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Research paper

Early outcomes of post-operative hip and proximal thigh wounds dressed with post-op opsite™ versus povidone-iodine based dressing: Protocol for a randomized trial

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ABSTRACT

This is a parallel group, randomized controlled trial to compare the early outcomes of post-operative wounds around the hip and proximal thigh dressed with povidone-iodine soaked gauze dressings versus post-operative opsite™ dressings.

Ninety-eight patients undergoing orthopaedic surgeries around the hip and proximal thigh in the Department of Orthopaedics, University College Hospital Ibadan will be recruited via block randomization into two intervention arms.

A datasheet will be filled, to collect socio-demographic data of the respondents, type of surgery, implant status, dressing application, day of first change of wound dressing after surgery and the indication for the change, number of wound dressing changes, pain score at wound dressing change and presence or absence of skin blistering and maceration at the operation site. Data entry, collation and analyses will be done using statistical packages; binary variables using chi-square and continuous variables using z-test, regression studies will also be done.

The findings from the study would improve knowledge in the care of post-operative patients in Orthopaedics and help with developing a protocol for care of wounds in the hip and proximal thigh.

1. Introduction

Good surgical techniques improve long-term wound coverage, ultimately restoring form and function [1]. Injury to the skin poses a challenge [2] with its healing being a complex, intricate process of multiple interactions resulting in wounds transiting through an acute inflammatory to proliferative and remodelling phases without complications. Unsatisfactory wound healing conditions may result in chronic wounds through infection or dehiscence [2]. Good skin preparation, good surgical technique especially soft tissue handling, and appropriate surgical wound dressings can optimize local factors.

In clean surgeries the risk of surgical site infections is between 1 and 5%, clean contaminated surgeries 3–11%, contaminated surgeries 10–17%, dirty surgeries above 27% [3].

Use of adequate wound dressings are integral in care of clean wounds. Characteristics of an ideal dressing include: adequate moisture, clean and warm environment, providing hydration, removes exudates, being non-traumatic, providing protection for the peri-wound area, allows gaseous exchange, is impermeable to micro-organisms, irritant free and conform to body contours, with minimal pain during application and removal. it must be easy to use and be cost effective [2].

In the Orthopaedics service of the University College Hospital Ibadan, povidone-iodine based sterile gauze dressings are used except in arthroplasties were composite dressings are used. The povidone-iodine dressings consists of an inner layer of povidone-iodine soaked-gauze, an absorbent layer of plain sterile gauze and an outer adherent (non-stretchable) plaster layer.

Opinions on use of iodine-based dressings are divergent, most trials showed no significant difference in beneficial or adverse reactions between iodine and other wound care methods; some however suggested tissue harm and wound healing delay [4]. Others noted them being good for chronic wounds when compared to other materials [5].

Post-operative skin blistering describes a consequence of continued post-surgical wound friction, resulting in shearing of the epidermis off

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the dermis [6]. Infections and blistering are the major wound complications for surgical wounds around the hip [6]. Up to 25% of patients with hip surgery had blisters as reported by Koval and colleagues, with a 41% skin blistering risk recorded [7] and a skin blistering incidence of 13–35% has been reported on orthopaedic wards [6]. Altering the nature of the tape used for dressing wounds is associated with reduced blistering rate [7], with the stretchable exclusive post-operative opsite™ being notably associated with reduction in the occurrence of blisters and maceration [8], as also noted with the use of strechable perforated materials [7]. The contours of the pelvis (hips), gluteus region and proximal thigh can exacerbate the risk of friction from non-stretchable materials, as skin folds and mobility of this area may impede securing wound dressings.

Post-op opsite™ meets many criteria of an ideal post-operative dressing by being anti-bacterial [9,10], reduces maceration [11–15], blistering [16,17], pain on removal [16,18], being water proof [14,19] and comfortable to wear. It manages exudate via its absorbent pad and breathable film [14,20]. These advantages are from its hydrophilic film that allows vapour to permeate the block polymer framework. Another advantage is from its low allergy acrylic pad without adhesives, minimizing pain on removal. These actions generate suction ultimately reducing skin maceration and number of wound dressing changes.

Gauze dressings dry and mechanically debride wounds at dressing change, thus disturbing epithelisation and causes pain [21].

1.1. Aim of the study

This study aims to assess the early outcomes of post-operative hip and proximal thigh wounds; comparing wounds dressed in conventional povidone iodine gauze wound dressings with wounds dressed with post-op opsite™ wound dressings.

1.2. Objectives of the study

General: To compare the early outcomes of the post-operative hip and proximal thigh wounds that will be dressed using post-operative opsite™ versus povidone-iodine based wound dressings in the orthopaedics service of the University College Hospital Ibadan, Nigeria.

Specific:

1. To compare the rate of post-operative hip and proximal thigh wound maceration and blistering between the use of povidone-iodine based wound dressings and post-op opsite™ for this study.
2. To compare the number of wound dressing changes of post-operative hip and proximal thigh wounds between the intervention arms of this study.
3. To compare the pain scores (using the numerical rating scale) following change of wound dressings of post-operative hip and proximal thigh wounds between the intervention arms for this study.
4. To compare the time-to-wound healing of the post-operative hip and proximal thigh wounds between the intervention arms for this study.

2. Materials and methods

2.1. Time of study

The study will run over a period of about one year.

2.2. Location of the study

All patients would be recruited from the department of orthopaedics and trauma unit through the surgical outpatient and the accident and emergency unit of the University College Hospital Ibadan. The University College Hospital Ibadan is a tertiary health facility for training and research located in the south western part of Nigeria, in Ibadan North local government area of Oyo state.

2.3. Study design

This study will be a parallel group, double blinded randomized controlled trial. It will involve two intervention arms; one arm would have their post-operative wounds dressed with post-op opsite™ (POOG). The other arm would have their wounds dressed with the current standard-of-care; povidone-iodine based sterile gauze dressings (PIGG), consisting of an inner layer of povidone-iodine (an antiseptic) soaked gauze, followed by a middle absorbent layer of four pieces of sterile gauze and then an outer layer of adherent non-stretchable plaster.

The wounds will be closed with simple interrupted polypropylene sutures and cleaned with isopropyl alcohol before application of the wound dressings. The wound dressings would be applied by the principal investigator or other senior registrars in the department of orthopaedics and trauma, who would be instructed on the dressing mode each. Preoperatively, the surgical site will be scrubbed with savlon™ (cetrimide and chlorhexidine gluconate), mopped dry and followed by isopropyl alcohol and other aseptic protocols will be strictly adhered to.

The wound dressings would be inspected daily looking out for evidence of loosening of the wound dressing, soak through of the wound dressing necessitating early change of wound dressings, for dressings that are satisfactory wounds would be reviewed on post -operative day five. Sutures would have removed on day fourteen unless early removal is indicated which may be due to surgical site infection.

2.4. Blinding and elimination of bias

All surgeries would be carried out by consultants. The surgeons would be blinded to the intervention arms and may be aware of it after the wound has been closed, when the a senior registrar in attendance will be advised by the trial administrator of the intervention arm the patient has been randomized to. The patients and outcome assessors will also be blinded. The outcome assessors will only access wounds that have been opened and surroundings cleaned by the managing surgical team.

2.5. Randomization and allocation

The participants will be recruited into intervention arms by permuted block randomization, aiming to balance out the subjects' characteristics and reduce selection bias. We would use four blocks sequentially until our sample size is achieved as follows for example; 'O' signifying the POGG and 'I' signifying PIGG, [OOII], [OIOI], [IOIO], [IIOO]. The randomization will be done by an independent data analyst who will notify the senior registrar to dress the wound when the wound is about to be dressed. The wounds would be monitored and reviewed by the principal investigator and other senior registrars in the division, who have been instructed on what to look for.

The allocation of subjects to intervention arms will be done by the trial administrator using the a-priori permitted blocks. After notification of a new patient, the administrator will review the allocation list to determine the next allocation in sequence, this will be communicated to the senior registrar at surgery with the dressing materials given to be opened at the end of surgery (completion of wound closure).

2.6. Eligibility criteria

This study will be delimited to the following participants:
Inclusion criteria.

- All consenting patients that will undergo surgeries around the hip and proximal thigh that are between eighteen and sixty five years of age.
- Patients would have to be on the ward for a minimum of five days

Exclusion criteria.

- Patients with open post-traumatic wounds
- Patients with pre-operatively compromised skin (e.g., burn wounds or previous scars) in the region of the surgery
- Patients with infective skin lesions around the surgical site
- Patients with bleeding disorders or on long term anticoagulant therapy
- Patient with dementia, psychiatric problems who may interfere with the wound

2.7. Calculation of sample size

The estimated sample size was calculated using the modified Kirkwood formula for two independent samples. Using a power of 90%, a 95% confidence interval, a difference in incidence rate of blistering between a pair of observations (composite & conventional wound dressing) from other studies of 15.4% and with assumed 50% clinical difference to change the incidence rate difference to 7.7%. The sample size per intervention arm derived was 44 patients; an additional 5 were added for an estimated 10% attrition rate. The total minimum study sample size will be 98 patients that will undergo hip and proximal thigh surgeries.

2.8. Clinical care protocol

Patients would be randomized into two groups as described in subsection 2.5 above. The wound dressings would be reviewed by doctors (who are not outcome assessors) daily for evidence of loosening, strike through (when the outermost layer of the wound dressing is stained by the wound exudate). Needed intervention like change of wound dressing would be noted. Assessment of pain score using the numeric rating scale for pain with change of wound dressings would be noted, sutures will be removed on fourteenth day post-operatively unless otherwise indicated.

2.9. Data entry and analysis

Data for the study will be collated and entered into STATA/MP version 16 (Stata Corp, College Station, TX). The binary variables (e.g., the presence or absence of skin maceration amongst the intervention arms) will be analysed using the Chi-square test and/or logistic regression studies for their risk and rate data. Linear regression studies and or z-test will be used for the continuous variables. Time-to-event data will subjected to survival analyses.

Data and safety will be at determined intervals be monitored by representatives of the UI/UCH research ethics committee, who will play the role of the data safety and monitoring board.

2.10. Exposures, outcomes and endpoints

2.10.1. Principal exposure

To compare outcomes for the two intervention arms - the POOG and PIGG as regards the occurrence of skin maceration, skin reaction and blistering and the number of wound dressing changes for patients who had surgeries around the proximal thigh and the hip.

2.10.2. Outcome variables

The outcomes will be assessed for at day five post-operatively, but in the event of the requirement to open the wounds following any of the daily wound dressing inspections. The outcome variables would include:

- Skin maceration (presence or absence); the presence of denuded peri-wound skin.
- Peri-wound blistering (presence or absence); the shearing of epidermis as evidenced by a visible thin fold of skin, with or without some fluid underneath(6)
- Wound dressing loosening/displacement (presence or absence)
- Pain score during change of wound dressings
- Number of changes of wound dressing before removal of stitches
- Time-to-wound healing (days); the time a matured scar is formed on the incision site

2.10.3. Endpoints

The *primary endpoint* is the onset of peri-wound blistering and skin maceration or reaching the fourteenth post-operative day.

The *Secondary endpoints* will be onset of any other post-operative complications in the patients, patient opting out from the study and/or being lost-to-follow-up.

2.11. Ethical considerations

Full ethical approval was obtained from the University of Ibadan/University College Hospital (UI/UCH) Health Ethical Review Committee and the ethical principles of confidentiality, beneficence, non-maleficence, and voluntariness would be ensured. The UI/UCH ethics committee assigned number is UI/EC/18/0425 and has initial approval dates covering from 10/12/2018 to 09/12/2019.

All prospective subjects will be given the study consent form and information sheet to review, seek clarifications and get answers to questions before they will sign the form.

To ensure confidentiality, all personal identifying information collected will be satisfactorily de-identified and all information collected will not be used for any information other than completing this study and other excerpts that will be culled for publication and presentation purposes.

The trial dataset will be cleaned and published in data repositories and after the initial study periods, the data will be made available for public use on written request by researchers to the authors. Plans for unrestricted public access will also be explored.

The authors have no external funding and hold no paid nor unpaid affiliation with any of the producers of materials to be used for the study.

2.12. Trial registration data

- Trial registration number: PACTR201903775777250
- Name of Registry: Pan African Clinical Trials Registry
- URL of trial registry: https://pactr.samrc.ac.za/TrialDisplay.aspx?TrialID=5763
- Date of registration: 3rd December 2018
- Trial status: Prospectively registered in accordance with WHO and ICMJE standards

The 22 elements WHO trial registration information are available via the trial URL online and on the International Clinical Trials Registry search portal online.

2.13. Limitations of the proposed study may include

- Potential inability of the investigators to supervise the wound dressings
- Potential inability of the surgeries to be done by one surgeon
- The assessment for wounds maceration is observer dependent

2.14. Projected expectations

We expect that the proximal thigh and hip wounds dressed post-operatively with post-operative opsite™ in comparison with those dressed with povidone-iodine based dressings will have reduced number of changes of wound dressing, reduced incidence of skin maceration, peri-wound blistering as well as reduced pain scores following changing of wound dressings.

2.15. Application to improve service

We hope that there would be an overall improvement in patient care (with reduced incidence of post-operative wound complications, due to putative reduction in pain score and number of wound dressings) and reduced work load on the surgeons and paramedics. These putative improvements in care can be adopted in the future as treatment protocol in our local practice for care of wounds around the hip and proximal thigh.

2.16. Authors' roles

Both (PTJ and AA) authors will equally participate in the study design, study management, data interpretation and writing of the report. Data collection will be done by AA and PTJ will execute the data analysis.

References

[1] C.K. Lee, S.L. Hansen, Management of acute wounds, Surg. Clin. N. Am. 89 (2009) 659–676.
[2] A. Sood, M.S. Granick, N.L. Tomaselli, Wound dressings and comparative effectiveness data, Adv Wound Care [Internet] 3 (8) (2014) 511–529. Available from: http://online.liebertpub.com/doi/abs/10.1089/wound.2012.0401.
[3] G. Ortega, D.S. Rhee, D.J. Papandria, J. Yang, A.M. Ibrahim, A.D. Shore, et al., An evaluation of surgical site infections by wound classification system using the ACS-NSQIP, J. Surg. Res. 174 (1) (2012) 33–38.
[4] H. Vermeulen, S.J. Westerbos, D.T. Ubbink, Benefit and harm of iodine in wound care: a systematic review, J. Hosp. Infect. 76 (2010) 191–199.
[5] V. Jones, J. Grey, K. Harding, ABC of wound healing: wound dressings, Br. Med. J. 332 (April) (2006) 777–780. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1420733/.
[6] M.J. Ravenscroft, J. Harker, K.A. Buch, A prospective randomized controlled trial comparing wound dressings used in hip and knee surgery: aquacel and Tegaderm versus Cutiplast, Ann. R. Coll. Surg. Engl. 88 (2006) 18–22.
[7] K.J. Koval, K.A. Egol, D.B. Polasch, M.A. Baskies, J.P. Homman, R.N. Hiebert, Tape blisters following hip surgery, J. Bone Jt. Surg. 85A (10) (2003) 1884–1887.
[8] R. Jester, L. Russell, S. Fell, et al., A one hospital study of the effect of wound dressings and other related factors on skin blistering following total hip and knee arthroplasty, J. Orthop. Nurs. 4 (2) (2000) 71–77.
[9] J.T. Scales, A.G. Towers, N. Goodman, Development and evaluation of A porous surgical dressing, Br. Med. J. 2 (4999) (1956) 962–968.
[10] reportSmith & Nephew Report Reference 0505004.
[11] M.C. Richardson, An in-vivo of the microbial proliferation beneath transport film dressings, in: D.G. Maki (Ed.), International Congress and Symposium Series No 179, Improving Catheter Site Care, Royal Society of Medicine London Series, London New York, 1991, 29-23.
[12] Joyeux B. OPSITE IV3000 versus Tegaderm on peripheral venous catheters. In Maki, DG, ed International Congress and Symposium Series No 179`Imroving Catheter Site Care', Royal Society of Medicine Series.
[13] reportSmith & Nephew Report Reference DS/07/115/R20a.
[14] reportSmith & Nephew Report Reference DS/07/208.
[15] Steel, R; Opsite Post-op Product Performance Evaluation.
[16] T. Cosker, S. Elsayed, S. Gupta, A.D. Mendonca, K.J.J. Tayton, Choice of dressing has a major impact on blistering and healing outcomes in orthopaedic patients, J. Wound Care 14 (1) (2005) 27–29, https://doi.org/10.12968/jowc.2005.14.1.26722.
[17] S. Bryne-Murphy, A prospective evaluation of a new dressing OPSITE Post-OP visible blistering following total hip and knee replacement, in: Poster Presentation at Wounds UK, Harrogate, UK, 2009.
[18] J.C. Willie, A. BLUSSE VAN Oud Albas, E.A.P.M. Thewessen, A comparison of two transparent film type dressing in central venous therapy, Hosp. infect 23 (1993) 113–121.
[19] reportSmith & Nephew Report Reference DS/08/149/R3.
[20] F. Downie, S. Egdell, A. Bielby, R. Searle, Barrier dressings in surgical site infection prevention strategies, Br. J. Nurs. 19 (20) (2010) s42–s46.
[21] A. Garnica Goyanes, C. Gil Lorenzo, M. Nieto Alonso, A. Ruiz López, L. Muñoz García, J.-E. Torra I Bou, Post-surgical conventional dressing versus interactive moist wound healing dressing: comparative evaluation in oncological surgical patients, Gerokomos 25 (1) (2014) 34–40, https://doi.org/10.4321/S1134-928X2014000100008.