

**Povidone-soaked Sutures versus Ordinary Sutures for  
Reducing Surgical Site Infection: Randomise Control  
Trial Study in General Surgery Cases of  
Hospital Universiti Sains Malaysia**

**Dr Siti Hafzan Bt Abd Karim**  
MD (WARSAW, POLAND)

DISSERTATION SUBMITTED IN PARTIAL FULFILMENT OF THE  
REQUIREMENTS FOR THE DEGREE OF MASTER OF MEDICINE  
(GENERAL SURGERY)



UNIVERSITI SAINS MALAYSIA  
NOVEMBER 2021

## ACKNOWLEDGEMENT

Firstly, I would like to express my deepest gratitude to my research supervisor Dr Ahmad Zuhdi Mamat, for guiding me throughout the writing of this thesis. I benefited from his guidance and insight at various stages of my writing. His vision, motivation and sincerity have inspired me to complete this thesis. I would also like to thank Dr Shahrulsalam Mohd Shah (co-supervisor), who has shared his wisdom in assisting me in completing my study and Mr Azmi as a statistician analysing the data.

I also owe a special thanks to all the staff working in the general operation theatre and ward for assisting me in completing this study. They have given me their kind cooperation and warmest help throughout my research. I am indebted to them for their assistance.

Finally, I am grateful to my parents and family for their support and encouragement in writing this thesis and for believing in me no matter what I am working on. In particular, I want them to know that I love them.

# TABLE OF CONTENTS

LIST OF TABLE AND FIGURES	V-VI
LIST OF ABBREVIATIONS	VII
ABSTRAK (IN BAHASA MALAYSIA)	1-2
ABSTRACT	3-4
CHAPTER 1: INTRODUCTION	5-7
CHAPTER 2: STUDY PROTOCOL	
2.1 Documents submitted for ethical approval	9-71
2.2 Ethical approval letter	72-74
CHAPTER 3: MANUSCRIPT	
3.1 Title, Authors, and affiliations	75
3.2 Abstract	
3.2.1 Introduction	76
3.2.2 Objective	76
3.2.3 Methodology	76
3.2.4 Results	77
3.2.5 Conclusion	77
3.2.6 Trial registration	77
3.2.7 Funding	77
3.3 Introduction	78-81
3.4 Methodology	
3.4.1 Study design	81
3.4.2 Inclusion and exclusion criteria	81-82
3.4.3 Concealment, randomisation	82-85

3.4.4 Sample size calculation	85
3.4.5 Data analysis	86
3.5 Results	87- 108
3.6 Discussion	109- 116
3.7 Conclusion	116
3.8 References	117- 119
<b>CHAPTER 4: APPENDICES</b>	
4.1 Raw data in SPSS	120
4.2 Photos of wound	121

## LIST OF TABLES AND FIGURES

<b>Figure 1</b>	CONSORT flowchart for participant recruitment and randomisation	87
<b>Figure 2</b>	Wound over the chest, post coronary artery bypass graft	121
<b>Figure 3</b>	Wound over forearm post arteriovenous fistula creation	121
<b>Figure 4</b>	Wound over lower limb post coronary artery bypass graft	121
<b>Figure 5</b>	Wound over lower limb post coronary artery bypass graft	121
<b>Table 1</b>	Demographic summary of Participants	88
<b>Table 2</b>	Clinical summary of Participants	89
<b>Table 3</b>	Surgical Procedure involving Operation Site, Prophylactic Antibiotic, Biochemical Parameter, Wound-related Features and Surgical Classification Summary	90
<b>Table 4</b>	Wound Finding Characteristics at D10 and D30	91-92
<b>Table 5</b>	Demographic Comparison between Povidone-soaked Sutures and Ordinary Sutures	92
<b>Table 6</b>	Clinical Characteristic comparison between sutures	93
<b>Table 7</b>	Surgical Procedure Comparison between Povidone-soaked Sutures and Ordinary Sutures	94-95
<b>Table 8</b>	Comparison of Surgical Site Infection at D10 and D30 between Povidone-soaked sutures and Ordinary Sutures	95
<b>Table 9</b>	Comparison of Surgical Site Infection Characteristic at D10 and D30 between Povidone-soaked sutures and Ordinary Sutures	96
<b>Table 10</b>	Comparison of Surgical Site Infection Intervention at D10 and D30 between sutures	97

<b>Table 11</b>	Association between demographic and SSI at D10	98
<b>Table 12</b>	Association between clinical characteristic and SSI at D10	98-99
<b>Table 13</b>	Association between surgical procedure characteristics and SSI at D10	99-100
<b>Table 14</b>	Association between demographic and SSI at D30	100
<b>Table 15</b>	Association between clinical characteristic and SSI at D30	101
<b>Table 16</b>	Association between surgical procedure characteristic and SSI at D30	102
<b>Table 17</b>	Demographic comparison between type of suture and Surgical Site Infection at D10 (n = 136)	103
<b>Table 18</b>	Clinical Characteristic comparison between type of suture and Surgical Site Infection at D10 (n = 136)	104
<b>Table 19</b>	Surgical procedure comparison between type of suture and Surgical Site Infection at D10 (n = 136)	105
<b>Table 20</b>	Demographic comparison between type of suture and Surgical Site Infection at D30 (n = 136)	106
<b>Table 21</b>	Clinical Characteristic comparison between type of suture and Surgical Site Infection at D30 (n = 136)	107
<b>Table 22</b>	Surgical procedure comparison between type of suture and Surgical Site Infection at D30 (n = 136)	108

## LIST OF ABBREVIATIONS

<b>ASA</b>	American Society of Anaesthesiology classification
<b>ACS</b>	Antibiotic Coated Suture
<b>BMI</b>	Body Mass Index
<b>CDC</b>	Centers for Disease Control
<b>HUSM</b>	Hospital Universiti Sains Malaysia
<b>IQR</b>	Interquartile range
<b>JEPeM</b>	The Human Research Ethics Committee of USM
<b>RCT</b>	Randomised Control Trial
<b>SD</b>	Standard deviation
<b>SOPD</b>	Surgical Out Patient Department
<b>SSI</b>	Surgical Site Infection
<b>WBC</b>	White Blood Cell
<b>WHO</b>	World Health Organization

# ABSTRAK

Benang Jahitan Rendaman Povidon dan Benang Jahitan Biasa bagi Mengurangkan Jangkitan di Kawasan Pembedahan: Kajian Terkawal Rawak bagi Kes Pembedahan Am Hospital Universiti Sains Malaysia

## Abstrak

### Pengenalan

Benang jahitan pembedahan digunakan untuk menutup kebanyakan jenis luka. Benang jahitan ideal membolehkan tisu pulih secukupnya dan memastikan luka tertutup apabila ia dibuang atau diserap. Benang jahitan menyebabkan jangkitan di kawasan pembedahan (SSI) kerana 66% SSI berkaitan dengan insisi. Benang jahitan pembedahan bersalut yang dilaksanakan pada tahun 2002 telah dilesenkan dan digunakan dengan meluas. Povidon-iodin telah dibuktikan membunuh strain rintang Methicillin *Staphylococcus aureus* dan strain rintang antibiotik yang lain.

### Objektif

Objektif am adalah menentukan keberkesanan penggunaan benang jahitan yang direndam povidon selama 3 minit untuk mengurangkan SSI semasa menutup luka.

Objektif khusus adalah mengukur kadar SSI antara benang jahitan rendaman povidon dan benang jahitan biasa serta menentukan tahap intervensi yang diperlukan untuk SSI bagi setiap kumpulan.



## **Reka Bentuk/Peserta/Kriteria/Metodologi**

Kajian terkawal rawak ini bersifat buta tunggal dan memenuhi kriteria inklusi, seperti berumur lebih 12 tahun, pembedahan bersih atau bersih tercemar, dan dijadualkan untuk pembedahan elektif. Urutan kod rawak dijana oleh komputer, dan urutan pengagihan dimasukkan ke dalam sampul surat legap dan dinomborkan secara berturutan. Kod ini menentukan sama ada penutupan luka dilakukan menggunakan benang jahitan rendaman povidon atau benang jahitan biasa. Keadaan pesakit dinilai pada hari kesepuluh (D10) dan hari ke-30 (D30) melalui panggilan telefon atau mesej yang diberikan.

## **Keputusan**

Seramai 140 pesakit dirawakkan dan 136 pesakit dianalisis antara kedua-dua kumpulan. Purata umur pesakit ialah 50.80 tahun, dan purata BMI pesakit ialah 25.04 kg. SSI berlaku dalam kumpulan tujuan merawat bagi 18 (13.2%) daripada keseluruhan 134 pesakit pada rawatan susulan D10. Kumpulan pesakit bagi benang jahitan rendaman povidon mempunyai kadarjangkitan luka yang sedikit tinggi manakala risiko untuk dijangkiti tidak signifikan. Nisbah risiko untuk dijangkiti pada D10 selepas pembedahan bagi benang jahitan rendaman povidon ialah 1.67 (95% selak keyakinan = 0.68, 4.04) dan pada D30 selepas pembedahan ialah 2.12 (95% selak keyakinan = 0.67, 6.71).

## **Kesimpulannya**

Jahitan rendaman povidon tidak mengurangkan kadar SSI berbanding jahitan biasa.

# ABSTRACT

Povidone-soaked Sutures versus Ordinary Sutures for Reducing Surgical Site Infection: Randomised Control Trial Study in General Surgery Cases of Hospital Universiti Sains Malaysia

## **Abstract**

### **Introduction**

Surgical suture materials are used in the closure of most wound types. The ideal suture should allow the healing tissue to recover sufficiently to keep the wound closed together once removed or absorbed. The suture material contributes to SSIs because 66% of SSIs are related to the incision. The coated surgical suture was implemented in 2002 and has been licensed and widely used. Povidone-iodine has been shown to kill methicillin-resistant *Staphylococcus aureus* and other antibiotic-resistant strains.

### **Objective**

The general objective is to determine the efficacy of using a 3-minute povidone-soaked suture to reduce surgical site infection during wound closure.

The specific objective is to measure the surgical site infection rate between the povidone-soaked suture and ordinary suture and determine the extent of intervention needed for surgical site infection in each group.

### **Design/Participants/Criteria/Methodology**

This randomised control trial, single-blinded, fulfils inclusion criteria such as age over 12 years old, clean or clean-contaminated surgery, and scheduled for elective surgery. The

randomisation sequence was computer-generated, and the allocation sequence was sealed in sequentially numbered and opaque envelopes. The code will determine whether the suture is povidone-soaked or an ordinary braided suture for wound closure. The patient's well-being was assessed on day ten and day 30 via phone calls or messages that had been provided.

## **Result**

140 patients were randomised, and 136 patients were analysed between both groups. Their mean age was 50.80 years old, and their mean BMI was 25.04kg. SSIs occurred in the intention to treat group in 18 (13.2%) of the total 134 patients on D10 follow up in this study. The povidone-soaked suture group had a slightly higher proportion of infected wounds, the risk of getting infected was not significantly higher. The risk ratio of getting infected at D10 postoperative for povidone-soaked suture was 1.67 (95% CI=0.68, 4.04), and at D30 postoperative was 2.12 (95% CI=0.67, 6.71).

## **Conclusion**

Povidone-soaked sutures do not reduce the occurrence rate of SSIs compared with ordinary sutures.

## **Trial Registration**

Clinicaltrial.gov. Identifier: NCT05090176

## **Funding**

Partially funded Universiti Sains Malaysia

## **Keywords**

Suture, povidone, surgical site infection

## **CHAPTER 1**

### **INTRODUCTION**

Surgical site infections (SSIs) are the second most common cause of hospital-acquired infection in Europe and the United States of America, with higher rates in low-income countries. SSIs are preventable yet continue to result in significant financial burden due to more extended postoperative hospital stays additional surgical procedures, treatment in intensive care units and higher mortality (1). Prevention of SSIs is a multifactorial process, beginning preoperatively continuing to postoperative care, relying on a multidisciplinary team engaging in good theatre etiquette and the administrative process and quality improvement (2).

In 2016, the World Health Organization (WHO) released international guidelines to tackle SSIs. Twenty-six individual recommendations were published within the guidelines covering preoperative, intraoperative, and postoperative practice. With the publication of a robust set of WHO guidelines, one might expect SSI rates to decrease following 2016 (2).

The suture material contributes to SSIs because 66% of SSIs are related to the incision. Microorganisms adhere to the non-shedding surface of the suture and form biofilms. The presence of foreign material in the wound enhances the patient's susceptibility to infection (3).

Surgical suture materials are used in the closure of most wound types. The ideal suture should allow the healing tissue to recover sufficiently to keep the wound closed together once removed or absorbed. Broadly, sutures can be classified into absorbable or non-absorbable materials. They can be further sub-classified into synthetic or natural sutures and monofilament or multifilament sutures. The ideal suture is the smallest possible to produce uniform tensile strength, securely hold the wound for the required time for healing, then be absorbed. It should be predictable, easy to handle, have a minimal reaction, and knot securely.

The monofilament suture is a single-stranded filament suture, which they have a lower infection risk and have poor knot security and ease of handling. Whereby multifilament suture is made of several filaments twisted together (e.g. braided silk or vicryl), which are easy to handle and hold their shape for good knot security yet can harbour infections.

The healing of the postoperative wound infection is a complicated process that may retard normal wound healing and induce life-threatening situations. Recent studies have been focusing on designing antibiotic-coated sutures to minimise the risk factors of infections. Antibiotic-coated sutures are demonstrated to have antibacterial efficacy using in vitro laboratory tests, in vivo animal experiments, as well as clinical studies (4)

The US Food and Drug Administration approved the first coated surgical suture in 2002, coated with antimicrobial polyglactin 910. Since then, various triclosan-coated sutures have been licensed and widely used, including triclosan-coated poliglecaprone 25 antimicrobial suture and triclosan-coated polydioxanone antimicrobial suture (5).

Properties of an ideal antiseptic include a broad spectrum of activity, the ability to penetrate biofilms, necrotic tissue, and eschar, a low potential for acquired resistance, supportive effects for wound healing by impeding excessive inflammation good local tolerability. Few antiseptics remain relevant for the prevention and treatment of infection in wound care. These include iodine carriers with polyvinylpyrrolidone iodine (povidone) and silver, chlorhexidine, benzalkonium chloride, triclosan, octenidine, and polyhexanide and selected dyes such as eosin (6).

Antisepsis refers to the process of reducing or inhibiting the growth of microorganisms on the skin or mucous membranes. Products of antisepsis are called antiseptics. Interventions to prevent and reduce the risk of SSIs can be classified broadly into three periods: preoperative,

intraoperative, and postoperative. Safe practice in antisepsis and skin preparation is vital during this perioperative journey to reduce the risk of SSIs (7).

Povidone-iodine is a chemical complex of polyvinylpyrrolidone and elemental iodine. Free iodine is gradually released from this complex and is chemically toxic to microorganisms. This antiseptic provides broad-spectrum bactericidal activity at a low cost and minimal toxicity (8). In antimicrobial testing, povidone-iodine has been shown to kill methicillin-resistant *Staphylococcus aureus* and other antibiotic-resistant strains within 20-30 seconds of exposure (8). A study also proved the in vitro polymicrobial efficacy of povidone-iodine against *Staphylococcus epidermidis*, *Hemophilus influenza*, *Pseudomonas aeruginosa*, *Burkholderia cepacia*, and *Escherichia coli* (9).

Various studies in vitro and in vivo showed that triclosan-coated sutures interfere with microbial lipid synthesis and subsequently attenuate bacterial growth and colonisation in broad-spectrum patients. In our hospital, povidone-iodine has been widely used as skin preparation perioperatively, wound irrigation for acute and chronic wound and intraoperative irrigation, and wound irrigation before skin closure. However, this study uses ordinary absorbable sutures soaked with povidone instead of antiseptic coated suture such as triclosan-coated sutures. It is mainly to determine the efficacy of reducing SSIs rate non-povidone-soaked ordinary absorbable suture and assess the extent of intervention needed for SSIs.

## **CHAPTER 2**

### **STUDY PROTOCOL**

#### **2.1 DOCUMENT SUBMITTED FOR ETHICAL APPROVAL**

# **Povidone-soaked Sutures versus Ordinary Sutures for Reducing Surgical Site Infection: Randomise Control Trial Study in General Surgery Cases of Hospital Universiti Sains Malaysia**

Dr Siti Hafzan Bt Abd Karim

P-UM 0046/18

Department of Surgery

Health Campus University Science Malaysia (USM)

Supervisor:

Dr Ahmad Zuhdi B Mamat

Co-supervisor:

Dr Mohd Shahrulsalam B Mohd Shah

## **Introduction**

Surgical site infections (SSIs) are the second most common cause of hospital-acquired infection in Europe and the United States of America, with higher rates in low-income countries. SSIs are preventable yet continue to result in significant financial burden due to more extended postoperative hospital stays, additional surgical procedures, treatment in intensive care units and higher mortality (1). Prevention of SSIs is a multifactorial process, beginning preoperatively continuing through to postoperative care, relying on a multidisciplinary team engaging in good theatre etiquette and with the administrative process and quality improvement (2).

In 2016, the World Health Organization (WHO) released a set of international guidelines to tackle SSIs. Twenty-six individual recommendations were published within the guidelines covering preoperative, intraoperative, and postoperative practice. With the publication of a robust set of WHO guidelines, one might expect SSI rates to decrease following 2016 (2).

The suture material is a contributory factor in SSIs because 66% of SSIs are incision-related. Microorganisms adhere to the non-shedding surface of the suture and form biofilms. The presence of foreign material in the wound enhances the patient's susceptibility to infection (3).

Surgical suture materials are used in the closure of most wound types. The ideal suture should allow the healing tissue to recover sufficiently to keep the wound closed together once they are removed or absorbed. Broadly, sutures can be classified into absorbable or non-absorbable materials. They can be further sub-classified into synthetic or natural sutures, and monofilament or multifilament sutures. The ideal suture is the smallest possible to produce



uniform tensile strength, securely hold the wound for the required time for healing, then be absorbed. It should be predictable, easy to handle, have a minimal reaction, and knot securely.

The monofilament suture is a single-stranded filament suture, which they have a lower infection risk and have poor knot security and ease of handling. Whereby multifilament suture is made of several filaments twisted together (e.g. braided silk or vicryl) that are easy to handle and hold their shape for good knot security yet can harbour infections.

The healing of the postoperative wound infection is a complicated process that may retard normal wound healing and induce life-threatening situations. To minimise the risk factors for wound infections, recent studies have focused on designing antibiotic-coated sutures. Antibiotic-coated sutures are demonstrated to have antibacterial efficacy using in vitro laboratory tests, in vivo animal experiments, as well as clinical studies (4).

The US Food and Drug Administration approved the first coated surgical suture in 2002, which was coated with antimicrobial polyglactin 910. Since then, various triclosan-coated sutures have been licensed and are widely used, including triclosan-coated poliglecaprone 25 antimicrobial suture and triclosan-coated polydioxanone antimicrobial suture (5).

Properties of an ideal antiseptic include a broad spectrum of activity, the ability to penetrate biofilms, necrotic tissue, and eschar, a low potential for acquired resistance, supportive effects for wound healing by impeding excessive inflammation good local tolerability. Few antiseptics remain relevant for the prevention and treatment of infection in wound care. These include

iodine carriers with polyvinylpyrrolidone iodine (povidone) and silver, chlorhexidine, benzalkonium chloride, triclosan, octenidine and polyhexanide and selected dyes such as eosin (6).

Antisepsis refers to the process of reducing or inhibiting the growth of microorganisms on the skin or mucous membranes. The product of antisepsis is called antiseptics. Interventions in preventing and reducing the risk of SSIs can be classified broadly into three periods: preoperative, intraoperative, and postoperative. Safe practice in antisepsis and skin preparation is vital during this perioperative journey to reduce the risk of SSIs (7)

Povidone-iodine is a chemical complex of polyvinylpyrrolidone and elemental iodine. Free iodine is gradually released from this complex and is chemically toxic to microorganisms. This antiseptic provides broad-spectrum bactericidal activity at a low cost and minimal toxicity (8) In antimicrobial testing, povidone-iodine has been shown to kill methicillin-resistant *Staphylococcus aureus* and other antibiotic-resistant strains within 20-30 seconds of exposure (8). A study also proved that in vitro polymicrobial efficacy of povidone-iodine against *Staphylococcus epidermidis*, *Hemophilus influenza*, *Pseudomonas aeruginosa*, *Burkholderia cepacia*, and *Escherichia coli* (9).

Various studies conducted in vitro and in vivo have shown that triclosan-coated sutures interfere with microbial lipid synthesis and subsequently attenuate bacterial growth and colonisation in broad-spectrum patients. In our hospital, povidone-iodine has been widely used as skin preparation perioperatively, wound irrigation for acute and chronic wound and

intraoperative irrigation, and as wound irrigation before skin closure. However, in this study, we are using ordinary absorbable sutures soaked with povidone instead of antiseptic coated suture such as triclosan-coated suture to determine the efficacy in reducing SSIs rate comparing with non-povidone soaked ordinary absorbable suture mainly and to determine the extent of intervention needed for SSIs.

## **Literature review**

Most literature reviews showed that coated sutured with an antimicrobial reduces surgical site infection. Standard practice in Hospital Universiti Sains Malaysia during subcutaneous closure uses absorbable braided sutures such as vicryl, which is uncoated by an antimicrobial. Instead of purchasing the ready-made coated suture by antimicrobial as mentioned in most of the literature, we use povidone-iodine, a solution proven to kill methicillin-resistant *Staphylococcus aureus* and other antibiotic-resistant strains.

A systematic review regarding the prevalence of SSIs in clean and clean-contaminated surgeries by *D. Curcio et al.* in 2019 found that SSIs in the developing world is higher than in the developed world.

*C. Edmiston et al.*, 2006 did a study to evaluate the adherence of bacterial isolates to both sutures and the duration of antimicrobial activity of triclosan-coated sutures. They used an uncoated polyglactin 910 braided suture and triclosan-coated suture to compare. The result showed a reduction in gram-positive and gram-negative bacterial adherence on triclosan-coated sutures, and the antibacterial activity persisted for at least 96 hours.

In 2013, a study by *C Justinger et al.* used a PDS loop and triclosan-impregnated PDS suture for abdominal closure. It was a multicentre randomised control trial involving 856 samples. After two weeks of follow-up the patients showed that triclosan-impregnated suture decreased wound infection.

Multiple randomised control trials have been done for the past ten years. *M. Diener et al., 2014* did a multicentre study between PDS II and PDS II plus suture during abdominal fascial closure. Still, the result showed no significant reduction in SSIs within 30 days of follow-up.

*M. Renko et al., 2016* did a study in a single centre with a sample size of 1633 between the ordinary suture and triclosan-containing suture during wound closure of clean and clean-contaminated surgery. Results showed that triclosan-containing sutures reduced SSIs in children on day 30 of follow-up.

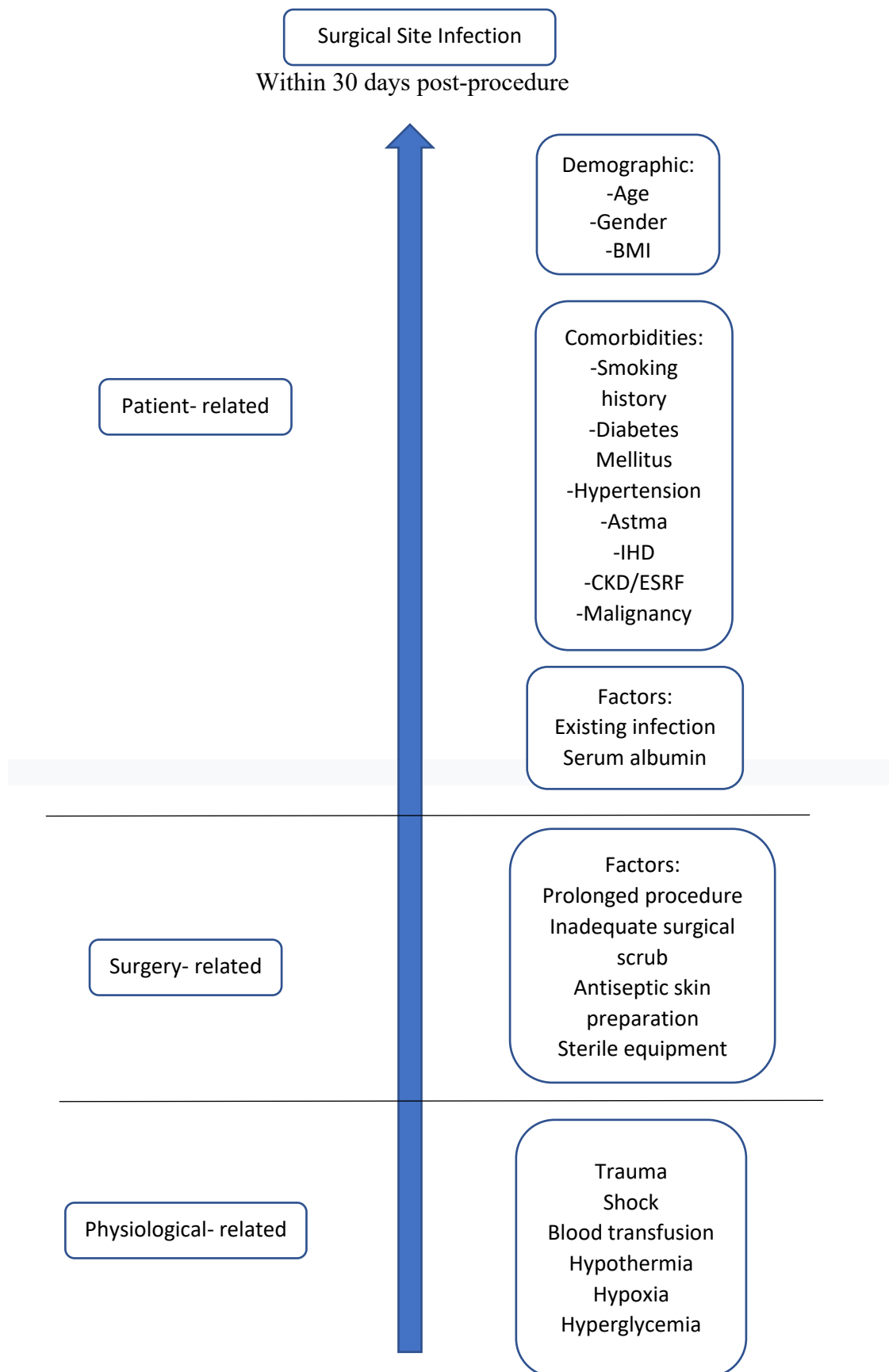
A recent study in 2020 by *J Ruiz Tovar et al.* published a multicentric randomising control trial regarding fascial closure of the abdominal wound with 150 patients involved. In this study, they used a stratafix, PDS and PDS plus suture during the closure, and the result showed triclosan-coated suture reduced incidence of SSIs.

A retrospective study done by *K. Yamashita et al.* in 2016 in a single centre used a conventional method and PDS plus for fascia and skin closure of the abdominal wound. The result showed that the incidence of SSIs is less in the study group, which is PDS plus.

*J. Guo et al.* published a metaanalysis study of 5256 sample size in the year 2016 regarding an uncoated suture and triclosan-coated suture. The result showed triclosan antimicrobial coated suture was associated with a decrease in SSIs in a selected patient population.

A systematic review was done by *P. Bigliardi et al.* regarding the preclinical and clinical safety and efficacy of using povidone-iodine in wound healing and its implications for controlling infection and inflammation. This study involved multicentre in many countries. The results showed povidone-iodine has a wound-healing characteristic, broad antimicrobial spectrum, lack of resistance, efficacy against biofilm, good tolerability and good effect on excessive inflammation.

## Conceptual Framework



## **Problem statement & Study rationale**

Multiple studies have proven that antimicrobial coated sutures may reduce surgical site infection. Povidone-iodine is widely used in our hospital for perioperative skin preparation for antiseptic purposes following World Health Organization (WHO) and Centers for Disease Control (CDC) guidelines. However, there is no previous study about povidone-soaked sutures in surgical practices. It is cost-effective because of the availability in our hospital, and the equipment needed is used regularly. This study aims to assess the effectiveness of povidone-soaked sutures in reducing SSIs rate compared to ordinary sutures and determine the required intervention if SSIs occur.

## **Research Question(s)**

1. Is there any difference in outcome using povidone-soaked suture and ordinary suture?
2. Is there any association between the povidone-soaked suture and ordinary suture in reducing surgical site infection rate?
3. What is the extent of intervention taken in managing SSIs?

## **Objectives**

General objective: 1) To determine the efficacy of using 3 minutes povidone-soaked suture in reducing surgical site infection during wound closure.

Specific objective: 1) To measure surgical site infection rate between the povidone-soaked suture and ordinary suture.

- 2) To determine the extent of intervention needed for surgical site infection in each group.

## **Research hypothesis**

### First Hypothesis

H1: There is a difference in outcome using povidone-soaked sutures and ordinary sutures.

H0: There is no difference of outcome using povidone-soaked suture and ordinary suture

### Second Hypothesis

H2: There is an association between the povidone-soaked suture and ordinary suture in  
reducing surgical site infection.

H0: There is no association between the povidone-soaked suture and ordinary suture in  
reducing surgical site infection.

### Third hypothesis

H3: There is a difference in the extent of intervention needed to manage SSIs in wounds closed  
with povidone-soaked suture and ordinary suture.

H0: There is no difference in the extent of intervention needed to manage wounds closed  
with povidone-soaked suture and ordinary suture.



## **Methodology**

### **Research design**

Randomise Control Trial, single-blinded

Independent two groups comparison

Control group: Ordinary absorbable suture (non-coated suture)

Study group: Povidone-soaked absorbable suture (suture soak in the povidone-iodine solution for 3 minutes before wound closure)

### **Study area**

Hospital Universiti Sains Malaysia

This tertiary hospital receives patients within its proximity and from 2 district hospitals: Hospital Besut, Terengganu and Hospital Tengku Anis, Pasir Puteh, Kelantan.

### **Operational definition**

Surgical site infection can be divided into two based on Centres for Disease Control (CDC): superficial and deep wound infection. Superficial SSI is defined as occurring within thirty days after surgical procedure, involving only skin and subcutaneous tissue around the incision and at least one of the following signs and symptoms of purulent drainage, organism isolated by culture, pain or tenderness, localised swelling, redness or incision open by surgeon or physician.

Deep SSIs are defined as occurring within thirty days after surgical procedure and related to the procedure and involve deep soft tissues such as fascia or muscle plus at least one of the signs and symptoms of purulent drainage from the incision but not from organ or space of the surgical site, dehiscence of deep incision or wound open by the surgeon due to pain, abscess or evidence of infection.

American Society of Anesthesiology (ASA) classification score can be divided into 4 which are 1 is normal healthy patient, 2 is patient with mild systemic disease, 3 is a patient severe systemic disease, 4 is patient with severe systemic disease that is the constant threat to life, and 5 is a moribund patient who is not expected to survive without the operation. A patient who has an ASA score of more than 2 is considered to have high mortality.

Clean surgery is typically an elective surgery in a non-contaminated, non-traumatic and non-inflamed surgical site.

Clean-contaminated surgery involves respiratory, gastrointestinal, or genitourinary systems, for example, hollow organs.

## **Study population**

Reference population: General surgery patients at the outpatient clinic (SOPD).

Emergency Department patients who get admitted for surgery.

General Surgery ward patients of Hospital Sains Malaysia.

Target population : Patients who are planning for surgery.

Source of population : Patients who are planned for surgery from 1 January 2021 until 30 September 2021

Sampling frame : Patients who are planned for surgery from 1 January 2021 until 30 September 2021 who fulfil study criteria.

## **Subject criteria**

Inclusion criteria:

1. Age more than 12 years old
2. Clean surgery or Clean- contaminated surgery
3. Elective surgery

Exclusion criteria:

1. Age less than 12 years old
2. Contaminated wound
3. Dirty wound
4. Allergy to povidone-iodine
5. Pregnant

6. Laparoscopic

7. Emergency surgery

Withdrawal criteria: 1. The case was selected based on inclusion criteria but intraoperatively an exclusion criterion has been established.

### **Sample size estimation**

The sample size is calculated by using PS software.

The confidence interval is 95%

The power of the study is 80%

$\alpha$  (two tailed) = 0.05      *Threshold probability for rejecting the null hypothesis. Type I error*

$\beta$  = 0.2      *Probability of failing to reject the null hypothesis under the alternative hypothesis. Type II error*

$q_1$  = 0.5      *Proportion of subjects that are in Group 1 (exposed)*

$q_0$  = 0.500      *Proportion of subjects that are in Group 0 (unexposed);  $1 - q_1$*

$E$  = 0.5      *Effect size*

$S$  = 1      *Standard deviation of the outcome in the population*

$N_1$  = 63

$N_0$  = 63

Total = 126 (assumption 80% success rate)

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

This is a randomise control trial study, which will be carried out in Hospital Universiti Sains Malaysia, Kubang Kerian, after the approval by the hospital and the University Ethics Committee. All patients above 12 years old in Hospital Universiti Sains Malaysia diagnosed with benign or malignant diseases planned for surgery during the study period that fulfil the study criteria are included. The source population is patients over 12 years old undergoing clean or clean-contaminated HUSM and elective schedule surgery. Exclusion criteria for this study include patients aged less than 12 years old, pregnant, contaminated wounds, dirty wounds, patient allergy to povidone-iodine, laparoscopic surgery, and emergency surgery.

The results of this descriptive record are based on data collection starting from the time patients are first seen with the presenting symptoms either in the outpatient clinic (SOPD) or patient presented to the emergency department and admitted to the ward. If not optimised preoperatively, the patient will be explained regarding factors that may contribute to surgical site infection (stop smoking two weeks before the procedure, diabetic control, control of underlying disease and dietary intake). The patient will fast 6 hours before operation if under

general anaesthesia and unfasted if under local anaesthesia. The operating rooms use standard hygienic procedures to prevent SSIs, following the Centers for Disease Control and Prevention recommendations.

The patients will be randomly assigned to receive either povidone-soaked sutures or ordinary absorbable sutures during surgery using a web-based device (randomiser software) for randomisation, with a specific code for participating centre, to achieve an equivalent group. Permuted-block randomisation with an allocation ratio of 1:1 and block size 10 is obtained. Numbered opaque envelopes containing a code for the study group will be prepared and sealed accordingly. After written informed consent is received, before the patient enters the operation room, the study nurse will open the envelope to reveal the code (A or B) for the study sutures. The study code and the form are then attached to the patient's file, accompanying the patient to the operating room.

Packages with code A or B will be taped with an opaque envelope so that only the code is visible to the operating room staff. Only nurses in the operating room who mask the packages are aware of the study code. They will not participate in collecting or entering the data. The code will determine whether the suture that will be used during wound closure is a povidone-soaked or ordinary braided suture. The patient or guardian is blinded to the study code.

When the patient is prepared in the operating room, patients undergo routine scrub and site preparation according to the established standards of operating centres. During the wound closure, the trial intervention uses povidone-soaked absorbable braided suture or ordinary

absorbable braided suture. Wound closure is achieved by subcutaneous suturing. No suture material or suture techniques apart from that protocol is allowed.

If a povidone-soaked suture is used, any absorbable braided suture must be soaked into 10% povidone for 3 minutes manually before starting subcutaneous suturing. The performing surgeon will fill-up the form for intraoperative details as needed.

Postoperative care will be done if the patient is in the ward. If the patient is eligible to be discharged home, a consultation on wound care is explained and provided as a reference for follow up.

At recruitment, the patient will be asked whether they prefer an email or phone call as primary means to monitor the healing process and patient recovery. The patient will be told to contact me immediately if any problems with the wound and possible signs and symptoms of SSI. The email link will be provided to online questionnaires through phone calls or WhatsApp application on days ten and thirty after operations. Standard practice, the patient will be followed up one month postoperative. Suppose any problems occur related to the procedure. In that case, the patient will be asked to go to the nearest clinic or hospital to get treatment if they live far away or if the patient lives nearby, they are suggested to come to HUSM for further assessment.

If any problems arise with the wound, a checkup visit is arranged, and bacterial cultures are taken if indicated. The wound will be assessed by the surgeon/physician, superficial or deep