HMC RESEARCH PROTOCOL

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Hamad Medical Corporation
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مركز البحوث الطبية
Medical Research Center

Study Title:	**Orthopedic Wound Dressing Using Sterile Versus Clean Non-sterile Techniques At Hamad General Hospital.** Prospective Pilot Study
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Contents

1. Synopsis

Surgical site infection (SSI) is a serious complication in patients undergoing orthopedic procedures.

SSI can be defined by the presence of microorganisms in sufficient quantity that may lead to tissue injury or delayed wound healing. It can be divided into acute (superficial) and chronic (deep), which may occur postoperatively up to 30 days and 12 months, respectively.

Following orthopedic procedures, the use of sterile or clean non-sterile technique for wound care and dressing varies widely. However, there is no evidence in the literature to determine which technique is more effective in preventing acute SSI.

Sterile (aseptic) technique implies the use of a sterile gloves, sterile field and sterile equipment. Clean non-sterile technique implies the use of a clean non-sterile gloves, sterile field and equipment.

Hamad Medical Corporation (HMC) wound care policies do not recommend whether to use sterile or clean non-sterile technique for wound care and dressing after major orthopedic procedures such as joint replacement and reconstructive surgery.

Considering the need for evidence-based practice, this study aims to evaluate the rate of acute SSI following elective orthopedic procedures in the aforementioned techniques.

3. Abbreviations and Acronyms

SG : Sterile Gloves

NSG : Non-sterile Gloves

SSI : Surgical site infection

5. Introduction / Background

SSI following orthopaedic surgeries is not uncommon. If an infection occurs, it may lead to debilitating results, increased reoperations, hospital stay, and healthcare costs [1].

SSI was defined by the Centres for Disease Control and Prevention/ National Nosocomial Infections Surveillance system. The definition included superficial and deep SSI with an onset within 30 days and 12 months, respectively, following the operation [2].

Because there is no current standard of care to use sterile or clean nonsterile technique for wound care and dressing following elective orthopaedic procedures, further studies are needed to determine which technique is more effective in preventing acute SSI [3,4].

The sterile technique was defined in a systematic review by Kent by the use of sterile field, sterile gloves, and sterile instruments. Whereas clean technique implies the use of a clean procedure field, clean non-sterile gloves and ensuring that the gloves, field, and supplies are free of contamination [3].

Some studies have compared the use of sterile and clean non-sterile techniques to determine the effect on wound infections in cutaneous

surgical procedures and chronic wounds [4,5,7]. Ghafouri et al.[1] reported the SSI rate of 2.02% and 4.6% in patients underwent contaminated laceration wound repair using sterile and clean non-sterile techniques, respectively. The incidence of infection was not significantly different between the two groups.

A Systematic Review and Meta-analysis have concluded that there was no difference in the rate of infection between outpatient surgical procedures performed with sterile versus non-sterile gloves [3,5]. Other studies concluded that each health care organization has to establish its own guidelines for wound care because the existing evidence base does not support the preferential selection of either technique [6]. A prospective randomized controlled study had concluded that clean non-sterile gloves are not inferior to sterile gloves for minor skin excisions in general practice regarding SSI [7].

To the best of our knowledge, there are no studies available that have compared the rate of acute postoperative SSI between the use of sterile versus clean non-sterile gloves for wound care and dressing after knee arthroscopy, ACL repair (infection rate is low (0.14%-1.7%) following ACL reconstruction) [19] or simple isolated fracture fixation. This pilot study aims to evaluate the rate of acute SSI following this orthopedic procedures in sterile versus clean non-sterile techniques.

7. Objectives

Hypothesis:

No difference in the rate of SSI between the use of sterile or clean non-sterile techniques following knee arthroscopy, ACL repair or simple isolated fracture fixation for wound care and dressing.

Primary Objective:

To compare the rate of significant SSI within the 6 weeks following orthopedic procedure between both techniques. (Significant SSI which needs treatment with antibiotics or further management, eg: wound debridement.)

Secondary Objectives:

Hospital stay and need for readmission.

Need for second operation or treatment.

To compare the cost of dressing changes.

8. Study Methodology

Study design: Randomized prospective pilot study

Sample size: Since limited data is available to calculate sample size, especially from the orthopedic surgery field, we will recruit 100 patients with 50 patients being in each group. Then we will do a post hoc analysis to calculate the adequacy of sample size to adjust the sample size according to 80% power with less than 20% type 2 error and less than 5% P-value.[15]

Method:

The study will be designed as a prospective pilot study to compare the rate of acute SSI up to 6 weeks following knee arthroscopy, ACL repair or simple isolated fracture fixation between the use of sterile versus clean non-sterile techniques for wound care and dressing. The main reason behind this design is that no previous studies reported the rate of acute SSI following the aforementioned procedures.

All patients will be treated using the same postoperative protocol. Dressing will be changed once by the one specialist nurse practitioner on day 5 after the procedure. Patients will be assessed in the outpatient clinic on day 14 for dressing changes and for suture removal. The final assessment will be at the outpatient visit on week six postoperatively.

The study is limited to procedures done by one nurse only when the patient is in the hospital or in the clinic.

Adult patients (age >= 18) who will undergo clean knee arthroscopy, ACL repair or isolated fracture fixation at our orthopaedic surgery ward will be screened for recruitment. Patients who meet the inclusion criteria and are willing to participate in the study will be asked to sign a consent form. Once a patient is eligible for recruitment, informed consent will be obtained. The randomization sequence will be generated beforehand and the allocated treatments will be in sealed opaque envelopes. A sealed envelope will be opened and the allocated treatment will consist of either dressing change with the use of sterile or clean non-sterile technique during the post-operative course. Neither patients nor the research team will be blinded for dressing type.

Baseline variable that will be collected includes:

- Patient demographics
- Type of elective orthopaedic procedure
- Duration of the operation
- Estimated blood loss
- Number of dressing changes and any days
- Preventive measure such as pre-op staph aureus decolonization, dental check-up, hair removal, nutrition status will be screened before the surgery.

For patients in both groups, World Health Organization (WHO) Hand Hygiene Technique with Soap and Water will be implemented [8]. Then the

use of one pair of clean non-sterile gloves during the opening of the dressing. The skin will be disinfected with a chlorhexidine stick. Depending on the patient treatment allocation, a sterile or clean non-sterile technique (using sterile to sterile procedure when handling materials and supplies for sterile technique) will be utilized for dressing application.

Patients will be followed during the hospital stay, 2 weeks and 6 weeks after the procedure. At each follow-up visit, SSI indicators will be collected. Lab test will be done only for patient with high clinical impression of infection, as part of routine patient care. White blood cell count, c-reactive protein and wound culture will obtained in patient who have clinical indications of SSI.

We will document any other operative complications and reoperations during the postoperative 6 weeks as well.

Dressing type will be changed using Mepilex Border Flex 7.5*7.5

We will use the below questioners to detect the rate of significant SSI [14]:

Fever (>38.0°C [>100.3°F]) at presentation with

clinical assessment

Wound Assessment (Impression)

0 - No or slight erythema (No evidence of infection)

1 - Erythema not >1 cm from the suture line (Slight inflammation does not require antibiotics)

2 - Erythema >1 cm from suture line ±edema (Significant infection requires antibiotics)

3 - Pus ±1 or 2 (Severe infection requires an immediate referral for exploration and debridement + antibiotics)

SSI with be considered significant in 2 and 3.

10. Study Population and Study Setting/ Location

Study Setting:

Orthopedic surgery ward, Hamad General Hospital.

Eligibility criteria: [17]

Age more than 18 and less than 65 years

knee arthroscopy, ACL repair or isolated

fracture fixation.

Operating time < 2 hours

Patients with ASA 0 to ASA1

Non smoker

No previous surgical scar in the knee

Informed consent

Any patient that has, previous superficial or deep infection at the site of surgery, polytrauma, transfusion of blood products, obesity (BMI > 40 kg/m^2), diabetes mellitus, revision procedure or immune-compromised, patient preparationrelated factor (inadequate antiseptic skin preparation, preoperative hair removal), skin disease, current use of antibiotics instructed by the treating physician (eg, contaminated wounds) will be excluded.

12. Study procedures

Total Study duration: 12 months

Task	Timepoint
Study preparation	1 Month
Recruitment and follow-up	6 Months
Final Statistical Analyses	3 Months
Publication in relevant journals	2 Months

Informed Consent

Adult patients (age >= 18) who underwent knee arthroscopy +\- ACL repair will be invited postoperatively by the research team to take part in the trial. Patients will have 24 hours to decide whether they want to participate or not.

Risk

Since the literature shows no difference in the incidence of SSI in other fields, we expected a relative risk for both techniques. Moreover, we may conclude which technique is better and help introduce a new policy for future practice in HMC.

Bio-Specimens & Sample Collection

Wound culture

Blood tests including a white blood cell counts, C-reactive protein and Procalcitonin.

Outcomes

The primary objection is to compare the rate of acute SSI between the use of sterile and clean non-sterile techniques for post-operative orthopedic wound care.

Data Collection & Confidentiality

Data and medical record will be stored on a separate data spread sheets

The study data will be only accessible by the research team members, to prevent privacy breach.

Data will be protected with password encryption and will be stored on an online drive using Microsoft OneDrive.

The Data spreadsheet will be physically stored at a computer in the orthopedic surgery department in Hamad General Hospital.

Data identifiers will be destroyed after we complete data collection and validation. The de identified study data will be stored for 5 years after study completion.

The following data will be collected on a spreadsheet:

- Demographic data (Age ,gender, BMI)
- Comorbidities: (DM, HTN)
- Type of procedure
- Hospital course (TICU admission)
- Transfusion of PRBC
- Clinical signs of infection:
    - Vital signs (Temperature, Heart Rate)
    - Signs of Infection

-Purulent discharge
-Pain or tenderness
-Localized swelling
-Redness or heat at site
-Lab tests in cases with significant SSI (WBCs > 14.0 K/ml, C-Reactive Protein > 18.5 mg/ml , Procalcitonin > 187.5 pg/ml) [6].
-Positive Wound Culture.

Subject Withdrawal/ Withdrawal of Consent

Patients have the right to withdraw from the study at any time point. This will not affect their care in anyway. We will ask the withdrawing patients if we can

publish and use the data we collected up to the point of withdrawal. If the patient refuses to share any of the data, we will delete it permanently.

14. Statistical Consideration and Data Analysis

Stata statistical package 15.1IC will be used for statistical analyses. The primary outcome and secondary outcomes that are nominal (categorical) will be analyzed in both groups using a chi-square test or the Fischer exact test. The statistical analysis will be carried out by a biostatistician from HMC MRC.

Categorical data will be expressed as proportions, and continuous data will be presented as mean with standard deviation (SD) for normally distributed variables or as medians (interquartile range, IQR) for non-normally distributed variables.

Unpaired t or Mann Whitney U tests will be applied to compare quantitative data and outcomes (such as length of hospital stay, BMI etc.) between SSI and non-SSI groups .

- In addition, exploratory statistical analyses using logistic regression method will be performed to assess and explore various potential factors and covariates that might affect SSI rate.
- All P values presented will be two-tailed, and P values <0.05 will be considered as statistically significant. All Statistical analyses will be done using statistical packages SPSS 23.0 (SPSS Inc. Chicago, IL) and Epi-info (Centers for Disease Control and Prevention, Atlanta, GA) software.

16. Adverse Event Reporting

Since the literature shows no difference in the incidence of SSI in other fields, we expected a relative risk for both techniques. Moreover, we may conclude which technique is better and help introduce a new policy for future practice in HMC.

1-Adverse event (AE):

An AE is defined as any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in patients.

2-Serious adverse event (SAE)

A SAE is defined as any AE that:

- Led to death
- Led to a serious deterioration in health of the patient that either resulted in
  - a life-threatening illness or injury, or
  - a permanent impairment of a body structure or a body function, or
  - inpatient or prolonged hospitalization, or
  - a medical or surgical intervention to prevent life-threatening illness or injury or permanent
  - impairment to a body structure or a body function

3-Adverse event documentation

The following information is collected:

- Name and description of the event
- Start date of the event (if applicable)
- Actions taken due to the occurrence of the event
- Outcome of the event
- Date the patient has recovered from the event
- Relationship to treatment under investigation
- Severity of the event
- Seriousness of the event

4-As soon as a research team member becomes aware of an SAE, this person will ensure that the following people will be notified:

- PI
- MRC/IRB

5-The following steps need to be taken after a study patient has experienced an SAE:

Initial SAE report:

The investigator collects as much of the following information as possible for reporting to MRC/IRB:

- Subject demographics
- Date of occurrence of the event
- Description of the event, including severity and relationship to the treatment
- Possible cause of SAE other than the investigational device
- Relevant medical history
- Relevant test/laboratory data
- Concomitant medications
- Name and contact details of the person who has reported the event.

6- Follow up of adverse events

Each AE will be followed up until resolved with or without persistent damage or until the end of the patient's study participation. All patients experiencing an AE must be monitored until the symptoms subside and any clinically relevant changes in laboratory values have returned to baseline, or until there is a satisfactory explanation for the changes observed.

18. Ethical Consideration

Ethical approval will be obtained from Hamad Medical Corporation Institutional Review Board prior to initiating the study. All study personnel will adhere to GCP guidelines and the rules and regulations set by the Ministry of Public Health in Qatar.

20. Sponsor, Funding & Collaborator Information

Hamad Medical Corporation fund for publication and conference fees.

22. Dissemination of Results and Publication policy

The research team will work on publishing the results in regional and international Journal, upon completion of the study. Moreover, the study material will be served for educational purposes.

24. References

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19. Infections in Anterior Cruciate Ligament Reconstruction Charlton Stucken, MD,† David N. Garras, MD,† Julie L. Shaner, MD,† and Steven B. Cohen, MD*†

26. Appendices

Data Collection sheet (uploaded with research proposal on Abhath.hamad.qa)