

COVER PAGE

Research Protocol

OFFICIAL TITLE: Secondary Intention Wound Healing, in Patients Subjected to Surgical Resection of Pilonidal Cyst, Using Alginate Dressings With Silver and High-G Cellulose, Compared to the Use of Simple Gauze Dressings: Examination of the Quality of Life.

BRIEF TITLE: Alginate Dressings Versus Gauge Dressings After Pilonidal Cyst Resection: Examination of the Quality of Life

UNIQUE PROTOCOL ID: Pilonidal QoL

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CHAPTER 1

INTRODUCTION

Pilonidal cyst was first described by Hodges in 1880¹. The disease of pilonidal cyst is also known as “Jeep disease”, due to the fact that, during World War II (1941-1945), several American soldiers (about 80,000) suffered from this disease, because, either they were driving for long hours on uneven, destroyed by war, roads, or, they were spending time sitting at military vehicles like jeep, trucks and tankers, resulting in being submitted to surgical operation, in order to alleviate the arousing pilonidal cyst problem, at USA military hospitals.

Pilonidal cyst, is considered as one of the most common diseases of the subcutaneous tissues of the sacrococcygeal region. This situation is the result of hair penetrating into the skin, a situation not uncommon in this anatomical area. In a study including 50,000 college students, pilonidal cyst occurrence, in males, was 1.1%, which was 10 times higher compared to females², although a considerable rate of them was asymptomatic. Evidence from studies in England, also, indicate that the disease is more frequent in men than women (1 to 3)³. The disease is more common in Caucasians than in Asians or Africans due to the differences in their hair characteristics and the respective hair development pattern⁴. Risk factors include the following: sedentary life (44%), positive family history (38%), obesity (50%) and regional irritation (34%)⁵. The disease usually presents during the age of 16–20 and prevalence is decreasing drastically after the 25th year of age. This disease rarely develops before the adolescence and after the 40th year of age⁶.

Treatment usually depends on the condition of the disease. An acute abscess is usually controlled with incision and drainage. A chronic pilonidal cyst is best treated with a surgical procedure that involves complete resection of the cyst along with the coexisting fistulas, in order to ensure the minimum reoccurrence rate⁷. There are two choices after surgical resection, secondary intention wound healing⁸ or primary trauma closure, with or without a flap^{9,10}. The surgical procedure can be performed with the administration of local anesthesia in the outpatient office or in a day-clinic, or with the use of general anesthesia depending on the condition of the patient.

Post operatively secondary intention wound healing is applied in many cases, especially when factors like infection, necrotic tissue or inflammatory tissue are

introduced¹¹ . There are many dressings that can be used for the care of a surgical trauma. The ideal dressing used should have some special characteristics such as absorption of exudates without leakage, provision of a dry environment that prevents bacteria from entering the wound and facilitation of easy appliance, as well as removal ¹². Choosing the right dressing is not based on a certain protocol, but mostly on the surgeon preference¹³⁻¹⁸.

In the current study our objective is the comparison between different wound dressings and how they can affect secondary intention wound healing in patients that have been subjected to surgical resection of pilonidal cyst. Emphasis will be given at the postoperative quality of life of these patients.

CHAPTER 2

OBJECTIVE

The current study aims at comparing two groups of patients that will be subjected to surgical resection of pilonidal cyst and secondary intention wound healing. In the first group, dressings like alginate cord with silver and high G cellulose will be used for filling of the wound cavity and a hydrocapillary dressing for sealing and waterproofing the wound. In the other group, simple gauze dressings for the coverage of the wound cavity will be used. Comparison of the two groups will involve all the endpoints that indicate whether such dressings can facilitate faster wound healing, enabling, thus, patients to faster return to their everyday activities. Furthermore, a parameter that has not been, previously, studied, the quality of life after the surgical excision of the pilonidal cyst, by using the SF – 36 and the Quality of life with Chronic Wound questionnaire, will, also, be investigated.

CHAPTER 3

MATERIALS AND METHODS

1. Estimation of the necessary study sample size

According to literature, the mean time required for wound healing of patients subjected to pilonidal cyst resection is 60.4 ± 6.2 days¹⁴. Therefore for a 5% decrease in the duration of the healing process and with an 1:1 enrollment ratio between the two groups, with alpha 0,05 and 90% power, the required number of patients in each group is 89. The total amount of patients required for completion of the study is 178. Patients that will not complete follow-up will be excluded and replaced by other patients.

2. Disease staging system

Pilonidal cyst will be staged according to the following classification system.

Type I Pit(s) on the natal cleft

IA Asymptomatic one or more pit(s) on the natal cleft without a history of abscess

IB Symptomatic and / or more than one pit on the natal cleft

Type II Pit(s) on either side of the natal cleft

IIA Distance from the natal cleft < 2.5 cm

IIB Distance from the natal cleft > 2.5 cm

Type III Pits on both side of the natal cleft

Type IV Recurrent pilonidal disease

3. Inclusion Criteria

- Male or female
- Pilonidal cyst
- Age: 18 to 80 years
- American Society of Anesthesiologists (ASA) score: I, II, III, IV
- Disease stage I,II,III and IV

4. Exclusion Criteria

- Pilonidal abscess
- Patient age ≥ 80 years or < 18 years

- Pilonidal abscess

5. Randomization

The randomization of the patients, between the two groups, will be performed using a software and a 1: 1 allocation ratio will be performed. Furthermore, an opaque envelope, which will contain the allocation group for the specific patient, will be opened preoperatively upon the entry of the patient into the surgical room.

6. Blinding

Blinding will exist at the level of the investigator who will record the data postoperatively. There will be no blinding at the level of the surgeon or the patient.

7. Endpoints

Primary Outcome Measure:

- Wound healing time. Postoperative required time for wound healing. Measurement unit: days. [Time Frame: Maximum time frame 50 days postoperatively]

Secondary Outcome Measures:

- Postoperative return to everyday activities. Time required for returning to everyday activities. Measurement unit: days [Time Frame: Maximum time frame 50 days postoperatively]
- Postoperative pain level. Pain level after surgery, quantified with the use of the VAS scale. [Time Frame: 7, 14, 21, 28, 35, 42 and 49 days postoperatively]
- Postoperative analgesics consumption. Number of analgesic pills consumed per day after surgery. Measurement unit: pills per day [Time Frame: 7, 14, 21, 28, 35, 42 and 49 days postoperatively]
- Overall satisfaction level. Satisfaction level measured at a 0-10 scale [Time Frame: 50 days postoperatively]
- Cost of the material. Overall cost of the dressings applied [Time Frame: Maximum time frame 50 days postoperatively]
- Wound care visits. Number of required visits for postoperative wound care for each patient per week.[Time Frame: 7, 14, 21, 28, 35, 42 and 49 days postoperatively]
- Trauma secretions. Trauma secretions leading to extra dressing care. If such an episode occurs, then it will be defined as=1 'YES' If such an episode does not occur,

then it will be defined as=0 'NO' [Time Frame: 7, 14, 21, 28, 35, 42 and 49 days postoperatively]

- Wound contamination. Contamination of the wound trauma. If such an episode occurs, then it will be defined as=1 'YES' If such an episode does not occur, then it will be defined as=0 'NO' [Time Frame: Maximum time frame 50 days postoperatively]
- Wound erythema. Erythema of the wound. If such an episode occurs, then it will be defined as=1 'YES' If such an episode does not occur, then it will be defined as=0 'NO' [Time Frame: Maximum time frame 50 days postoperatively]
- Wound hematoma. Hematoma of the wound. If such an episode occurs, then it will be defined as=1 'YES' If such an episode does not occur, then it will be defined as=0 'NO' [Time Frame: Maximum time frame 50 days postoperatively]
- Disease recurrence. Disease recurrence rate. If such an episode occurs, then it will be defined as=1 'YES' If such an episode does not occur, then it will be defined as=0 'NO' [Time Frame: Maximum time frame 1 year postoperatively]
- Difference in the quality of life of the patient. Difference in the quality of life of the patient based on the Quality of Life with Chronic Wounds Wounds (Qol) Questionnaire [Time Frame: 7, 14 and 21 days postoperatively]
- Medium term quality of life. Quality of life of the patient based on the Short Form 36 (SF-36) questionnaire [Time Frame: 28 days postoperatively]
- Treatment satisfaction. Patient satisfaction regarding the treatment results measured at a 1-5 scale [Time Frame: 35 days postoperatively]
- Treatment acceptance. Patient acceptance regarding the re-application of the treatment measured at a 1-5 scale [Time Frame: 35 days postoperatively]

8. Experimental Group

The pilonidal cyst will be resected, with the use of a scalpel and then hemostasis will be performed with diathermy.

Alginate dressings with silver and high-G cellulose, which combine increased absorption properties, antimicrobial action and high coherence will be used. The size of the dressings will be 3cm X 45cm and 1 cm cord will be used for filling the wound cavity. Dressings with perimetric adhesive layer from natural materials for latent breathing of the skin with dressing dimensions based on the wound size, will be also placed.

Wound care will be performed in a specific way each time that the dressings will be removed. The wound will be irrigated with normal saline and betadine solution and finally without pressure the trauma will be dried.

9. Active Comparator

The pilonidal cyst will be resected, with the use of a scalpel and then hemostasis will be performed with diathermy.

Wound care will be performed with the application of simple gauze dressings. Wound care will be performed in a specific way each time that the dressings will be removed. The wound will be irrigated with normal saline and betadine solution and finally without pressure the trauma will be dried.

10. The questionnaires used for evaluation of the patients quality of life participating in this study.

Two questionnaires will be used, SF-36 and Quality of life with Chronic Wound. The first one will be the Greek version of the questionnaire and the second one will be in the original English version and will be answered by patients that have the necessary knowledge of the English language. SF-36 will be answered from the patients every four weeks. Quality of life with Chronic Wound will be answered every seven days by phone or during reevaluation.

11. Consent Form.

Every patient will sign preoperatively a consent form agreeing to participate in the study after being informed.

12. Trial.

The present non-commercial prospective randomized controlled study will be conducted in the Department of Surgery of the University Hospital of Larissa. Patient data will be recorded both in the patient charts and in an electronic database. The hospital will not be addressed with any form of economic burden. There will be no form of financial support for the present study.

LITERATURE

1. DWIGHT RW, MALOY JK. Pilonidal sinus; experience with 449 cases. *N Engl J Med.* 1953 Dec 3;249(23):926-30. PubMed ID: 13111384
2. BUIE LA, CURTISS RK. Pilonidal disease. *Surg Clin North Am.* 1952 Aug;1247-59. PubMed ID: 14950701
3. Berry DP. Pilonidal sinus disease. *J Wound Care.* 1992 Sep 2;1(3):29-32. PubMed ID: 27911182
4. Søndena K, Andersen E, Nesvik I, Søreide JA. Patient characteristics and symptoms in chronic pilonidal sinus disease. *Int J Colorectal Dis.* 1995;10(1):39-42. PubMed ID: 7745322
5. Kronborg O, Christensen K, Zimmermann-Nielsen C. Chronic pilonidal disease: a randomized trial with a complete 3-year follow-up. *Br J Surg.* 1985 Apr;72(4):303-4. PubMed ID: 3886069
6. Søndena K, Diab R, Nesvik I, Gullaksen FP, Kristiansen RM, Saebø A, Kømer H. Influence of failure of primary wound healing on subsequent recurrence of pilonidal sinus. combined prospective study and randomised controlled trial. *Eur J Surg.* 2002;168(11):614-8. PubMed ID: 12699097
7. Karydakakis GE. New approach to the problem of pilonidal sinus. *Lancet.* 1973 Dec 22;2(7843):1414-5. PubMed ID: 4128725
8. Schultz GS, Sibbald RG, Falanga V, Ayello EA, Dowsett C, Harding K, Romanelli M, Stacey MC, Teot L, Vanscheidt W. Wound bed preparation: a systematic approach to wound management. *Wound Repair Regen.* 2003 Mar;11 Suppl 1:S1-28. Review. PubMed ID: 12654015
9. Gruessner U, Clemens M, Pahlplatz PV, Sperling P, Witte J, Rosen HR; Septocoll Study Group. Improvement of perineal wound healing by local administration of gentamicin-impregnated collagen fleeces after abdominoperineal excision of rectal cancer. *Am J Surg.* 2001 Nov;182(5):502-9. PubMed ID: 11754859
10. Lewis R, Whiting P, ter Riet G, O'Meara S, Glanville J. A rapid and systematic review of the clinical effectiveness and cost-effectiveness of debriding agents in treating surgical wounds healing by secondary intention. *Health Technol Assess.* 2001;5(14):1-131. Review. PubMed ID: 11399237
11. Armstrong JH, Barcia PJ. Pilonidal sinus disease. The conservative approach. *Arch Surg.* 1994 Sep;129(9):914-7; discussion 917-9. PubMed ID: 8080372
12. Clothier PR, Haywood IR. The natural history of the post anal (pilonidal) sinus. *Ann R Coll Surg Engl.* 1984 May;66(3):201-3. PubMed ID: 6721409
13. Blanco G, Giordano M, Torelli I. [Surgical treatment of pilonidal sinus with open surgical technique]. *Minerva Chir.* 2003 Apr;58(2):181-7. Review. Italian. PubMed ID: 12738928
14. Al-Salamah SM, Hussain MI, Mirza SM. Excision with or without primary closure for pilonidal sinus disease. *J Pak Med Assoc.* 2007 Aug;57(8):388-91. PubMed ID: 17902520
15. Irkörüçü O, Erdem H, Reyhan E. The best therapy for pilonidal disease: which management for which type? *World J Surg.* 2012 Mar;36(3):691-2. doi: 10.1007/s00268-011-1285-2. PubMed ID: 21956594
16. Anagnostopoulos F, Niakas D, Pappa E. Construct validation of the Greek SF-36 Health Survey. *Qual Life Res.* 2005 Oct;14(8):1959-65. PubMed ID: 16155784
17. Blome C, Baade K, Debus ES, Price P, Augustin M. The "Wound-QoL": a short questionnaire measuring quality of life in patients with chronic wounds based on three established disease-specific instruments. *Wound Repair Regen.* 2014 Jul-Aug;22(4):504-14. doi: 10.1111/wrr.12193. PubMed ID: 24899053
18. Deutsch CJ, Edwards DM, Myers S. Wound dressings. *Br J Hosp Med (Lond).* 2017 Jul 2;78(7):C103-C109. doi: 10.12968/hmed.2017.78.7.C103. PubMed ID: 28692373