIA)

Tajuk Penyelidikan:

Keberkesanan dan Keselamatan Antara "Heparin Saline Lock" dan tanpa "Heparin Saline Lock" Dalam Proses Pembilasan Tiub Untuk Mengekalkan Patensi Tiub Dada Intercostal Kecil (ICC)

[SENSHIP TRIAL]

Nama Penyelidik:

Dr Yusra binti Hashim / Associate Prof Dr Mohamed Faisal Abdul Hamid/ Dr Mas Fazlin binti Mohamad Jailaini

Tempat Penyelidikan:

Hospital Canselor Tuanku Muhriz, HUKM.

Pengenalan:

Penyakit ruang rongga paru-paru adalah merupakan antara penyakit yang paling banyak ditemui oleh pengamal perubatan di fasiliti kesihatan di Malaysia bahkan seluruh dunia. Kebanyakan pesakit yang mempunyai masalah ruang rongga paru-paru memerlukan prosedur dimana cairan yang berkumpul di dalam ruang rongga paru-paru perlu dikeluarkan. Di dalam garis panduan British Thoracic Society yang terkini, pakar-pakar respiratori sepakat mengatakan bahawa penggunaan tiub rongga paru-paru bersaiz kecil adalah pilihan utama dalam perawatan pesakit. Namun, terdapat limitasi mengenai data-data menggunakan tiub rongga paru-paru bersaiz kecil apabila dibandingkan bersama.

Tujuan Penyelidikan:

Kajian ini bertujuan untuk mengetahui lebih lanjut mengenai tahap peratusan oklusi di antara 2 kumpulan yang berbeza dalam kalangan pesakit-pesakit yang dimasukkan ke wad untuk masalah ruang rongga paru paru. Selain itu, kajian ini juga bertujuan untuk menentukan tahap keselamatan pesakit yang memerlukan tiub rongga.

Kaedah Kajian:

Peserta akan diberikan boring keizinan bertulis bagi menyertai kajian ini. Semasa perjumpaan di wad perubatan, kami akan mengambil data sosiodemografik, status penyakit dan senarai ubat-ubatan dari rekod perubatan dan sesi temubual. Satu set soal selidik berkaitan kajian akan diberikan semasa perjumpaan di dalam wad. Staff di dalam ward akan diberikan set kajian mengikut ketetapan. Sekiranya anda terpilih untuk menerima rawatan klinikal dalam kajian iaitu *Heparin Saline*, kaedah rawatan akan sedikit berbeza daripada terapi piawaian yang ditetapkan. Anda akan menerima *Heparin Saline* sebanyak lebih kurang 2ml sebagai cecair pengunci kateter untuk memastikan patensi kateter lebih lama.

Kelebihan:

Penyertaan pesakit dalam kajian ini akan membantu kami untuk penambah baikan dalam rawatan perubatan pesakit yang mempunyai masalah ruang rongga paru-paru

Risiko:

Terdapat beberapa kesan sampingan daripada procedure 'flushing' ini dimana segelintir pesakit akan berasa kurang selesa dan juga berasa sakit semasa procedure dibuat. Selain itu, prosedur ini juga mempunyai risiko yang rendah di mana berkemungkinan dapat menyebabkan jangkitan, risiko pendarahan dan juga sesak nafas semasa prosedur dilakukan.

Penyertaan anda dalam kajian ini adalah secara sukarela. Ia merupakan pilihan anda untuk menyertai kajian (atau membenarkan pesakit untuk terlibat). Walau apa pun pilihan anda, segala kualiti rawatan dan perkhidmatan akan diteruskan seperti biasa. Semua maklumat yang diperolehi akan direkodkan dan akan digunakan untuk analisa.

Kerahsiaan Maklumat:

Semua maklumat yang diperolehi sepanjang anda menyertai kajian ini akan disimpan secara Rashia. Semua maklumat hanya boleh diakses oleh pasukan penyelidik dan Research Ethics Committee Hospital Canselor Tuanku Muhriz. Tiada maklumat peribadi akan dilaporkan dalam kajian ini. Anda juga berhak mengetahui hasil daripada kajian ini.

Pembayaran balik:

Tiada kos tambahan akan dikenakan sepanjang tempoh kajian berlansung. Pesakit tidak akan diberikan wang imbuhan jika menyertai kajian ini.

Hak Untuk Menarik Diri:

Proses penyelidikan ini adalah secara sukarela, pesakit ataupun waris mempunyai hak untuk menarik diri daripada kajian pada bila-bila masa sahaja. Hak anda akan dihormati.

Penafian :

Penggunaan tiub ICC di dalam kalangan pesakit yang bersetuju menyertai kajian ini adalah untuk tujuan rawatan pesakit. Penggunaan tiub ICC bukan untuk tujuan kajian semata-mata.

Sebarang masalah, sila hubungi:

Dr Yusra binti Hashim (+60122838157)

Unit Respiratori, Jabatan Perubatan Dalaman, Hospital Canselor Tuanku Muhriz, HUKM.

CHAPTER 8

INFORMED CONSENT FORM

SAFETY AND EFFICACY OF 8 HOURLY NORMAL SALINE FLUSHING WITH AND WITHOUT HEPARIN LOCK IN MAINTAINING SMALL BORE INTERCOSTAL CHEST CATHETER (ICC) PATENCY ; A PROSPECTIVE PILOT STUDY

[SENSHIP TRIAL]

I …… I/C NO: …….....

I have read and understood the 'Patient Information Sheet' attached to this 'Patient Consent Form'. Information regarding the reasons for the study, how it will be carried out and the inconveniences that are expected has been explained to me. I have been allowed to ask questions about this study and these questions have been answered to my satisfaction.

I understand that my participation in this study is voluntary and I can withdraw myself from this study at any point of time during the test. My treatment will be continued and will not be affected by my decision to not participate in this study.

I hereby allow the collected information to be analysed in the computer and the information to be forwarded to the medical authorities, if necessary. I hereby consent to participate in this study

……..
Signature / Thumbprint of patient
Name : …….
IC No : …….
Date : …….

……
Signature / Thumbprint of witness
Name : ……....
IC No : …….....
Date : ……

……...
Signature of Doctor
Name : ……
IC No : ……
Date : ……

BORANG KEIZINAN PESAKIT

SAFETY AND EFFICACY OF 8 HOURLY NORMAL SALINE FLUSHING WITH AND WITHOUT HEPARIN LOCK IN MAINTAINING SMALL BORE INTERCOSTAL CHEST CATHETER (ICC) PATENCY ; A PROSPECTIVE PILOT STUDY

[SENSHIP TRIAL]

Saya ……..... No kad pengenalan ……..

Saya telah membaca dan memahami 'Lampiran Maklumat Pesakit' yang disertakan bersama dengan borang keizinan ini. Maklumat berkenaan tujuan kajian, bagaimana kajian dilakukan dan ketidakselesaan yang mungkin dihadapi semasa kajian dilakukan telah diterangkan kepada saya. Saya dibenarkan untuk bertanya soalan mengenai kajian ini dan soalan saya telah dijawab dengan memuaskan.

Saya fahami bahawa penyertaan saya di dalam penyelidikan ini adalah secara sukarela dan saya berhak untuk keluar dari penyelidikan ini pada bila-bila masa ketika kajian dijalankan. Rawatan saya akan diteruskan dan tidak akan terjejas jika saya membuat keputusan untuk tidak menyertai kajian ini.

Saya bersetuju keputusan kajian ini dikumpulkan dan digunakan untuk analisis berkomputer dan diserahkan kepada pihak kesihatan berkenaan. Saya bersetuju untuk menyertai kajian ini.

……
Tandatangan/ Cap jari pesakit
Nama: .....
No KP: .....
Tarikh: .....

…….....	…….....
Tanda tangan saksi	Tanda tangan pegawai perubatan
Nama: ……..	Nama: …….
No K/P:	No K/P: .....
Tarikh:	Tarikh: .....

CHAPTER 9

DATA COLLECTION SHEET

Patient's sticker

Contact number: Date:

1. Demographic and comorbidities

Age ☐

Gender ☐ Male
☐ Female

Ethnicity ☐ Malay
☐ Chinese
☐ Indian
☐ Others: _____

Comorbidities ☐ Diabetes mellitus
☐ Hypertension
☐ Ischemic heart disease
☐ Heart failure
☐ OSA
☐ Previous stroke
☐ Others: _____

2.

pH	
LDH	

Pleural Fluid Analysis

Size of ICC : ☐

3. Timing of ICC Insertion and Removal

	Time	**(Hours)**
Time of Insertion		
Time of Partial Occlusion		
Time of Total Occlusion		
Time of Removal		

4. Blood Parameters

	0 hours	**48 hours**
Platelets		
aPTT		

PT			Patient sticker here

Chest Drain Observation Chart

Drain Side: ☐ **R** ☐ **L**

- Please use one chart for each drain
- Total cumulative drainage **MUST** also be recorded on the **Fluid Balance Chart**
- Any variance requires mandatory medical officer (MO) review AND documentation in progress notes
- All bottle changes or flushing should be recorded by a line and descriptor across the observation chart row.

EQUIPMENT REQUIRED :

- Sterile gloves
- Disposable Dressing Set
- Sterile 0.9% Sodium Chloride and Heparin Saline 10IU/mL
- 20 ml Syringe and 3ml Syringe
- Chlorhexidine solutions
- Gauze / Cotton
- Sterile red bung to cap 3 way tap

INSTRUCTIONS :

1) Check patient prescription sheet regarding type of chest drain lock.
    a. **Without Heparin Saline**
    b. **With Heparin Saline**
2) Identify patient and reconfirm with patient's wrist tag.
3) Explain the procedure to the patient.
4) Wash hands and put on disposable gloves and apron.
5) Clean and prepare procedure tray
6) For **Group A** :

    - Draw up 20 mls sterile 0.9% Sodium Chloride
    - Turn 3 way tap to closed position to outside air
    - Remove red cap and clean entry port on 3 way tap with chlorhexidine solution
    - Attach sterile syringe to open port and turn to open position (close the drain bottle port)
    - Slowly administer 0.9% Sodium Chloride and observe the entry into the cathethers
    - Aspirate the volume of flush given and record total aspirate volume in the observation sheet.
    - Leave the catheter unclamp and record the total drainage volume

7) For **Group B** :

    - Draw up 20mls sterile 0.9% Sodium Chloride
    - Turn 3 way tap to closed position to outside air
    - Remove red cap and clean entry port on 3 way tap with chlorhexidine solution
    - Attach sterile syringe to open port and turn to open position (close the drain bottle port)
    - Slowly administer 0.9% Sodium Chloride and observe the entry into the catheter
    - Aspirate the volume of flush given and record total aspirate volume in the observation sheet
    - Administer 2 mls of Heparin Saline as locking solution and recap

- Clamp the catheter subsequently and unclamp after 1 hour, record the total drainage volume

Date	Time	Operator Name (HO/MO)	Flushing Volume (mL)	Aspirate Volume (mL)	Drainage Volume (mL)	Lock Volume (mL)

Frequency of chest drain observations : **<u>8 hourly</u>**

Cumulative total drainage (this chart) _____

CHAPTER 10

GANTT CHART

Progression/Timeline	January 2023-March 2023	March 2023-August 2023	August 2023-March 2024	March 2024-October 2025	November 2025-May 2026
Literature review and proposal write up					
Proposal submission and correction					
Presentation to ethics committee and approval					
Patient recruitment and conduction of study					
Statistical analysis and preparation of result					
Manuscript writing and submission					

CHAPTER 11

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