Effectiveness of polyurethane foam dressing compared with Mepilex dressing for pressure ulcer prevention in operating room: A randomized control clinical trial.

Project Title:

Effectiveness of polyurethane foam (pink pad) compared with Mepilex dressing for pressure ulcer prevention in operating room: A randomized control clinical trial.

Acronym

Version: version: 2

Principal Investigator: Ebtisam Abdellatif Ebrahim

Sponsor: King Abdullah Medical City in Holy Capital

Introduction

The application of standard evidence-based prevention interventions can decrease the incidence of pressure injuries (PIs). However, the development of serious PIs in high-risk patients in the early postoperative period remains a significant clinical challenge. Following surgery, PIs that appear within 1 to 5 days are often deep-tissue pressure injuries (DTPIs) [1].

The etiology of DTPIs remains a topic of ongoing discussion among experts, and a comprehensive understanding of the underlying pathophysiological mechanisms has yet to be achieved. One commonly accepted hypothesis posits that the occurrence of DTPIs can be attributed to the application of pressure or shear stresses, or a combination thereof, resulting in cellular deformation and eventual necrosis. The DTPIs exhibit a distinctive complexity due to the co-occurrence of ischemia and mechanical stress, thereby expediting the consequent harm [2,3]

DTPIs exhibit a discernible pattern of evolution. Initially, the affected area manifests abruptly as intact skin that exhibits discoloration, either in the form of purple or hyperpigmentation [2]. The lesions evolve into slender vesicles atop a dusky ulceration site, transformingrotic black eschar. Subsequently, the DTPI becomes unsealed, exposing a pressure injury that has penetrated through the entire thickness of the skin and underlying tissues, indicating a stage 3 or 4 injury [3,4]. According to a study conducted in 2013, it has been observed that wounds of this nature have the potential to heal without any loss of tissue. Nevertheless, it is imperative to provide sustained care and attention to prevent any deterioration [5].

Patients undergoing cardiac surgery are among those at the highest risk of developing PIs, with an incidence as high as 29.5% [6]. Among patients undergoing cardiac surgery, specific risk factors for PI include protracted exposure to pressure during lengthy surgical procedures, vascular disease, and/or postoperative vasopressor use [7]. The high incidence of PI among cardiac surgery patients suggests that conventional methods for preventing PI are inadequate for this population.

There are an increasing number of studies evaluating the efficacy of different dressings (typically multilayer foam dressings) in preventing pressure ulcers (PIs) of the sacrum, heel, and those related to medical devices in ICU and trauma patient populations [8,9]. Recent high-quality randomized controlled trials demonstrated that the use of specialty foam dressings over the sacrum can reduce the incidence of pressure ulcers in intensive care unit (ICU) patients and high-risk nursing home residents [10,11].

Although limited in design and/or sample size, additional research and quality improvement investigations support the efficacy of this intervention in preventing the formation of PIs [12]. The National Pressure Ulcer Advisory Panel, in collaboration with European and Pan-Pacific peer organizations, added a recommendation (with a "B" strength of evidence) to "consider applying a

polyurethane foam to bony prominences (e.g., heels, sacrum) for the prevention of pressure ulcers in anatomical areas frequently subjected to friction and shear" in its 2014 guidelines [13].

The market offers a variety of dressings distinguished by their composition (hydrocolloid, polyurethane foam, etc.), thickness, and dimension. Several in vitro studies compare the ability of the most popular dressings on the market regarding the redistribution of pressure, [15-17] the management of fluids/hydration and the application of friction, which are the primary factors in the onset of PU. In these in vitro investigations, the material that appears to be the most effective overall is polyurethane foam [18], particularly when composed of multiple layers [19]. In two recent clinical investigations involving intensive care unit (ICU) patients, the use of multi-layer foam dressings was found to be an effective method of preventing PU [20].

A systematic review revealed that the prevalence of pressure ulcers among surgical patients increased from 0.3% to 57%. In a study of Brazilian patients undergoing elective surgery, the prevalence of pressure ulcers reached 25 % [21]. 5–53.4% of hospital-acquired pressure ulcers are associated with protracted or multiple surgical procedures, according to studies [22]. In the operating room of a private hospital in western Indonesia, the incidence of pressure ulcers has increased from one case in 2018 to four cases in 2020.

Despite the fact that the data support the use of dressings as a preventative intervention, the reviewers deemed them inconclusive because of the flaws in the study designs, which increased the possibility of bias. Both evaluations recommended further methodologically rigorous research to generate proof of the effectiveness and kind of dressing to use for prevention as their conclusion. King Abdullah medical city has a cardiac center, and a lot of open-heart surgeries are performed there, and both polyurethane foam (pink Pad) and Mepilex dressing are applied to those patients. Therefore, the

Effectiveness of polyurethane foam dressing compared with Mepilex dressing for pressure ulcer prevention in operating room: A randomized control clinical trial.

present study was designed to compare the effects of polyurethane foam (pink Pad) versus Mepilex dressing for prevention of pressure ulcer in operating room.

OBJECTIVES:

The **primary objective** of this study is to:

- To evaluate the efficacy of using polyurethane foam (pink Pad) versus Mepilex dressing in pressure ulcer prevention for patients in operating room.

Secondary Objectives

- Identifying the incidence of post-operative pressure injury for cardiac surgery patients at king Abdullah medical city.

Objective measures

For the primary objective

Pressure ulcer incidence will be assessed by using Bates–Jensen Wound Assessment Tool (BWAT) after operation then day 3 and day 7 for both treatments.

For the secondary objective

The occurrence of pressure ulcer will be documented in data collection then calculated.

Research Design:

- Open label randomized control clinical trial study with a pilot study-using questionnaire.

Inclusion Criteria:

- Subjects ≥ 18.
- Willing to participate.
- Patients undergoing cardiac surgery.
- Patient who is at risk for PU development as measured with Braden scale.

- Patient who has skin intact and having a life expectancy greater than 72 hours as per clinical judgement.

Exclusion Criteria:

- Subjects under 18
- Not consenting to participate
- Patients with suspected hypersensitivity reactions to any of the dressing formulation's ingredients.
- Patients who are unable to continue the study because of death or change in the care setting.

Randomization

Electronic randomization will be used as a simple technique of randomization. The randomization list was generated electronically using R and the Random Allocation Rule by a member of the research center who was not actively involved in the trial's enrollment and recruitment. A member of the research center will identify the participant for this concealment. To determine which treatment a participant will receive, an allocation sequence and envelopes containing the sequence will be generated. Each envelope will not be opened until the patient has consented and been enrolled in the study.

Blinding

Open label study as True blinding for patients and the research nurse who will apply the dressing and Polyurethane foams (Pink Pad) will be difficult as there is a significant difference between the two treatment methods in presentation. Moreover, the skin imprint after the foam removal made it impossible to blind the outcome assessor.

Study Procedure:

There are two types of intervention available in King Abdullah medical city for operating room pressure ulcer prevention. **Polyurethane foams** (Pink Pad) are a single use system for use in surgical procedures. The system consists of a proprietary formulation for the pink foam pad, non-woven lift sheet, body straps, head rests, and boot liners. It aids hospital facilities in providing a safe and effective method of management of the patient for pressure ulcers and non-movement for patients in the Trendelenburg position.

Mepilex Border Sacrum dressings are self-adherent, multilayer foam dressings designed for use on sacrum aiming to prevent pressure ulcers. The dressings are used in addition to standard care protocols for pressure ulcer prevention.

After getting official permission from KAMC IRB, the subject will be randomized using electronic randomization 1:1 ratio. The randomization list was generated electronically through R using the Random Allocation Rule. Patients will equally be allocated into 2 groups randomly. The polyurethane foam group and Mepilex Border Sacrum dressings group.

Standard PUs preventive care - All included patients received standard PU prevention according to hospital protocols, based on contextualization and adaptation of International guidelines (European Pressure Ulcer Advisory Panel, 2021), which involved: assessment of PU risk through the Braden Scale at hospital admission, every seven days and when clinically indicated (for example after surgery); full skin assessment during every shift, three times per day combined with routine positioning every 2 h or when required; use of active support surfaces (higher- specification foam mattress or dynamic anti-decubitus mattress) in case of Braden < 16, aiming at preventing damaging tissue deformation and providing an environment that enhances perfusion of at risk tissues; incontinence skin care.

Prior to surgery, Mepilex Border Sacrum dressings 20 X 20 (Molnlycke Health Care) will be applied to the patient's sacrum for Mepilex Border Sacrum dressings group and polyurethane foam will be used to the patient's sacrum for polyurethane foam group. A nurse in the preoperative patient receiving area will apply the Mepilex Border Sacrum dressings. The perioperative nurse will examine the dressing in the operating room to ensure its integrity. If the perioperative nurse observed any alterations to the original application, such as rolling or displacement, she will reapply it. If the dressing is not applied by the nurse before transferring the patient to the operation room the perioperative nurse will apply it. For polyurethane foam (pink Pad) it will be used only by operating room nurses as it is available only in the operating room. Both types of intervention will be available in the operating room.

Patient will be examined by head nurse of wound management team after the operation then at day 3- and 7-days post operation. The dressing should be removed after 7 days post operation or if there is any clinical indication for removal. If a patient is discharged before 7 days post operation for any reason the head nurse of wound management team will examine the patient before discharge. Follow up will be for maximum 7 days post operation for each subject. Any patient will be unable to continue the study because of death or change in the care setting will be excluded from the study.

Pilot study:

It will conduct before data collection on 10% of patients to explore feasibility for future RCT, the efficiency, internal validity and fundamentally, the delivery of proposed trial and identify barriers and facilitators. **Mepilex Border Sacrum** dressings will be applied to 4 patients before the procedure and **Polyurethane foams (pink pad)** will be applied to 4 patients before the procedure. The data collection tool will be tested, and these patients will be excluded from the study, after completion the patient will have routine care for pressure ulcer treatment.

Sample Size calculation:

A Convenience sample of 80 cardiac surgery patients who are expected to have long procedures (more than 4 hours) will be included in this study. These patients will be divided randomly into two groups; the polyurethane foam (pink pad) group (40 patients), and Mepilex Border Sacrum dressings group (40 patients).

Ep-info program was used to find sample size using the following information:

Population size = 90 patients.

Expected frequency=50%.

Acceptable error=5%.

Confidence coefficient=99%.

Minimal sample size=79.

Duration of the Study: 6 months in total. The enrolment will be for 20 days. Follow up will be for maximum 7 days post operation for each subject. A period of 4 months will be for analysis and closing.

Setting:

This study will be carried out at the operating room, cardiac surgery intensive care unit and cardiac surgery ward at King Abdullah Medical City, Holy Makkah.

Data Collection and Management:

After the official approval from KAMC IRB and the local authority approval. All the research nurses had taken part in designing the protocol and had specific training in research methodology and prevention, treatment, and classification of PU. The principal investigator will convene a meeting with

the study team to provide an overview of the study's implementation, with the aim of ensuring adherence to quality standards and regulatory requirements. Researchers will explain the study to the participants and take written consent if they want to participate. In cases where a patient is unconscious, written consent will be obtained from their Legally Acceptable Representative in accordance with legal protocols. Voluntary and anonymous participation will be ensured. In case of passing away the collected data will not be used, and safety reports will be submitted as per the local gaudiness. The data collection sheets will be securely stored in a locked file cabinet under the custody of the researchers.

Study outcome measurement:

Data will be collected through one tool that will be collected by the assessor. It will include two sections as follows:

Section I: Patients' demographic data

This section was developed by the PI based on relevant literature. It will include demographic and medical history data will be collected from the patients' medical records without identifier such as age, sex, body mass index, history of smoking, diagnosis at the time of admission, and laboratory parameters including erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) will be recorded. Nutritional status of patients will be evaluated considering route of nutritional support (enteral or parenteral). Subject will be identified via serial codes.

Section II: Pressure ulcer assessment.

If there is any incidence of pressure ulcer this section will be recorded. The most common location for PI is the sacrum, which is particularly vulnerable to injury and difficult to treat [(23)]. This section will be adopted from Bates-Jensen 2010 [27]. The Bates–Jensen Wound Assessment Tool (BWAT) will be used to assess pressure ulcers. It is a validated wound assessment tool which is used in many healthcare settings for wound assessment. BWAT is straight forward to use and allows nurses to have an objective, comprehensive assessment of wounds. It consists of 13 items to evaluate wound size, type and depth, amount of necrotic tissue, amount and characteristics of exudate, the presence of granulation tissue,

epithelialization, and peri- 6 wound skin. PU length and width was measured with a disposable ruler and expressed as cm2. The patient will be examined after operation then day 3 and day 7. Follow up will be for maximum 7 days post operation for each subject. If the any patient will be unable to continue the study because of death or change in the care setting the researcher will be excluded from the study.

Statistical Analysis Plan

Data obtained from the study will be coded and transformed into coding sheets. The results will be checked. Then, the data will be entered into SPSS system files (SPSS package version 22). Following data entry, checking and verification will be done to avoid errors during data entry. Finally, analysis and interpretation of data will be conducted. Categorical variables will be expressed as number and percentage while continuous variables will be expressed as mean and standard deviation.

Publication:

The results of this research will be published to either national or international publications. The main credit in publication will go to King Abdullah Medical City in Holy Capital and to the principal investigator and co-investigators. Others who have contributed less substantially will have an acknowledgement in the manuscript.

Ethical Part & Confidentiality:

Ethical approval will be sought from KAMC IRB, local authority as applicable and will do study accordingly. Researchers will explain the study to the participants and take written consent if they want to participate. The participation will be voluntary and anonymous.

REFERENCES

1. Honaker J, Brockopp D, Moe K. Suspected deep tissue injury profile: a pilot study. Adv Skin Wound Care 2014;27(3):133-40.
2. Gefen A, Farid KJ, Shaywitz I. A review of deep tissue injury development, detection, and prevention: shear savvy. Ostomy Wound Manag 2013;59(2):26-35.

3. Highlights from the International Forum on Deep Tissue Injury Evolution: a research based scientific collaborative. Ostomy Wound Manag 2014;60(2):18-28.
4. National Pressure Ulcer Advisory Panel. National Pressure Ulcer Advisory Panel (NPUAP) announces a change in terminology from pressure ulcer to pressure injury and updates the stages of pressure injury. 2016. www.npuap.org/national-pressure-ulcer-advisorypanel- npuap-announces-a-change-in-terminology-from-pressure-ulcer-to-pressureinjury-and-updates-the-stages-of-pressure-injury. Last accessed November 13, 2018.
5. Sullivan R. A two-year retrospective review of suspected deep tissue injury evolution in adult acute care patients. Ostomy Wound Manag 2013;59(9):30-9.
6. Feuchtinger J, Halfens RJG, Dassen T. Pressure ulcer risk factors in cardiac surgery: a review of the research literature. Heart Lung 2005;34(6):375-85.
7. Rao AD, Preston AM, Strauss R, Stamm R, Zalman DC. Risk factors associated with pressure ulcer formation in critically ill cardiac surgery patients: a systematic review. J Wound Ostomy Continence Nurs 2016;43(June):1-6.
8. Ramundo J, Pike C, Pittman J. Do prophylactic foam dressings reduce heel pressure injuries? J Wound Ostomy Continence Nurs 2018;45(1):75-82.
9. Santamaria N, Gerdtz M, Liu W, et al. Clinical effectiveness of a silicone foam dressing for the prevention of heel pressure ulcers in critically ill patients: Border II trial. J Wound Care 2015;24(8):340-5.
10. Kalowes P, Messina V, Li M. Five-layered soft silicone foam dressing to prevent pressure ulcers in the intensive care unit. Am J Crit Care 2016;25(6):108-20.
11. Santamaria N, Gerdtz M, Sage S, et al. A randomised controlled trial of the effectiveness of soft silicone multi-layered foam dressings in the prevention of sacral and heel pressure ulcers in trauma and critically ill patients: the border trial. Int Wound J 2013:302-8.
12. Santamaria N, Gerdtz M, Kapp S, Wilson L, Gefen A. A randomised controlled trial of the clinical effectiveness of multi-layer silicone foam dressings for the prevention of pressure injuries in high-risk aged care residents: the Border III Trial. Int Wound J 2018; 15(3):482-90.
13. Brindle CT, Wegelin JA. Prophylactic dressing application to reduce pressure ulcer formation in cardiac surgery patients. J Wound Ostomy Continence Nurs 2012;39(2):133-42.

14. National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline. Washington, DC: National Pressure Ulcer Advisory Panel; 2014.
15. Call E, Pedersen J, Bill B, et al. Enhancing pressure ulcer prevention using wound dressings: what are the modes of action? Int Wound J. 2015;12: 408-413.
16. Matsuzaki K, Kishi K. Investigating the pressure-reducing effect of wound dressings. J Wound Care. 2015;24(512):514-517.
17. Miller SK, Sharma N, Aberegg LC, Blasiole KN, Fulton JA. Analysis of the pressure distribution qualities of a silicon border foam dressing. J Wound Ostomy Continence Nurs. 2015; 42:346-351
18. Dutra RA, Salomé GM, Alves JR, et al. Using transparent polyurethane film and hydrocolloid dressings to prevent pressure ulcers. J Wound Care. 2015; 24:268–275.
19. Black J, Clark M, Dealey C, et al. Dressings as an adjunct to pressure ulcer prevention: consensus panel recommendations. Int Wound J. 2015; 12:484-488.
20. Kalowes P, Messina V, Li M. Five-layered soft silicone foam dressing to prevent pressure ulcers in the intensive care unit. Am J Crit Care. 2016;25: e108-e119.
21. Peixoto CA, Ferreira MB, Felix MM, Pires P, Barichello E, Barbosa MH. Risk assessment for perioperative pressure injuries. Rev Latin Am Enferm. 2019;27: e3117. https://doi. org/10.1590/1518-8345.2677-3117 PMid:30698218
22. Kirkland-Walsh H, Teleten O, Wilson M, Raingruber B. Pressure mapping comparison of four OR surfaces. AORN J. 2015;102(1):61. e1-619. https://dx.doi.org/10.1016%2Fj. aorn.2015.05.012 PMid:26119617
23. European Pressure Ulcer Advisory Panel, N. P. I. A. P. A. P. P. P. P. I. A. 2019. Preven- tion and Treatment of Pressure Ulcers/Injuries: clinical Practice Guideline. The International Guideline. In: (ED.)., E. H. (ed.). EPUAP/NPIAP/PPPIA.
24. Palese, A., Trevisani, B., Guarnier, A., Barelli, P., Zambiasi, P., Allegrini, E., Bazoli, L., Casson, P., Marin, M., Padovan, M., Picogna, M., Taddia, P., Salmaso, D., Chiari, P., Marognolli, O., Federica, C., Saiani, L., Ambrosi, E., 2017. Prevalence and inci- dence density of unavoidable pressure ulcers in elderly patients admitted to medical units. J. Tissue Viability 26, 85–88.

25. Chiari, P., Forni, C., Guberti, M., Gazineo, D., Ronzoni, S., D'Alessandro, F, 2017. Predictive factors for pressure ulcers in an older adult population hospitalized for hip fractures: a prognostic cohort study. PLoS ONE 12, e0169909.
26. Forni, C., D'Alessandro, F., Gallerani, P., Genco, R., Bolzon, A., Bombino, C., Mini, S., Rocchegiani, L., Notarnicola, T., Vitulli, A., Amodeo, A., Celli, G., Taddia, P, 2018. Effectiveness of using a new polyurethane foam multi-layer dressing in the sacral area to prevent the onset of pressure ulcer in the elderly with hip frac- tures: a pragmatic randomised controlled trial. Int. Wound J. 15, 383–390.
27. Harris, C., Bates-Jensen, B., Parslow, N., Raizman, R., Singh, M., & Ketchen, R. (2010). BatesJensen wound assessment tool: pictorial guide validation project. Journal of wound, ostomy, and continence nursing: official publication of The Wound, Ostomy and Continence Nurses Society, 37(3), 253–259. https://doi.org/10.1097/WON.0b013e3181d73aab