RESEARCH TITLE: THE EFFICACY OF DISINFECTING CONTAMINATED SCREWS WITH CHLORHEXIDINE 0.5%, POVIDONE-IODINE 10% AND ALCOHOL 70%.

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LISTS OF ABBREVIATIONS AND DEFINITIONS

List of abbreviations:

HUSM refers to Hospital Universiti Sains Malaysia

OT refers to Operation Theatre

HRPZ2 refers to Hospital Raja Perempuan Zainab 2

PI refers to povidone iodine

G refers to growth

Ng refers to no growth

NS refers to normal saline

ABSTRAK

KEBERKESANAN DIKONTAMINASI SCREWS DENGAN MENGGUNAKAN CHLORHEXIDINE 0.5%, POVIDONE-IODINE 10% SERTA ALCOHOL 70%.

Pengenalan

Terdapat banyak sekali berlakunya keadaan alat-alat pembedahan terjatuh di atas lantai di dewan bedah semasa pembedahan sedang berlangsung. Selalunya akan sentiasa ada alat pengganti yang tersedia.Walau bagaimanapun, ada kalanya pakar bedah perlu menggunakan semula cantuman atau implan yang telah berada di atas lantai, dan menggunakannya semula untuk pesakit selepas dikontaminasi telah dilakukan. Pada masa lalu, dekontaminasi dilakukan dengan penggunaan iodin povidone. Kaedah pengesyoran semasa untuk dekontaminasi ialah chlorhexidine. Dekontaminasi boleh dicapai dengan menggunakan 10% povidone iodin, chlorhexidine 0.5% dan alkohol 70%.

Objektif kajian ini adalah untuk menentukan keberkesanan pembasmian kuman skru tercemar dengan 0.5% chlorhexidine, 10% povidone-iodine, 70% alkohol.

Kaedah Kajian

Ini adalah kajian prospektif yang dilakukan di Hospital Raja Perempuan Zainab 2. Sebanyak 134 skru steril telah digunakan dan diautoklaf sebelum diagihkan kepada 4 kumpulan, kawalan positif, 0.5% chlorhexidine, 10% povidone-iodin, 70% alkohol. Setiap skru dijatuhkan 1 jam ke dalam pembedahan.Skru dijatuhkan dari ketinggian 1 meter. Skru yang berada pada diameter 1 meter di sekeliling meja operasi dibenarkan diletakkan di atas lantai selama 30 saat sebelum diambil dengan forsep steril. Skru kemudiannya diletakkan dalam larutan masing-masing selama 10 minit sebelum dibersihkan dengan kain kasa steril. Setiap skru kemudiannya diletakkan ke dalam media sup nutrien sendiri dan dihantar ke makmal untuk melihat sama ada ia menghasilkan sebarang pertumbuhan.

Keputusan

Sejumlah 136 screw telah digunakan dalam kajian ini. Selepas screw dihantar ke makmal untuk mendapatkan jumlah yang mempunyai ketumbuhan microorganisma, kuputusanya adalah seperti berikut :(setiap kumpulan mempunyai 34 screw)

1) Control positive	31(91.1%)
2)10% povidone iodine,	24(70.5%)
3) Chlorhexidine 0.5%	3(8.8%)
4) Alcohol 70%	30(88.2%)

Kesimpulan

Daripada kajian ini, didapati klorheksidin $p<0.001$ merupakan larutan yang paling berkesan yang boleh digunakan untuk penyahcemaran. Penemuan ini konsisten dengan kebanyakan kajian yang telah dilakukan pada masa lalu mendedahkan bahawa chlorhexidine adalah lebih baik. Povidone iodin p 0.040 pernah menjadi penyelesaian pilihan tetapi terbukti bahawa ia tidak lebih baik daripada chlorhexidine. Oleh itu, kami mencadangkan penggunaan chlorhexidine sebagai penyelesaian untuk penyahcemaran sekiranya perlu.

Kata kunci:

Keberkesanan Dekontaminasi, Screw, Chlorhexidine 0.5%, Povidone iodine 10 %, Alcohol70%

ABSTRACT

THE EFFICACY OF DISINFECTING CONTAMINATED SCREWS WITH CHLORHEXIDINE 0.5%, POVIDONE-IODINE 10% AND ALCOHOL 70%.

Introduction

The inevitability of dropping an implant, graft or other surgical instruments during a surgery onto the surgical floor is unavoidable. Most of the times there will always be a replacement available. However there are times in which a surgeon needs to reuse a graft or implant that has been on the floor, and reuse it for the patient after decontamination has been done. In the past decontamination was done with the use of povidone iodine. The current recommendation method for decontamination currently is chlorhexidine. Decontamination can be achieved by the use of 10% povidone iodine, chlorhexidine 0.5% and alcohol 70%.

The objective of this study is to determine the efficacy of disinfecting contaminated screws with 0.5% chlorhexidine, 10% povidone-iodine, 70% alcohol.

Materials and methods

This was a prospective study performed at Hospital Raja Perempuan Zainab 2. A total of 134 sterilized screws were used and autoclaved before being distributed into 4 groups, control positive, 0.5% chlorhexidine, 10% povidone-iodine, 70% alcohol. Each screw was dropped 1 hour into surgery.the screws were dropped from a 1 meter height. Screws that were at a 1 meter diameter around the operation table were allowed to rest on the floor for 30 seconds before being picked up with sterile forceps. The screws were then placed in their respective solutions for 10 minutes before being cleaned with a sterile gauze. Each screw were then placed into its own nutrient broth media and sent to the lab to see if they yield any growth.

Results

There were a total of 134 screws dropped and were divided into groups of 34 screws each. The results that were obtained from the lab revealed:

1) Control positive	31(91.1%) growth
2) 10% povidone iodine,	24(70.5%) growth, p 0.040
3) Chlorhexidine 0.5%	3(8.8%) growth, p <0.001
4) Alcohol 70%	30(88.2%) growth, p 0.691

Conclusion

From this study, it was found that chlorhexidine p<0.001 was the most superior solution that can be used for decontamination. This finding is consistent with most of the studies that have been done in the past revealing that chlorhexidine was superior. Povidone iodine p 0.040 was once a solution of choice but it is evident that it's not superior to chlorhexidine from this study. Therefore we suggest the use of chlorhexidine as a solution for decontamination should the need ever arise.

Key words:

Disinfection ,Screw, Chlorhexidine 0.5%, Povidone iodine 10 %, Alcohol70%

CHAPTER 1: INTRODUCTION

1.1 Introduction

A common complication faced during surgery is inadvertently dropping of screws, plates, grafts or essential equipment's on the operating floor. Some implants such as screws for common cases are easily replaced with another sterile screw. The issue arises especially at smaller centre where there is a lack of implants or some specific implants that the patient has paid for which can't be replaced. This leaves the surgeon with a conundrum where the surgeon has to decide to either discard the screw, use a screw of shorter length which will reduce the stability of the construct or to decontaminate the screw and reuse it, after taking into consideration the risk of infection associated with contaminated screws.

The ideal method of choice for decontamination is sterilization which destroys all form of an organism including the spore and at the same time not causing any harmful effects on the implant. An ideal method of sterilization should also be safe, quick and will not interrupt the whole process of surgical procedure. Using autoclave, gamma irradiation and ethylene oxide for sterilization is not optimal, as they are expensive and time consuming. Another method that can be used and which is more cost effective is decontamination with the use of antiseptic solution such as chlorhexidine, povidone-iodine and alcohol solutions.

The concern when considering to disinfect a contaminated screw is the effectiveness of the antiseptic solutions available in the operation theatre. Bauer experimented a contaminated bone grafts and reported that chlorhexidine and dry povidone-iodine decontaminated all bone samples, but not wet povidone-iodine [1]. Yazdi claimed that chlorhexidine 0.4% as the best antiseptic solution for contaminated bones in rabbit [2]. Hooe found that 10% povidone-iodine to be superior than 4% chlorhexidine solution in decontaminating graft soiled with *Pseudomonas aeruginosa* and *Staphylococcus aureus* [3]. On the other hand, Goebel found

that 10% povidone-iodine and a triple antibiotic solutions were ineffective in decontaminating rabbit bone patella tendon bone grafts [4].

In our current local setting, when the surgeons encounter incident of unintentionally dropping an implant during surgery is disinfection using povidone-iodine. Centeno reported that 10% povidone-iodine solution was the most popular antiseptic solution used among a group or 223 surveyed surgeons in disinfecting dropped grafts [5]. This is an interesting finding given the fact that the current practice seems contradicting with what the literature ascertains, as the it was demonstrated that 4% chlorhexidine solutions to be the most effective methods of decontamination [4]. This data is also consistent with a later study by Bruce, reporting that 4% chlorhexidine as the most effective decontaminating agent [6].

Povidone iodine is a small molecule that rapidly penetrates microorganisms and oxidizes its key proteins, nucleotides, and fatty acids, eventually leading to cell death. (23). Alcohol 70 % works by coagulation/denaturation of proteins and solubility of the alcohols in lipids. The mechanism of action of chlorhexidine is explained by its reaction towards cell membranes alteration leading to changes in electrostatic binding between its catatonic molecule and its negatively charged cell resulting in precipitation and coagulation of cytoplasmic proteins leading to cell death.

From the literature review it is clear that the use of all the mentioned disinfection were mostly used for the disinfection of biological materials. There are very little journals available for the disinfection of other surgical materials.

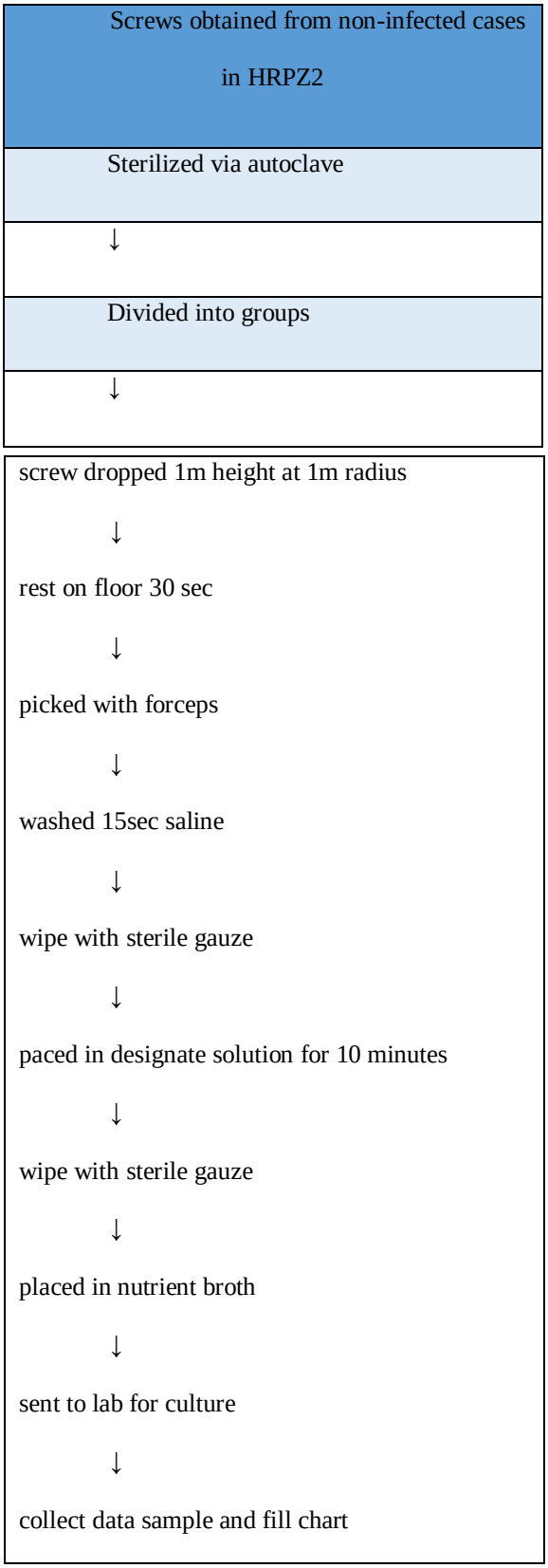
This study was done to serve as a guide for surgeons in aiding their decision of what solution can be used and which of the disinfection solution may help in reducing the risk of contamination.

1.2 Problem statement & Study rationale

As of now there are no investigations or studies that have been conducted where an implant of whatever kind being dropped followed by their assessment for infection rates for reuse. Most studies currently involves the use of biological material reuse post dropping in the operative theatre such as grafts, bones and tendons.

This study was done in order to review the level of contamination in dropped screws and also to serve as a guide to surgeons to determine what is the best solution to use in the decontamination of implants prior to their reuse in patients.

1.3 CONCEPTUAL FRAMEWORK



1.4 Research Question(s)

Research Questions

1) Will there be a difference in the disinfection of contaminated screws with the use of chlorhexidine, 0.5%, povidone- iodine 10% and alcohol 70%.

2) Which solution will provide the best disinfection rate

3) Which solution will yield the lowest disinfection rate

Research Hypothesis

1) There will be a clear difference in contamination level based on the different solution used

2) Chlorhexidine will yield the highest disinfection

3) Alcohol will yield the lowest disinfection rate

1.5 Objectives:

General Objectives

To determine the efficiency of chlorhexidine 0.5%, alcohol 70%, and povidone-iodine 10% in the disinfection on contaminated screws.

Specific Objectives

To determine the incidence of positive cultures from the screws that have been dropped in operation theatre floor of Hospital Raja Perempuan Zainab II, Kota Bharu, Kelantan.

To compare effectiveness of 10% povidone -iodine, chlorhexidine 0.5% and alcohol 70% in disinfection of screws.

CHAPTER 2: LITERATURE REVIEW

2.1 Literature review

Fall of instruments in the theatre is a common problem all over the world. It leads to increased operating time and extra resources and can hamper the end result of surgery. During the literature review for this thesis it was notes that there were no real guidelines on what exactly can be done if an instrument has been dropped and how or what to use for the sterilization the said implant or instrument. In fact, most of the papers online mostly reviewed dropped bones or ligaments.

Bruce et al demonstrated the culture positive rate was 70% for contaminated bones. Coagulase-negative Staphylococcus was the commonest cultured microorganism. It was also noted that the varying exposure time to the chemical agents did not make a significant difference in decontamination rates. Mechanical scrubbing was superior to mechanical saline solution lavage (zero of fifty-six cultures compared with twenty of fifty-six cultures were positive for coagulase-negative Staphylococcus; $p < 0.001$). Bactericidal agents were found to be more effective decontaminating agents than normal saline solution. Povidone-iodine and 4% chlorhexidine gluconate were the most effective decontaminating agents. (2)

Lana kang at al demonstrated that 1in 3 surgeons dropped autologous bone grafts during their surgeries. The study involved a total of 104 orthopedic surgeons were reviewed. Also noted in this same study was the various methods of decontamination methods that were used during the incidence of dropping bones which included; low pressure lavage, soak in Bactrim solution, soak in povidone iodine solution, autoclave, soak in hydrogen peroxide, and other unspecific methods (7). Also noted that the graft infection rate was 70%. (7)

Yazid H at al conducted a study to determine the efficacy of three different solutions. The study comprised of 4 groups. Group one was control group, group two used neomycin and polymyxin, group three chlorhexidine 0.4% and lastly group four comprising of povidone iodine 10%. A total of 200 specimens were used. The specimen that were used were that of femur bone of rabbits that was cut into chips. The bone chips were dropped on the operating theatre floor. Specimens were left on the floor for 15 seconds. In this study it was noted that 10 days' post dropping of the femur chips yielded no cultures for chlorhexidine 0.4% although it did not have any significant differences when compared to povidone iodine 6% positive cultures and antibiotic solution yielded 4% positive cultures. (2)

A study conducted by Khan Sa et al was done to evaluate the instances of accidental falls of instruments and implants during orthopaedics surgery. It was noted that in a total of 120 surgeries observed prospectively over a period of 18 months. In this study the cause of falls as well as the offending personal were identified. It was found that the instances of instruments falling in emergency surgeries were higher when compared to elective surgeries. The rate of falls was 24 (61%) and 15 (38%0 respectively. Of these falls 67% of the falls were directly caused by the surgeons, 17.9% by the assisting surgeon and 7.7% by the scrub nurse. 7.7% of the falls were unaccounted for. (8)

Bachner et al demonstrated a review of multiple studies for anterior cruciate ligament grafts that were dropped intraoperatively and the various cleaning agents that were used. The list of cleaning agents included that of:

1) Pulsatile irrigation with 3L of 2% chlorhexidine
2) 100 ml Polymyxin B and Bactrim
3) Soak with 10% povidone iodine for 5 minutes
4) 40 mg neomycin sulphate with 200000 U polymyxin B sulphate in 1L normal saline

5) 4% chlorhexidine soak for 3 minutes
6) Pulsatile irrigation with 3L normal saline

From this review it was apparent that the most successful protocols were that of 7-8 minutes of irrigation with 3L of 2% chlorhexidine and mechanical agitation and serial dilution with a polymyxin B-Bactrim solution which both showing sterility of 100%.
Sterilization with soaking in 4% chlorhexidine for 90 seconds produced rates of 98%.
Rate of contamination of dropped grafts were as high as 60%. A survey that was done revealed 75% of surgeons would reuse dropped grafts and the remainder 25% would discard the grafts and use one from another source. (9)

Centeno RF et all did a study on the incidence of contaminated autologous grafts in plastic surgery and the steps that were taken in the decontamination along with the level of contamination that were seen in the grafts. There were a total of 223 surgeons that participated in the study. 70% of the participating surgeons had at least 1 graft contaminated. The commonest cause of graft contamination in these cases were dropped grafts on the floor amounting to up to 70%. The commonest method of decontamination used by these surgeons was to soak with povidone iodine despite being contrary to the recommendations in the literature. Only 3 surgeons amounting to 1.9% noted that there was clinical infection following decontamination of grafts. Patients were not informed in 60% of the graft incidents (5). It was concluded that contaminated grafts in plastic surgery could be safely decontaminated with little risk of clinical sequelae.

Muhammad Fadhil et al conducted a study on the efficacy of chlorhexidine, povidone iodine, and alcohol in disinfecting contaminated bones. In this study involved 225 bone specimens that were obtained from discarded bone fragments form 45 knee and hip

arthroplasty cases at HRPZ2. These bones fragments were cut into cubes of identical size. The cubes were then allocated to 5 different groups:

1) Control positive

2) Control negative

3)0.5% chlorhexidine

4)10% povidone-iodine

5)70% alcohol

The later three in the list were disinfectants that were readily available in the hospital where the study were conducted. All the specimens were dropped on the theatre floor and were subsequently disinfected in their respective solutions for a duration of 10 minutes except the control positive specimen. These specimens were then transported for microbiology review after being immersed in nutrient broth.

There was 86.5% of incidence of positive cultures from dropped specimens. The incidence of infected grafts that were decontaminated are mentioned below:

1) 5% chlorhexidine had 2 positive specimens amounting to 5.4%
2) 10% povidone-iodine had 25 positive specimens amounting to 67.6%
3) 70% alcohol had 30 positive specimens amounting to 81.1%

It was concluded that 0.5% chlorhexidine was superior in disinfecting bones. (10)

A study done by Shen X et al it was noted that the use of chlorhexidine 4% was superior in the disinfecting of ACL grafts (17). The study done included the comparison of chlorhexidine 4%, povidone iodine 10% and antibiotic solution. The antibiotic solution were those of gentamicin, clindamycin, polymyxin, and bacitracin. In this paper is was demonstrated that antibiotics solutions yielded better disinfectant outcome compared to povidone iodine but still less than that of chlorhexidine.

In a study by Badran MA et al, ACL grafts were soaked in 10 % povidone–iodine solution, 4 % chlorhexidine and bacitracin (50,000 U/1 L normal saline), respectively, for three minutes, collected in sterile containers and cultured(18). This study involved the use of 90 ACL grafts. The grafts that were used were the extra portions of the ACL graft that was taken for ACL reconstruction. In this study it was noted that chlorhexidine is the most efficient decontaminating agent, followed by an antibiotic solution when applied to actual hamstring auto-graft tissue.

Povidone iodine is a small molecule that rapidly penetrates microorganisms and oxidizes its key proteins, nucleotides, and fatty acids, eventually leading to cell death. Povidone iodine has a broad antimicrobial spectrum with activity against Gram-positive and Gram-negative bacteria, including antibiotic-resistant and antiseptic-resistant strains, fungi, and protozoa. It is also active against a wide range of enveloped and non-enveloped viruses, as well as some bacterial spores with increased exposure time (23).

Alcohol 70 % mode of action is related to coagulation/denaturation of proteins and solubility of the alcohols in lipids. Without water, coagulation cannot occur, therefore a 70% solution of isopropyl alcohol or ethanol will be more effective than higher concentrations of alcohol. Biocidal activity drops sharply when diluted below 50% alcohol concentration (24).

The mechanism of action of chlorhexidine is explained by its reaction towards cell membranes. At a higher dose of 2%, the integrity of cell membranes are altered leading to an alteration in its electrostatic binding between its catatonic molecule and its negatively charged cell wall causing chlorhexidine to exert bactericidal action, resulting in precipitation and coagulation of cytoplasmic proteins leading to cell death. At a lower dose of 0.2%, the cell integrity is altered resulting in a bacteriostatic effect to leaking of low molecular weight bacterial components (25).

The present systematic review and meta-analysis done by X Shen et al results demonstrated that the contamination of dropped ACL grafts during ACL reconstruction occurred at a relatively high rate, with staphylococci and bacilli being the most common microorganisms in dropped ACL grafts. Decontamination using a 4% chlorhexidine solution reliably disinfected ACL grafts that dropped on the operating room floor, with a disinfection rate of 97.7%

CHAPTER 3: METHODOLOGY

3.1 METHODOLOGY

Research design

This research uses a prospective experimental study approach to determine the incidence of contamination in dropped screws in the orthopaedics operative theatre.

Study area

Hospital Raja Perempuan Zainab 2

Study population

All screws were obtained from infection free patients that were removed cleaned and autoclave to achieve sterilization.

3.2 Study Criteria

Inclusion criteria

All screws that were previously removed from patients.

All removed screws that have been sterilized via autoclave.

Exclusion criteria

Screws from cases where the removal was due to infections.

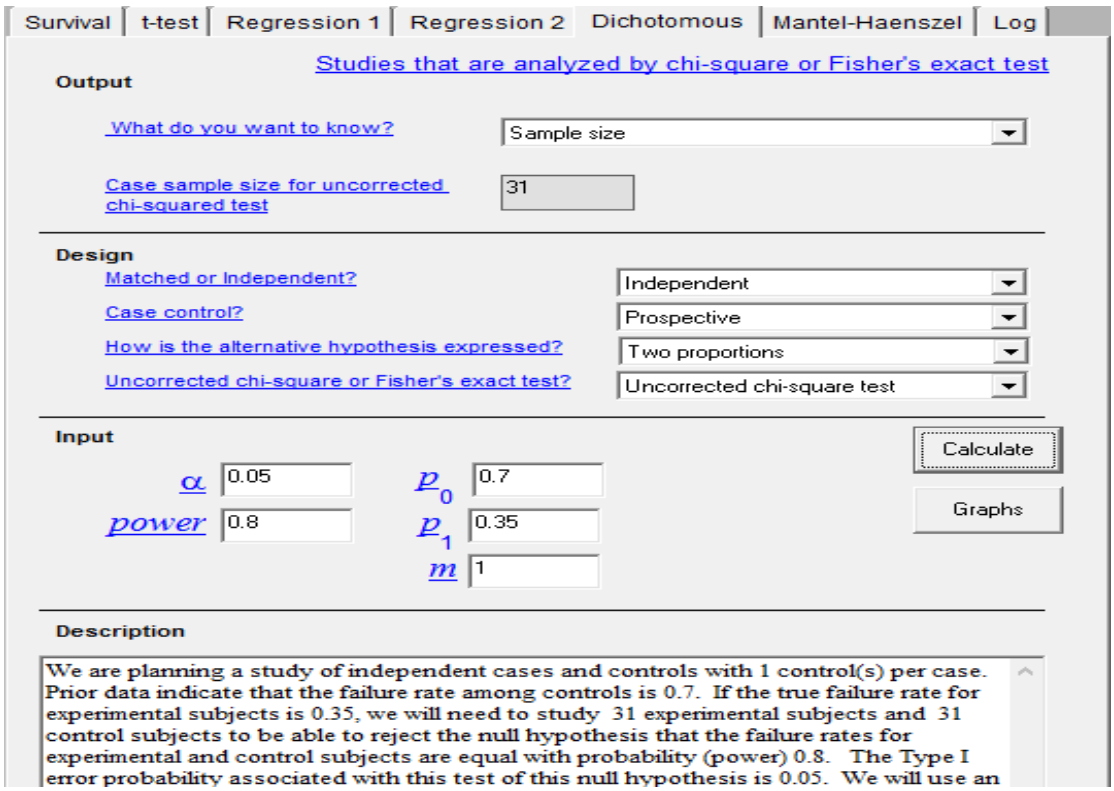
Screws that are visually damaged

3.3 Sample size estimation

Sampling method and subject recruitment

Sample size

Based on a power of 80 %, alpha of 0.05, the incidence of cultures from a previous study, P=0.7 (Bruce et all), an expected outcome difference of 16% and s.d. of 8% between the 2 study interventions, P1, the probability of outcome in this experimental subject, taken as 0.35. m is the ratio of control case so experimental case. Decision was made to have a similar number of control experimental subject ratio of 1:1.



Calculated by 0.0,by using chi-squaretest the calculated size is 31 for each experimental group designated.

Hence the total sample size will be 31x4=124. Considering the 10% drop out the total sample size would be 136. This means that each group would have a total of 34 screws.

Sample size =31

Sample size with drop out =34

Total sample size 34x4=136

3.4 Sampling method and subject recruitment

Screws were chosen after strictly following the inclusion and exclusion criteria.

All screws were obtained free from discarded screws that have been taken from HRPZ2.

All the screws were sent for autoclave prior to the experiment.

The screws were then be divided into their respective groups:

1) Control positive

2)10% povidone iodine,

3) Chlorhexidine 0.5%

4) Alcohol 70%

In this study there was no control negative group. This was because all the screws were cleaned and autoclave was done as well. This ensured the sterility of the screws. Therefore a decision was made not to include a control negative group.

The screws were dropped from a one meter height, and one meter around the operative table. This was the predetermined area as this is the average height of the operative table and this is also the area that is most contaminated in the operative theatre during surgery. Screws will be dropped after 60 minutes of surgery (predetermined in previous study as the optimal time).

Screws were left on the floor for a duration of 30 seconds to simulate the time it takes for the average surgeon to decide the need to pick up and reuse the implant.

The screws were then be washed with saline and placed into their designated disinfection solution for 10 minutes. After which the screws were washed with sterile saline and then placed into the nutrient broth media and transported to the laboratory to be incubated.

The incubation was done for 24 hours in the nutrient broth. After this 24 hours period, screws were then placed on nutrient agar for another 48 hours of incubation before they were accessed for presence of growth.

3.5 Research tool, operational definition and data collection method

Research tool

To gain all the required information for the study, a prospective study was done at HRPZ2.

There was no involvement of any patients in the study.

Nutrient broth media were obtained from the microbiology lab from HRPZ2 before conducting the study and were sent back to the lab for incubation and interpretation.

Screws were obtained from HRPZ2 (size 3.5x 16mm cortical screws)

Operational definition

Dependent variables

All screws used were that of standard cortical screws of the same type.

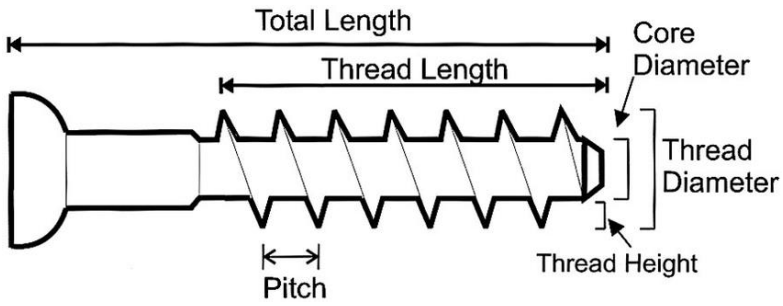


Figure 1: Anatomy of a screw.

The pitch, thread, diameter, length need to be the same to standardize the study.

Data collection method

A preliminary study was done to evaluate the degree of contamination present on the operating theatre floor. The purpose of this preliminary study was determine the degree of contamination present in the operating theatre, specific to the floor. This preliminary study was done to decide the best time to drop the screws for the study.

The previous study done by Fadhil et al did a preliminary study involving six sets of floor swabs during knee or hip arthroplasty surgery. One set consisted of 4 swabs taken were; (1) before the surgery started (after floor cleaning), (2) at 30 min, (3) at 1 hour and (4) at 2 hours after surgery has started[8]. Floor swabs were taken within the parameter of one-meter radius from operation theatre table, using sterile cotton swab sticks, which were subsequently streaked on the agar plates, before being transported to the microbiology lab for incubation to determine number of bacterial colonies.

All floor swabs taken before operation started yield no bacterial growth, except one swab had two colonies of coagulase negative *Staphylococcus*. As surgery progressed, the bacterial colonies on the blood agar increased. The bacterial load on the operation theatre floor amplified dramatically after 60 minutes' surgery started .Simple linear regression analysis demonstrated a statistically significant positive association between bacterial load on the operation theatre floor and duration of surgery ($p<0.001$).

It was decided that 60 minutes is the optimal time to drop screw specimens due to the high likelihoods of getting contaminated and taking into consideration the average duration of orthopedic surgeries.

Experimental study:

This experimental study involved discarded screws that were taken from non-infected implant removal cases. The study was conducted in a standardized operative theatre environment for removal of implant cases. The screws that were obtained were cleaned and sent for autoclave before being designated to one of 4 groups:

1) Control positive
2) 0.5% chlorhexidine
3) 10% povidone iodine
4) 70% alcohol

There was no control negative group for this study as an assumption was made that all the screws are sterile as they all underwent autoclave prior to their use in this experimental study. 0.5% chlorhexidine in aqueous 1:200, 10% povidone-iodine and 70% alcohol will be used in this study as they are readily available in the hospital theatre.

All the screws went through contamination by dropping the screws at a radius of 1 meter around the surgical operating table. This 1-meter radius was chosen because this area was where the doctors and staff move about around the operating field. The screws were dropped from a height of 1 meter as well and at 60 minutes during surgery. This was done to standardize the study as this is the average height of the operating table. Each screw were collected using sterile forceps after 30 seconds of resting on the floor as advocated by Bruce et al (6). All the screws were then be rinsed with sterile saline for 15 seconds and then wiped with a sterile dry gauze. Screws were then submerged into their designated solution for 10 minutes. As in picture 1, it takes 20 cc of solution to submerge the screw fully. After being submerged the screws were wiped dry with a sterile gauze and then placed into nutrient broth. Screws were then transported to microbiology lab (10).

The incubation of these screws was done for 24 hours in the nutrient broth. After this 24 hours period, screws were then placed on nutrient agar for another 48 hours of incubation before they were accessed for presence of growth.

There were a total of 136 screws that were used. (34 screws for each group): 34x4=136.

Picture 1: 20 cc of solution was required to fully submerge the 3.5 x 16 mm screw

3.6 Ethical consideration:

1. **Privacy and confidentiality**

   As there are no patients involved in this study, there was no breach of privacy or confidentiality

2. **Declaration of absence of conflict of interest**

   Hereby as a principal investigator of this study, I would like to declare myself as a non-beneficial party of the study and it is done solely for an academic purpose only.

3. **Honorarium and incentives**

   This study is not bound to any form of research grant and any minor portion of spending will be borne by the principal researcher. The laboratory technician will be compensated with RM 500.00.

Finance:

Screws - free

Nutrient broth media - RM1.80 per plate

Total = RM1.80x 136= RM244.80

Source of finance: self-paying.

CHAPTER 4: MANUSCRIPT

4.1 ABSTRACT

THE EFFICACY OF DISINFECTING CONTAMINATED SCREWS WITH CHLORHEXIDINE 0.5%, POVIDONE-IODINE 10% AND ALCOHOL 70%.

Introduction

The inevitability of dropping an implant, graft or other surgical instruments during a surgery onto the surgical floor is unavoidable. Most of the times there will always be a replacement available. However there are times in which a surgeon needs to reuse a graft or implant that has been on the floor, and reuse it for the patient after decontamination has been done. In the past decontamination was done with the use of povidone iodine. The current recommended method for decontamination currently is chlorhexidine. Decontamination can be achieved by 10% iodine, chlorhexidine 0.5%, alcohol 70%

Materials and methods

This was a prospective study that was performed at Hospital Raja Perempuan Zainab 2. In this study a total of 134 sterilized screws were dropped on the operation theatre floor. These screws were obtained from HRPZ2. The screws were autoclaved after selection. The screws were then distributed into 4 groups, Control positive, 0.5% chlorhexidine, 10% povidone-iodine, 70% alcohol. The screws were dropped 1 hour during surgery from a 1 meter height at a maximum of 1 meter diameter distribution surrounding the operation table. The screws were allowed to rest there for 30 seconds before being picked up with sterile forceps and placed in their respective solutions for 10 minutes before being cleaned with a sterile gauze. The screws were then placed into nutrient broth media and sent to the lab to see if they yield any growth.

Results

There were a total of 134 screws dropped and were divided into groups of 34 screws each. The results that were obtained from the lab revealed:

1) Control positive 31(91.1%)

2)10% iodine, 24(70.5%) p 0.040

3) Chlorhexidine 0.5% 3(8.8%) p<0.001

4) Alcohol 70% 30(88.2%) p0.691

Conclusion

It was found that chlorhexidine p<0.001 was the most superior solution that can be used for decontamination. This finding is consistent with most of the studies that have been done in the past revealing that chlorhexidine p<0.001 was superior. Povidone iodine p 0.040 was once a solution of choice but it is evident that it's not superior to chlorhexidine p<0.001 from this study. Therefore we suggest the use of chlorhexidine p<0.001 as a solution for decontamination should the need ever arise.

Key words:

Disinfection ,Screw, Chlorhexidine 0.5%, Povidone iodine 10 %, Alcohol 70%

4.2 Introduction

A common complication faced during surgery is inadvertently dropping of screws, plates, grafts or essential equipment's on the operating floor. Some implants such as screws for common cases are easily replaced with another sterile screw. The issue arises especially at smaller centers where there is a lack of implants or some specific implants that the patient has paid for which can't be replaced. This leaves the surgeon with a conundrum where the surgeon has to decide to either discard the screw, use a screw of shorter length which will reduce the stability of the construct or to disinfect the screw and reuse it. This is done after taking into consideration the risk of infection associated with contaminated screws.

The ideal method of choice for disinfectant is sterilization which destroys all form of an organism including the spore and at the same time not causing any harmful effects on the implant. An ideal method of sterilization should also be safe, quick and will not interrupt the whole process of surgical procedure. Using autoclave, gamma irradiation and ethylene oxide for sterilization is not optimal as they are expensive and time consuming. Another method that can be used and which is more cost effective is decontamination with the use of antiseptic solution such as chlorhexidine, povidone-iodine and alcohol solutions.

The concern when considering to disinfect a contaminated screw is the effectiveness of the antiseptic solutions available in the operation theatre. Bauer experimented a contaminated bone grafts and reported that chlorhexidine and dry povidone-iodine decontaminated all bone samples, but not wet povidone-iodine [1]. Yazdi claimed that chlorhexidine 0.4% as the best antiseptic solution for contaminated bones in rabbit [2]. Hooe found that 10% povidone-iodine to be superior than 4% chlorhexidine solution in decontaminating graft soiled with *Pseudomonas aeruginosa* and *Staphylococcus aureus* [3]. On the other hand, Goebel found

that 10% povidone-iodine and a triple antibiotic solutions were ineffective in decontaminating rabbit bone panatella tendon bone grafts [4].

In our current local setting, when the surgeons encounter incident of unintentionally dropping an implant during surgery is disinfection using povidone-iodine. Centeno reported that 10% povidone-iodine solution was the most popular antiseptic solution used among a group or 223 surveyed surgeons in disinfecting dropped grafts [5]. This is an interesting finding given the fact that the current practice seems contradicting with what the literature ascertains, as the it was demonstrated that 4% chlorhexidine solutions to be the most effective methods of decontamination [4]. This data is also consistent with a later study by Bruce, reporting that 4% chlorhexidine as the most effective decontaminating agent [6].

Povidone iodine is a small molecule that rapidly penetrates microorganisms and oxidizes its key proteins, nucleotides, and fatty acids, eventually leading to cell death. Povidone iodine has a broad antimicrobial spectrum with activity against Gram-positive and Gram-negative bacteria, including antibiotic-resistant and antiseptic-resistant strains, fungi, virus and protozoa. (23).

Alcohol 70 % mode of action is related to coagulation/denaturation of proteins and solubility of the alcohols in lipids. Biocidal activity of alcohol drops sharply when diluted below 50% alcohol concentration (24).

The mechanism of action of chlorhexidine is explained by its reaction towards cell membranes. At a higher dose of 2%, the integrity of cell membranes are altered leading to an alteration in its electrostatic binding between its catatonic molecule and its negatively charged cell wall causing chlorhexidine to exert bactericidal action, resulting in precipitation and coagulation of cytoplasmic proteins leading to cell death. At a lower dose of 0.2%, the cell integrity is altered resulting in a bacteriostatic effect to leaking of low molecular weight bacterial components (25).

4.3 Methodology

This research uses a prospective experimental study approach to determine the incidence of contamination in dropped screws in the orthopaedics operative theatre. The study was performed at a single tertiary centre, Hospital Raja Perempuan Zainab 2.

A preliminary study was done to evaluate the degree of contamination present on the operating theatre floor. The purpose of this preliminary study was to determine the degree of contamination present in the operating theatre, specific to the floor. This preliminary study serves the purpose to decide the best time to drop the screws for the study.

It was decided that 60 minutes is the optimal time to drop screw specimens due to the high likelihood of getting contaminated and taking into consideration the average duration of orthopedic surgeries.

This experimental study involved discarded screws that were taken from HRPZ2. The screws that were taken from HRPZ2 were those from implant removal cases that were not infected. All the screws that were taken were done based on the inclusion and exclusion criteria as per mentioned above. These screws were firstly thoroughly cleaned before they were sent to autoclave.

The screws were then be designated to one of 4 groups control positive, 0.5% chlorhexidine, 10% povidone iodine, 70% alcohol.

An assumption was made that all the screws are sterile as they will all undergo autoclave prior to their use in this experimental study, therefore there is no need for a control negative group for this study. The control positive set of screws did not undergo any decontamination. The control positive group was only cleaned with NS and was wiped with sterile gauze. The

other screws were submerged with 20 cc of their designated solution before being wiped with sterile gauze then placed in their own nutrient broth before being transported to the lab.

0.5% chlorhexidine in aqueous 1:200, 10% povidone-iodine and 70% alcohol was used in this study as they are readily available in the hospital theatre. This will help to simulate the actual available solutions in the OT.

The study was conducted in a standardized operative theatre environment. The study began one hour into a clean case surgery as this will best simulate the ideal conditions for implant related surgeries.

All the screws underwent contamination by dropping the screws at a radius of 1 meter around the surgical operating table. This 1-meter radius was chosen because this area was where the doctors and staff move around the operating field.

The screws were dropped from a height of 1 meter as well and at 60 minutes during surgery. This is done to standardize the study as this is the average height of the operating table. Only screws that fall in the one meter radius around the operating table were included in the experimentation. All screws that fell out of this 1 meter radius were excluded.

Each screw was collected using sterile forceps after 30 seconds of resting on the floor as advocated by Bruce et al (6). All the screws were then rinsed with sterile saline for 15 seconds and then cleaned with a sterile dry gauze. Screws were then placed into their respective disinfecting solutions for 10 minutes. The screws were then taken out of their respective solutions, wiped dry and were then transport to microbiology lab in their own nutrient broth media for incubation (10).

The incubation was done for 24 hours in the nutrient broth. After this 24 hours period, screws were then placed on nutrient agar for another 48 hours of incubation before they were accessed for presence of growth.

The experimentation was done by the same person who also sent the screws in the nutrient broth media to the lab. This eliminated any bias.

Three days after incubation the lab assistant checked to see if there are any growths present in the respective media as per mentioned above. All the samples were recorded and approved by both the sender and the lab assistant on the provided A4 lab sheet.

Data analysis was performed to explore and verify the hypothesis in order to answer the research questions. Compilation of the data was done using excel spreadsheet and the statistical analysis was done using SPSS version 24.

Simple comparison between the incidence of contaminated and non-contaminated screws was made to get the percentage of contaminated cases. Then the incidence of contaminated screws was be compared to determine the best decontamination method.

This study was approved by our institution Human Research Ethics Committee **USM/JEPeM/21020143**

Jawatankuasa etika dan penyelidikan perubatan **NMRR ID-21-01960-EIJ**

4.4 Results

There were at total of 134 screws that were dropped in the operating theatre in total. The duration of the experimentation was from the 23/11/2020 till the 20/05/2021.

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There were a total of 136 screws dropped and were divided into groups of 34 screws each. The results that were obtained from the lab revealed:

1) Control positive	31(91.1%) positive growth cultures
2)10%povidone- iodine,	24(70.5%) positive growth cultures (p0.040)
3) Chlorhexidine 0.5%	3(8.8%) positive growth cultures (p<0.001)
4) Alcohol 70%	30(88.2%) positive growth cultures (p0.691)

Result and Data Interpretation

Methods (Statistical Analysis)

In this analysis, all categorical data were presented in frequency and percentage. Comparisons of effectiveness between disinfectants, were made using Binomial Logistic Regression. The P level of less than 0.05 was considered statistically significant. The analysis was performed using version 26 of the SPSS software (SPSS Inc, Chicago, IL).

1. Descriptive

Table 1: Results (n=34)

Variables	No Growth		Growth	
	n	(%)	n	(%)
Control Group	3	8.8	31	91.2
0.5% chlorhexidine	31	91.2	3	8.8
10% povidone iodine	10	29.4	24	70.6
70% alcohol	4	11.8	30	88.2

Overall Growth

Table 2: Overall Growth

Variable	n	(%)
No growth	48	35.3
Has Growth	88	64.7

2. Statistical Analysis

Table 3: Effectiveness of Disinfectants (n=136)

Variables	Crude Odd Ratio (OR)	95% CI (Lower,	Upper)	p-value*
0.5% chlorhexidine	0.009	0.002	0.050	<0.001
10% povidone iodine	0.232	0.058	0.938	0.040
70% alcohol	0.726	0.150	3.520	0.691

**Binomial Logistic Regression*

Data Interpretation

1. 0.5% Chlorhexidine usage has 99.1% less likelihood of bacterial growth compared to control group and the association was significant (Crude OR 0.009, 95% CI:0.002-0.05), $p < 0.001$).
2. Also, 10% povidone iodine usage has 76.8% less likelihood of bacterial growth compared to control group and the association was significant (Crude OR 0.232, 95% CI:0.058-0.938), $p = 0.04$).
3. Meanwhile, 70% alcohol usage has 27.4% less likelihood of bacterial growth compared to control group, but the association was not significant (Crude OR 0.726, 95% CI:0.15-3.52), $p = 0.691$).

4.5 DISCUSSION

An important factor that influences the risk of contamination of the screws is the time of the screws were dropped during surgery. From previous studies it was demonstrated that the incidence of contamination in grafts was significantly higher the longer any surgical procedure is done (8). From the preliminary study that was done by Mat-salleh MF, et, al, it was demonstrated that the bacterial load on the operation theatre amplifies as the surgery time progressed.

As surgery gets prolonged, the risk of dropping screws, plates, nails and such items as grafts increases especially towards the end of a procedure(8), this in turn leads to an increase in the risk of contamination of the screws. This high risk of contamination is the main reason why surgeons do not reuse screws or surgical equipment's that have been dropped on the operation theatre regardless of the duration. When possible the surgeon would always opt for the use of new screws or equipment's as this will firstly prevent unnecessary risk of infections and at the same time will not disrupt the flow of surgery. The flow of surgery is very important especially in the orthopaedics surgical setting because each bone is of a different size leading to diff lengths in screws and also in the types such as locking screws, cortical screws, cancellous screws and also special screws such as blade screws of Herbert screws.

The issue of the reuse of screws tends to happen at a district setting or in a setting where there are a lack of equipment's or in cases where the patient has payed for an implant that cannot be replaced with a different set of screws. These are the times where the screws are reused by decontamination. The ideal technique is via autoclave that is proven to kill even the spores of an organism thus providing sterilization which in itself prevents risk of infection. The use of autoclave however is not practical as this takes a long time leading to longer surgical time

leading to the increase in the risk of infections in a patient. The current practice is via decontamination with the use of either chlorhexidine or classically 10% povidone iodine.

From the study that was conducted, the risk of contamination is as high as 91.1%. This is in keeping with previous studies that was conducted by Mat-salleh MF, et, al which was at 86.5 %(10). From the literature review it was noted that the evidence of contamination in dropped grafts and such in the operation theatre was as high as 10 %(13) and as low as 0 %(14).This earlier studies that were done in the 90's have very contradictory results in comparison to the study done.

Our study discovered that used 0.5% chlorhexidine is effective in the decontamination of screws. The incidence of positive cultures were 3 in a total of 34 dropped screws. This provided an incidence rate of 8.8%. The study that was done by Mat-salleh MF, et, al (10) was 5.4%. Another study by Yazdi et al using 0.4 % chlorhexidine was also comparable to our study. In our study it was also noted a high incidence of contamination in all other groups:

1. 0.5% Chlorhexidine usage has 99.1% less likelihood of bacterial growth compared to control group and the association was significant (Crude OR 0.009, 95% CI:0.002-0.05), $p < 0.001$).
2. Also, 10% povidone iodine usage has 76.8% less likelihood of bacterial growth compared to control group and the association was significant (Crude OR 0.232, 95% CI:0.058-0.938), $p = 0.04$).
3. Meanwhile, 70% alcohol usage has 27.4% less likelihood of bacterial growth compared to control group, but the association was not significant (Crude OR 0.726, 95% CI:0.15-3.52), $p =0.691$).

Our study that was conducted in a sterile operation theatre with the autoclave sterilized screws that were dropped at 60 minutes into surgery is a real situation simulation that is the main strength of our study. The use of standardized screws which were cortical screws size 3.5X16 mm also standardized the study and increasing in the strength as well. As all the screws were sterilized by the use of autoclave, the assumption was made that all the screws were sterile therefore there was no control negative group in the study.

The screws were dropped and were let to rest on the floor for 30 seconds as this was done to simulate the time it takes for the surgeon to make the decision to pick up the screw. The duration of 10 minutes of immersion in the respective decontamination fluids were in keeping to current practices and also is the most practical in real life situation. In other studies, Bauer et al immersed for 2 minutes (1) and Yazid et al immersed for 20 minutes (2). 10 minutes was determined as the most suitable time as it was less likely to interrupt the flow of surgery or the procedure itself. This is especially true in special implants such as proximal femoral nails where the blade screw has to be done prior to the distal screw. Longer duration of leaving the wound open would increase the risk of infections as well.

This study is different than other studies as there are not much studies that have been conducted on non biological substances. Other studies were all mostly related to the use of grafts such as bones, tendons, ligaments and dental implants.

4.6 Conclusion

In our study the use of 0.5% Chlorhexidine $p<0.001$ was the superior disinfectant when used in comparison with the other solutions. This was contradictory to the current general practice which was the use of povidone-iodine p0.04. This was in keeping with the previous studies that was done. Further studies need to be conducted with the use of cancellous screws to see if the increase in the pitch and depth or height of the screws may increase the incidence of contamination of the screws. The use of plates can also be done as the larger surface area may increase the contamination yield. Another study involving the distance of collected screws such as 2 meter radius around the operation theatre or the dropping of screws at longer duration intra-operatively as well may affect the contamination level.

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4.8 TABLES

Descriptive

Table 1

CONTROL

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No Growth	3	8.8	8.8	8.8
	Growth	31	91.2	91.2	100.0
	Total	34	100.0	100.0	

Table 2

chlorhexidine

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No Growth	31	91.2	91.2	91.2
	Growth	3	8.8	8.8	100.0
	Total	34	100.0	100.0	

Table 3

Ipovidone_iodine

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No Growth	10	29.4	29.4	29.4
	Growth	24	70.6	70.6	100.0
	Total	34	100.0	100.0	

Table 4

alcohol

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No Growth	4	11.8	11.8	11.8
	Growth	30	88.2	88.2	100.0
	Total	34	100.0	100.0	

Table 5

Disinfectant Type

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	control	34	25.0	25.0	25.0

	chlorhexidine	34	25.0	25.0	50.0
	Povidone	34	25.0	25.0	75.0
	Alcohol	34	25.0	25.0	100.0
	Total	136	100.0	100.0	

Table 6

Growth

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No growth	48	35.3	35.3	35.3
	Has Growth	88	64.7	64.7	100.0
	Total	136	100.0	100.0	

To compare effectiveness of 10% iodine, chlorhexidine 0.5% and alcohol 70% in disinfection of screws.

Chlorhexidine * CONTROL

Table 7

Crosstab

			CONTROL		
			No Growth	Growth	Total
chlorhexidine	No Growth	Count	2	29	31
		% within CONTROL	66.7%	93.5%	91.2%

	Growth	Count	1	2	3
		% within CONTROL	33.3%	6.5%	8.8%
Total		Count	3	31	34
		% within CONTROL	100.0%	100.0%	100.0%

Table 8

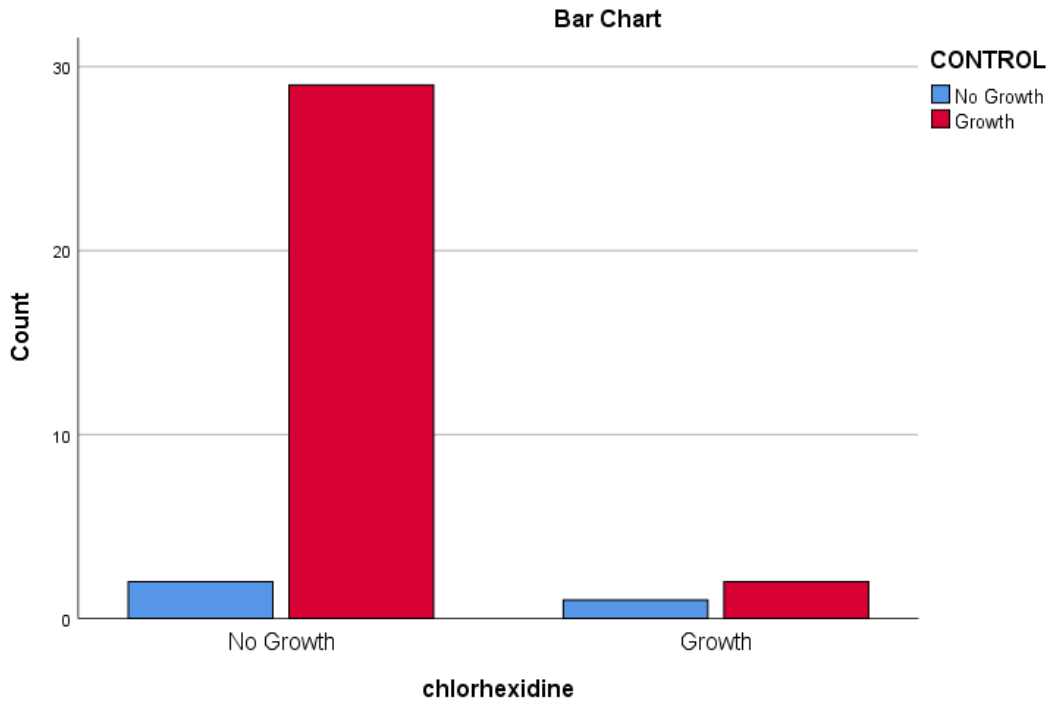
Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	2.457[a]	1	.117		
Continuity Correction[b]	.252	1	.616		
Likelihood Ratio	1.643	1	.200		
Fisher's Exact Test				.249	.249
Linear-by-Linear Association	2.385	1	.123		
N of Valid Cases	34				

a. 3 cells (75.0%) have expected count less than 5. The minimum expected count is .26.

b. Computed only for a 2x2 table

Chart 1



Ipovidone_iodine * CONTROL

Table 9

Crosstab

			CONTROL		
			No Growth	Growth	Total
Ipovidone_iodine	No Growth	Count	1	9	10
		% within CONTROL	33.3%	29.0%	29.4%
	Growth	Count	2	22	24
		% within CONTROL	66.7%	71.0%	70.6%
Total		Count	3	31	34

% within CONTROL	100.0%	100.0%	100.0%

Table 10

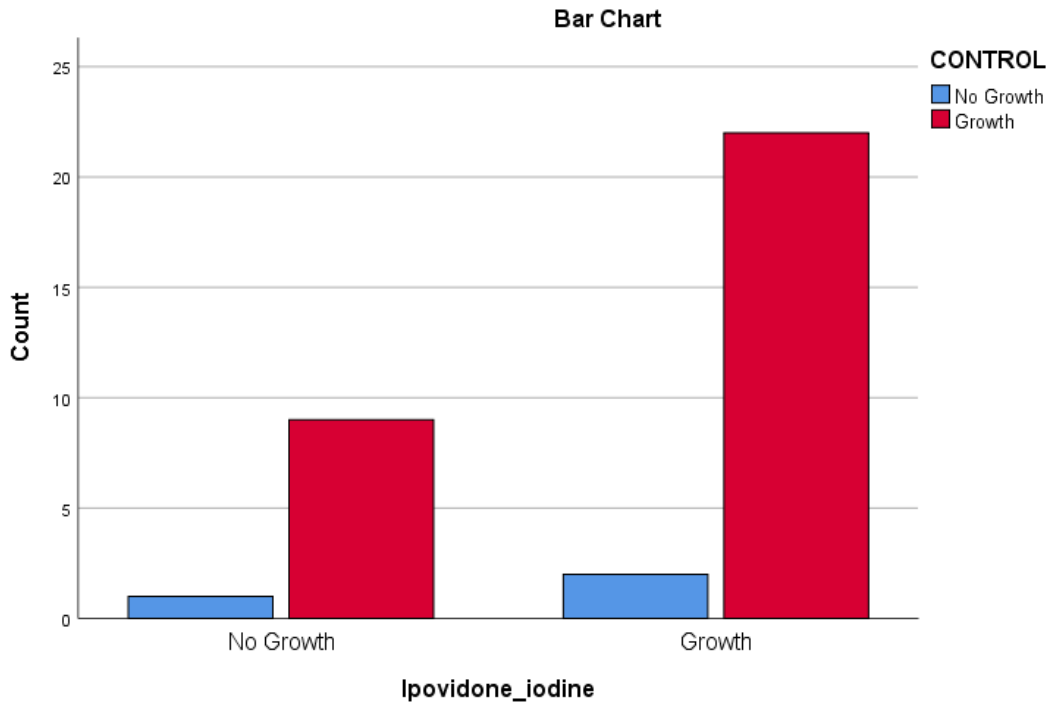
Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.024[a]	1	.876		
Continuity Correction[b]	.000	1	1.000		
Likelihood Ratio	.024	1	.877		
Fisher's Exact Test				1.000	.662
Linear-by-Linear Association	.024	1	.878		
N of Valid Cases	34				

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is .88.

b. Computed only for a 2x2 table

Chart 2



alcohol * CONTROL

Table 11

Crosstab

			CONTROL		
			No Growth	Growth	Total
alcohol	No Growth	Count	0	4	4
		% within CONTROL	0.0%	12.9%	11.8%
	Growth	Count	3	27	30

	% within CONTROL	100.0%	87.1%	88.2%
Total	Count	3	31	34
	% within CONTROL	100.0%	100.0%	100.0%

Table 12

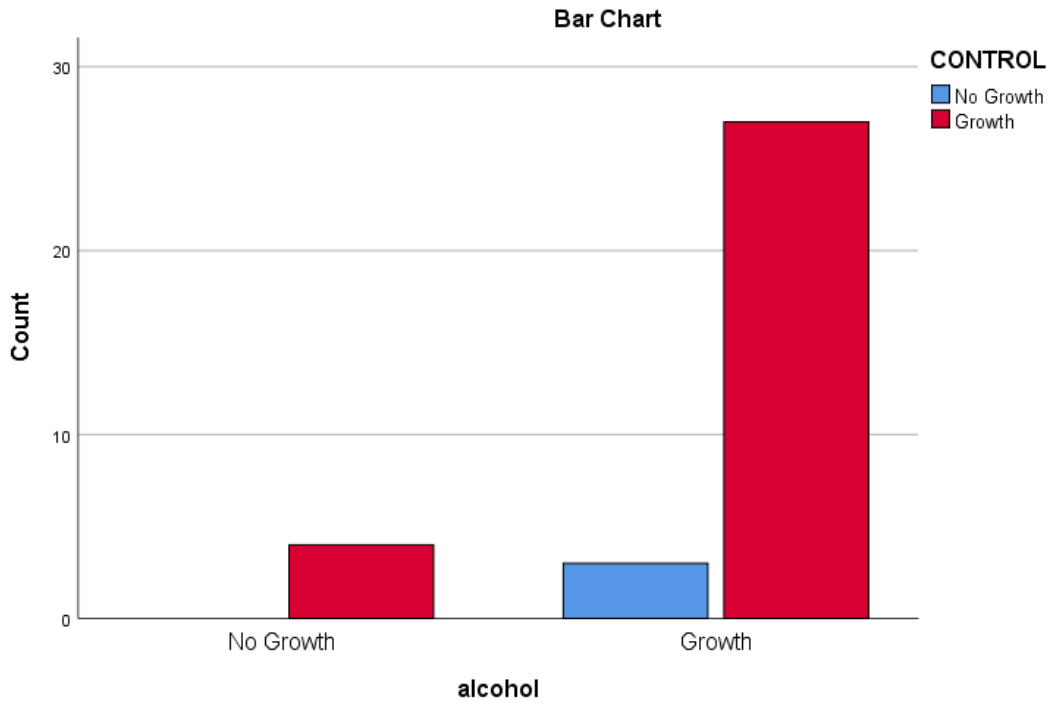
Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.439[a]	1	.508		
Continuity Correction[b]	.000	1	1.000		
Likelihood Ratio	.789	1	.375		
Fisher's Exact Test				1.000	.678
Linear-by-Linear Association	.426	1	.514		
N of Valid Cases	34				

a. 3 cells (75.0%) have expected count less than 5. The minimum expected count is .35.

b. Computed only for a 2x2 table

Chart 3



Ipovidone_iodine * chlorhexidine

Table 13

Crosstab

			chlorhexidine		
			No Growth	Growth	Total
Ipovidone_iodine	No Growth	Count	10	0	10
		% within chlorhexidine	32.3%	0.0%	29.4%
	Growth	Count	21	3	24
		% within chlorhexidine	67.7%	100.0%	70.6%
Total		Count	31	3	34
		% within chlorhexidine	100.0%	100.0%	100.0%

Table 14

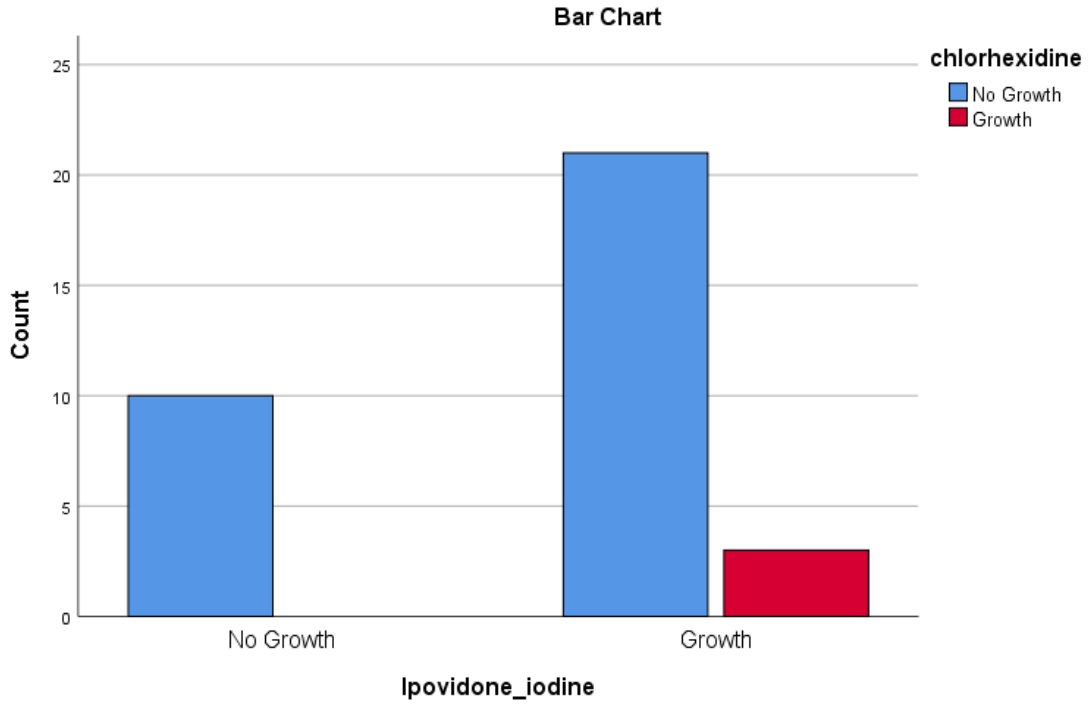
Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	1.371[a]	1	.242		
Continuity Correction[b]	.257	1	.612		
Likelihood Ratio	2.209	1	.137		
Fisher's Exact Test				.539	.338
Linear-by-Linear Association	1.331	1	.249		
N of Valid Cases	34				

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is .88.

b. Computed only for a 2x2 table

Chart 4



Alcohol * chlorhexidine

Table 15

Crosstab

			chlorhexidine		
			No Growth	Growth	Total
alcohol	No Growth	Count	3	1	4
		% within chlorhexidine	9.7%	33.3%	11.8%
	Growth	Count	28	2	30
		% within chlorhexidine	90.3%	66.7%	88.2%
Total		Count	31	3	34
		% within chlorhexidine	100.0%	100.0%	100.0%

Table 16

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	1.475[a]	1	.225		
Continuity Correction[b]	.076	1	.783		
Likelihood Ratio	1.099	1	.294		
Fisher's Exact Test				.322	.322
Linear-by-Linear Association	1.431	1	.232		

N of Valid Cases	34				

a. 3 cells (75.0%) have expected count less than 5. The minimum expected count is .35.

b. Computed only for a 2x2 table

Chart 5

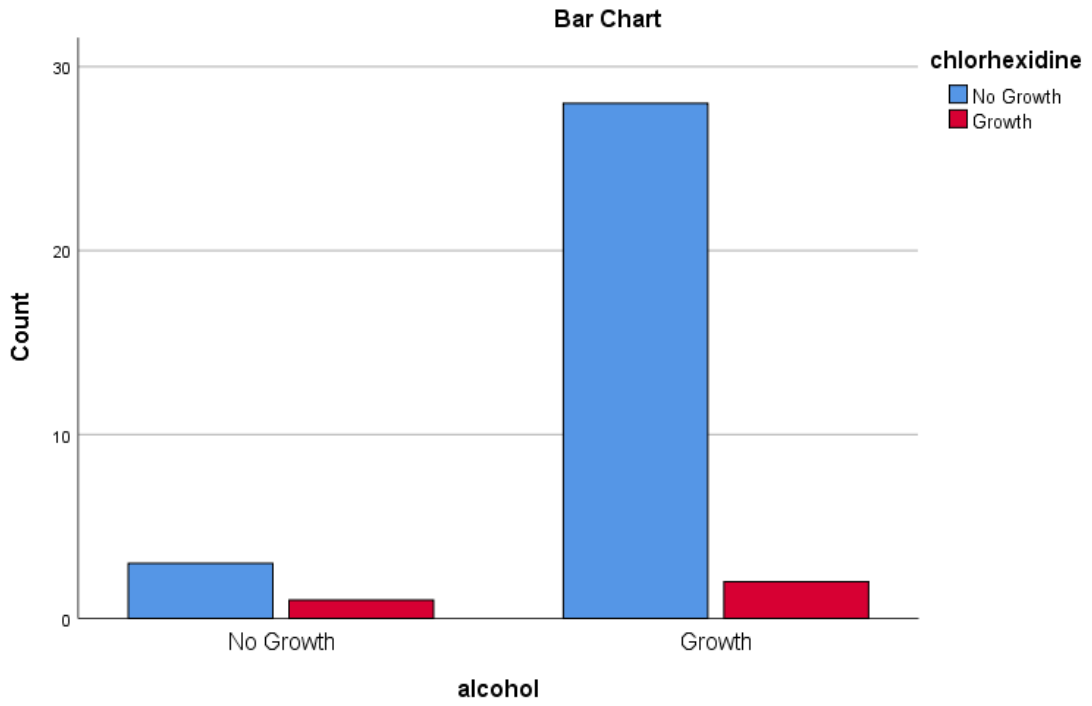


Table 17

Ipovidone_iodine * alcohol Crosstabulation

			alcohol		
			No Growth	Growth	Total
Ipovidone_iodine	No Growth	Count	0	10	10
		% within alcohol	0.0%	33.3%	29.4%
	Growth	Count	4	20	24
		% within alcohol	100.0%	66.7%	70.6%

Total	Count	4	30	34
	% within alcohol	100.0%	100.0%	100.0%

Table 18

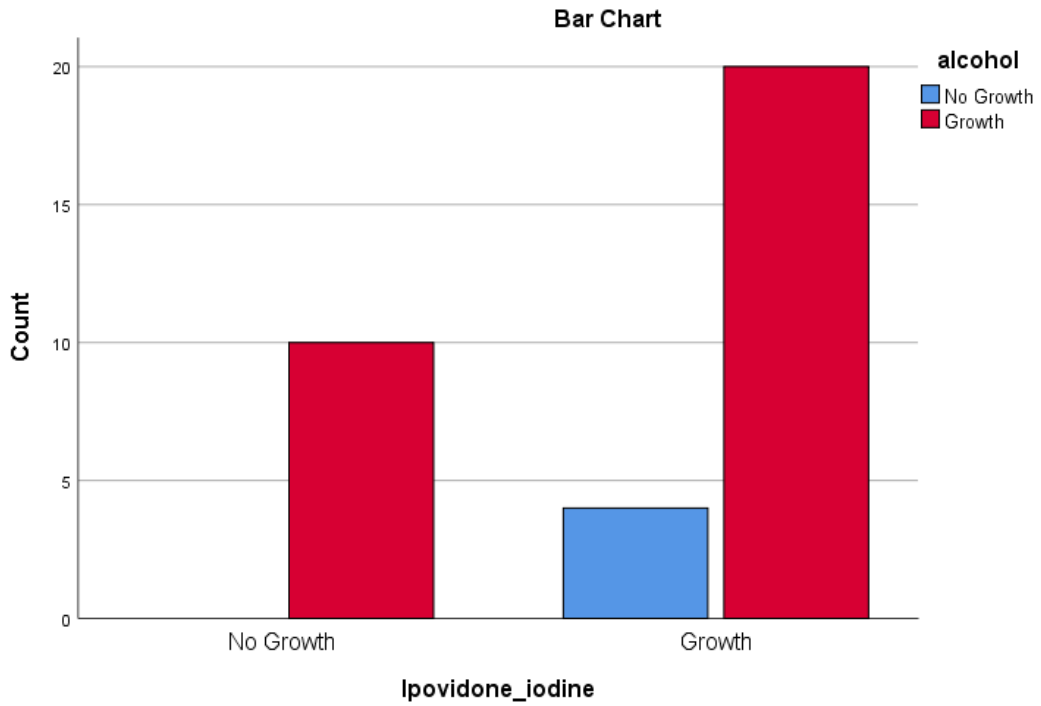
Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	1.889[a]	1	.169		
Continuity Correction[b]	.625	1	.429		
Likelihood Ratio	3.003	1	.083		
Fisher's Exact Test				.296	.229
Linear-by-Linear Association	1.833	1	.176		
N of Valid Cases	34				

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is 1.18.

b. Computed only for a 2x2 table

Chart 6



Simple Logistic Regression

Dependent Variable Encoding

Original Value	Internal Value
No growth	0
Has Growth	1

Categorical Variables Codings

			Parameter coding		
		Frequency	(1)	(2)	(3)
Disinfectant Type	control	34	.000	.000	.000
	chlorhexidine	34	1.000	.000	.000
	Ipovidone	34	.000	1.000	.000
	Alcohol	34	.000	.000	1.000

Block 0: Beginning Block

Table 19

Classification Table[a,b]

			Predicted		
			Growth		Percentage
	Observed		No growth	Has Growth	Correct
Step 0	Growth	No growth	0	48	.0
		Has Growth	0	88	100.0
	Overall Percentage				64.7

a. Constant is included in the model.

b. The cut value is .500

Table 20

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 0	Constant	.606	.179	11.411	1	.001	1.833

Table 21

Variables not in the Equation

			Score	df	Sig.
Step 0	Variables	Disinfectant Type	65.682	3	.000
		Disinfectant Type(1)	61.990	1	.000
		Disinfectant Type(2)	.687	1	.407
		Disinfectant Type(3)	10.990	1	.001
	Overall Statistics		65.682	3	.000

Block 1: Method = Enter

Table 22

Omnibus Tests of Model Coefficients

		Chi-square	df	Sig.
Step 1	Step	70.184	3	.000
	Block	70.184	3	.000
	Model	70.184	3	.000

Table 23

Model Summary

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	106.412[a]	.403	.554

a. Estimation terminated at iteration number 5 because parameter estimates changed by less than .001.

Table 24

Classification Table[a]

			Predicted		
			Growth		Percentage
	Observed		No growth	Has Growth	Correct
Step 1	Growth	No growth	31	17	64.6
		Has Growth	3	85	96.6
	Overall Percentage				85.3

a. The cut value is .500

Table 25

Variables in the Equation

								95% C.I.for EXP(B)	
		B	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
Step 1[a]	Disinfectant Type			38.575	3	.000			

	Disinfectant Type(1)	-4.671	.855	29.836	1	.000	.009	.002	.050
	Disinfectant Type(2)	-1.460	.712	4.202	1	.040	.232	.058	.938
	Disinfectant Type(3)	-.320	.806	.158	1	.691	.726	.150	3.520
	Constant	2.335	.605	14.918	1	.000	10.333		

a. Variable(s) entered on step 1: Disinfectant Type.

CHAPTER 5: APPENDICES

5.1Data Collection Sheet

Lab sheet

Efficacy of chlorhexidine, Povidone-iodine and alcohol in disinfecting contaminated screws

Date

Solution	Growth	No growth
Chlorhexidine 0.5%		
povidone-iodine 10%		
alcohol solutions 70%		
Control		

Specimen taken and sent by:

Specimen interpretation:

5.2 Data Analysis

Methods (Statistical Analysis)

In this analysis, all categorical data were presented in frequency and percentage. Comparisons of effectiveness between disinfectants, were made using Binomial Logistic Regression. The P level of less than 0.05 was considered statistically significant. The analysis was performed using version 26 of the SPSS software (SPSS Inc, Chicago, IL).

3. Descriptive

Table 4: Results (n=34)

Variables	No Growth		Growth	
	n	(%)	n	(%)
Control Group	3	8.8	31	91.2
0.5% chlorhexidine	31	91.2	3	8.8
10% povidone iodine	10	29.4	24	70.6
70% alcohol	4	11.8	30	88.2

Overall Growth

Table 5: Overall Growth

Variable	n	(%)
No growth	48	35.3
Has Growth	88	64.7

4. Statistical Analysis

Table 6: Effectiveness of Disinfectants (n=136)

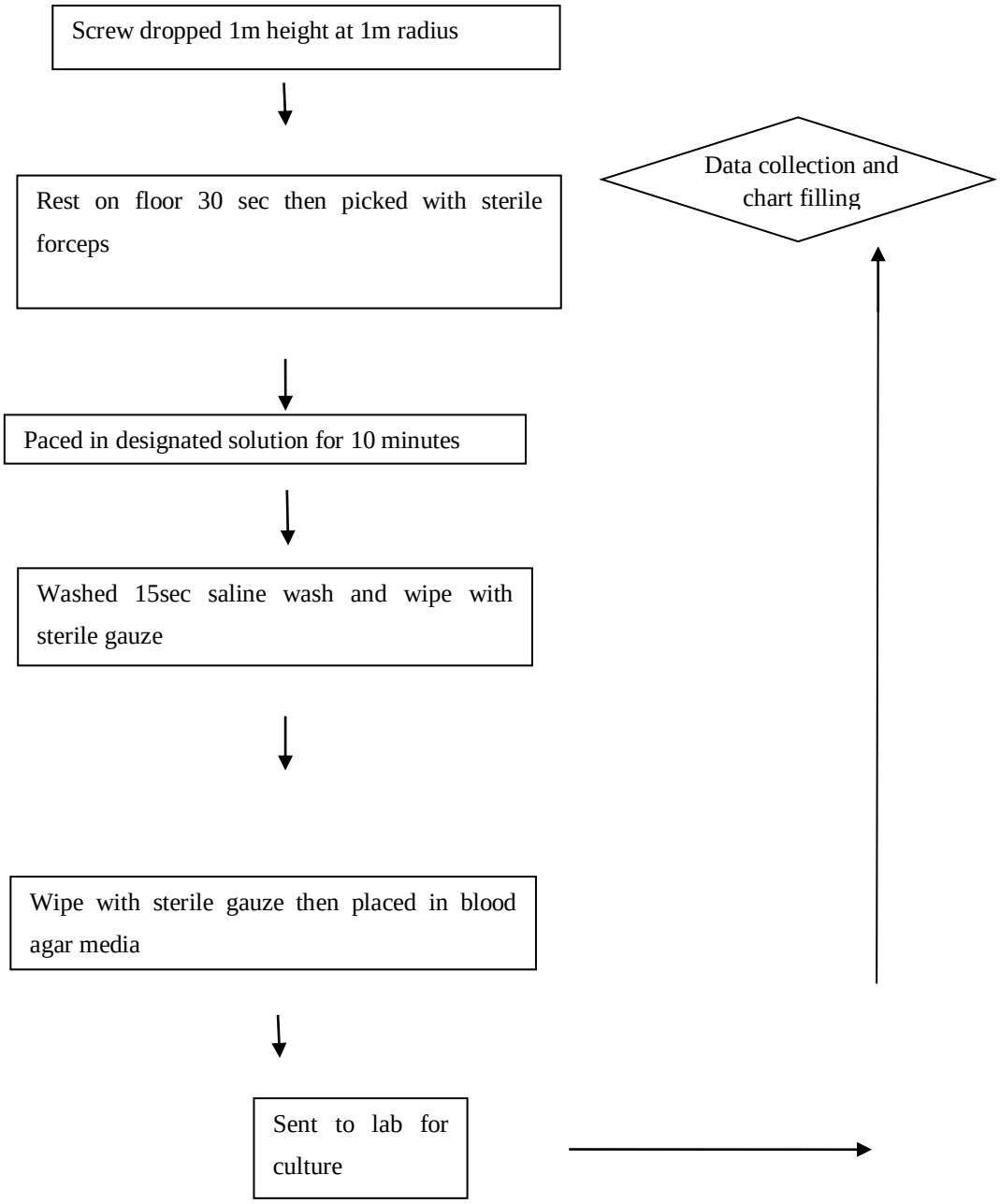
Variables	Crude Odd Ratio (OR)	95% CI (Lower, Upper)		p-value*
0.5% chlorhexidine	0.009	0.002	0.050	<0.001
10% povidone iodine	0.232	0.058	0.938	0.040
70% alcohol	0.726	0.150	3.520	0.691

**Binomial Logistic Regression*

Data Interpretation

4. 0.5% Chlorhexidine usage has 99.1% less likelihood of bacterial growth compared to control group and the association was significant (Crude OR 0.009, 95% CI:0.002-0.05), $p < 0.001$).
5. Also, 10% povidone iodine usage has 76.8% less likelihood of bacterial growth compared to control group and the association was significant (Crude OR 0.232, 95% CI:0.058-0.938), $p = 0.04$).
6. Meanwhile, 70% alcohol usage has 27.4% less likelihood of bacterial growth compared to control group, but the association was not significant (Crude OR 0.726, 95% CI:0.15-3.52), $p = 0.691$).

5.3 Study flowchart



5.4 Gantt chart & milestone

ACTIVITIES	TIME								
	2020					2021			
	APR-MAY	JUNE-SEPT	OCT	NOV	DEC	JAN-MAR	APR-JUNE	JUL-SEPT	OCT-NOV
RESEARCH PROPOSAL									
PRESENTATION PROPOSAL AT DEPARTMENT									
ETHICAL PRESENTATION AND APPROVAL									
DATA COLLECTION									
DATA ANALYSIS									
REPORT									

WRITING									
SUBMISSION AND CORRECTION									

5.5 RAW DATA:

Date	**CHLORHEXIDINE 0.5%**	**IPOVIDONE-IODINE 10%**	**ALCOHOL 70%.**	**CONTROL**
23/11/20	**Ng**	**G**	**G**	**G**
23/11/20	**Ng**	**Ng**	**G**	**G**
14/12/20	**Ng**	**G**	**Ng**	**G**
14/12/20	**Ng**	**G**	**G**	**Ng**
21/12/20	**Ng**	**G**	**G**	**G**
21/12/20	**G**	**G**	**G**	**G**
28/12/20	**Ng**	**Ng**	**G**	**G**
28/12/20	**Ng**	**G**	**G**	**G**
15/1/21	**Ng**	**G**	**G**	**G**
15/1/21	**G**	**G**	**G**	**Ng**

18/1/21	**Ng**	**Ng**	**G**	**G**
18/1/21	**Ng**	**G**	**G**	**G**
25/1/21	**Ng**	**G**	**G**	**G**
25/1/21	**Ng**	**Ng**	**G**	**G**
8/2/21	**Ng**	**G**	**Ng**	**G**
8/2/21	**Ng**	**Ng**	**G**	**G**
15/2/21	**G**	**G**	**Ng**	**G**
15/2/21	**Ng**	**G**	**G**	**G**
22/2/21	**Ng**	**Ng**	**G**	**G**
22/2/21	**Ng**	**G**	**G**	**G**
3/3/21	**Ng**	**G**	**Ng**	**G**
3/3/21	**Ng**	**Ng**	**G**	**G**
10/3/21	**Ng**	**G**	**G**	**G**
10/3/21	**Ng**	**G**	**G**	**G**
24/3/21	**Ng**	**G**	**G**	**G**
24/3/21	**Ng**	**Ng**	**G**	**G**
7/4/21	**Ng**	**Ng**	**G**	**Ng**
7/4/21	**Ng**	**G**	**G**	**G**

14/4/21	**Ng**	**G**	**G**	**G**
14/4/21	**Ng**	**G**	**G**	**G**
21/4/21	**Ng**	**G**	**G**	**G**
21/4/21	**Ng**	**G**	**G**	**G**
28/4/21	**Ng**	**Ng**	**G**	**G**
28/4/21	**Ng**	**G**	**G**	**G**
Total	**3 growth**	**24 growth**	**30 growth**	**31 growth**

5.6 Ethics approval

Jawatankuasa Etika
Penyelidikan Manusia USM (JEPeM)

Human Research Ethics Committee USM (HREC)

Universiti Sains Malaysia
Kampus Kesihatan
16150 Kubang Kerian, Kelantan. Malaysia.
Tel : +609 - 767 3000/2354/2362
Fax. : +609 - 767 2351
Email: jepem@usm.my
Laman Web : www.jepem.kk.usm.my
www.usm.my

12th May 2021

Dr. Arunjit Singh Sandhu
Department of Orthopaedics
School of Medical Sciences
Universiti Sains Malaysia
16150 Kubang Kerian, Kelantan.

JEPeM Code : USM/JEPeM/21020143
Protocol Title : The Efficacy of Disinfecting Contaminated Screws with Chlorhexidine 0.5%, Povidone-Iodine 10% and Alcohol 70%.

Dear Dr.,

We wish to inform you that your study protocol has been reviewed and is hereby granted approval for implementation by the Jawatankuasa Etika Penyelidikan Manusia Universiti Sains Malaysia (JEPeM-USM). Your study has been assigned study protocol code **USM/JEPeM/21020143**, which should be used for all communications to JEPeM-USM in relation to this study. This ethical approval is valid from **12th May 2021** until **11th May 2022.**

Study Site: Hospital Raja Perempuan Zainab II, Kota Bharu, Kelantan.

The following researchers are also involved in this study:

1. Dr. Mohammad Paiman

The following documents have been approved for use in the study.

1. Research Proposal

While the study is in progress, we request you to submit to us the following documents:

1. Application for renewal of ethical approval 60 days before the expiration date of this approval through submission of **JEPeM-USM FORM 3(B) 2019: Continuing Review Application Form.**
2. Any changes in the protocol, especially those that may adversely affect the safety of the participants during the conduct of the trial including changes in personnel, must be submitted or reported using **JEPeM-USM FORM 3(A) 2019: Study Protocol Amendment Submission Form.**
3. Revisions in the informed consent form using the **JEPeM-USM FORM 3(A) 2019: Study Protocol Amendment Submission Form.**
4. Reports of adverse events including from other study sites (national, international) using the **JEPeM-USM FORM 3(G) 2019: Adverse Events Report.**
5. Notice of early termination of the study and reasons for such using **JEPeM-USM FORM 3(E) 2019.**
6. Any event which may have ethical significance.
7. Any information which is needed by the JEPeM-USM to do ongoing review.
8. Notice of time of completion of the study using **JEPeM-USM FORM 3(C) 2019: Final Report Form.**

Please note that forms may be downloaded from the JEPeM-USM website: **www.jepem.kk.usm.my**

JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.

Thank you.

Sincerely,

PROF. DR. HANS AMIN VAN ROSTENBERGHE
Chairperson
Jawatankuasa Etika Penyelidikan (Manusia) JEPeM
Universiti Sains Malaysia

JAWATANKUASA ETIKA & PENYELIDIKAN PERUBATA

(*Medical Research & Ethics Committee*)

KEMENTERIAN KESIHATAN MALAYSIA

d/a Kompleks Institut Kesihatan Negara Blok A, No 1, Jalan Setia Murni U13/52, Seksyen U13, Bandar Setia Alam,

40170 Shah Alam, Selangor. Tel: 03-3362

Ruj.Kami : 21-01960-EIJ

Tarikh : 16-November-2021

ARUNJIT SINGH SANDHU

HOSPITAL RAJA PEREMPUAN ZAINAB II

Dear Sir/ Mdm,

ETHICAL INITIAL APPROVAL: NMRR ID-21-01960-EIJ

THE EFFICACY OF DISINFECTING CONTAMINATED SCREWS WITH CHLORHEXIDINE 0.5%, POVIDONE-IODINE 10% AND ALCOHOL 70%

This letter is made in reference to the above study.

2. The Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia (MOH) has determined that this study **DOES NOT** require MREC review / approval as **this study does not involve human subject.**

3. You may conduct your research without the need for further submission or reports to MREC. Please be reminded to obtain the appropriate publication consent from individual subjects in a case series as per journal requirements.

”WAWASAN KEMAKMURAN
BERSAMA 2030” "BERKHIDMAT
UNTUK NEGARA"

Yours Sincerely,

.....

..... DR HJH

SALINA ABDUL AZIZ

Chairperson

Medical Research & Ethics

Committee Ministry of

Health Malaysia

MMC No: 27117

NA/Exempt/Approval2021/Mrecshare

5.7 GUIDELINES/INSTRUCTIONS TO AUTHORS OF SELECTED JOURNAL

This manuscript is produced in concordance with the format given by the Malaysian orthopedic Journal.

Malaysian Orthopaedic Journal

General Format of Manuscript

The manuscript should be prepared using size 12 point font Times New Roman throughout (including abstracts, references, tables and illustrations). Other than the main section headings, subheadings are not recommended. The text should be "left hand" justified only. All pages should be numbered on the top right corner.

Measurement should use SI units. Spell out "one" to "ten" at the beginning of a sentence, and "one" at all times. Arabic numerals should be used otherwise. Each of the following manuscript components should begin with a new page.

Generic names of drugs should be used. For specific implants, instruments and devices, the manufacturer, city, and country should be provided in square brackets.

Authors wishing to include figures, tables, or text passages that have already been published elsewhere are required to obtain written permission from the copyright owner. Evidence that such permission has been granted must be submitted together with the manuscript.

Abstract

- Should consist not more than 350 words.
- Both structured and unstructured abstracts can be accepted.
- For original articles, result and conclusion should be included.
- Below the abstract, provide not more than 5 keywords or short phrases to assist in cross indexing of the article.

Introduction

- Provide only relevant information and references
- Do not review the subject extensively.
- Do not include results or conclusion of the study.
- State the purpose of the study clearly.

Material and method

- Specify the selection of subjects or study groups clearly.
- Describe the methods, apparatus (including manufacturer's name in parenthesis) and procedures in sufficient detail to allow others to reproduce the study.
- Provide reference to established methods, brief descriptions for methods that are not well-known.
- Describe new or substantially modified methods, giving reasons for using them and evaluate their limitations
- Describe the chemicals and drugs used (including generic names, dosages and routes of administration).
- Describe statistical methods used with adequate details to enable a knowledgeable reader to verify the reported results.
- Ethics:
    - When reporting experiments on human subjects, indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional or regional) and with the Helsinki Declaration of 1975, as revised in 1983.
    - Do not use patients' names, initials, or hospital numbers, especially in illustrative material.

  When reporting experiments on animals, indicate whether the institution's or a national research council's guide for, or any national law on, the care and use of laboratory animals was followed.

Results

- Present the important findings in a logical sequence.
- The results can be supplemented with tables or illustrations.
- Do not repeat all the data contained in the tables or illustrations. Emphasize only the important observations.

Discussion

- Emphasize only important findings, their implications and limitations.
- Avoid repeating in detail data provided in the results and introduction.
- Relate the observations to other relevant studies.
- Avoid statements that are not completely supported by results of the study.
- Whenever recommendations for treatment are made, the patients groups and applicable conditions must be carefully defined.

Conclusion

- Link conclusions to the aim(s) of study
- All conclusions must be supported by the results of the study
- Avoid claiming priority to work that has not been completed.

References

- Number references consecutively in the order in which they are first mentioned in the text, tables or illustrations.
- Present references in Vancouver style. References in the text should be cited each by a reference number in 'Arabic numerals' in square brackets e.g. [1] or [2-3]
- List the first 6 authors followed by "et al".
- Journal titles should be abbreviated in accordance with ***Index Medicus***.
- Authors are responsible for the accuracy of references and must verify them against original documents.

Tables

- Use of tables should be kept to a minimum.
- Roman numerals should be used for numbering tables (e.g. Table I, Table II).
- Present each table on a separate page, with a clear legend ABOVE it.
- The content of a table should be clearly labelled so that it is comprehensive without reference to the text.

Illustrations

- Use of illustrations or diagrams should be kept to a minimum.
- Arabic numerals should be used for numbering illustrations, and present them as “Figures” (e.g. Figure1, Figure2).
- Describe each illustration on a separate page, with a clear legend BELOW it.
- All reproduced materials must have the written permission of the owner (publisher), and it must be so indicated in the legend.
- For electronic submission,
    - Higher resolution images (300 DPI or higher) should be submitted as separate files (JPEG or TIFF) and named according to figure numbers.