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Prospective Randomized Clinical Trial Comparing Outcomes of Secondary Intention Wound Care Methods

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Abstract

Background: The optimal method of postoperative secondary intention wound care, and the clinical effect of debridement on acute, postoperative wounds, is uncertain.

Objective: To study whether aggressive debridement is superior to minimal debridement for postoperative secondary intention wounds.

Methods: Prospective, randomized, clinical trial comparing aggressive debridement versus minimal debridement wound care methods in patients who underwent Mohs or excisional surgery and had wounds allowed to heal by second intention.

Results: 52 patients were screened to enroll a total of 8 patients. Mean time to healing for the aggressive debridement group was 56.8 days (Range 27-96, SD 29.8) and 61.5 days (Range 35-89, SD 30.0) for the minimal debridement group (p=0.82). The mean total Patient Satisfaction Assessment Questionnaire score was 39.8 (SD 6.9) for the aggressive debridement group and 45.0 (SD 6.5) for the minimal debridement group (p=0.36). The mean total Visual Analog Scale score for the aggressive debridement group was 32.3 (SD 12.7) and 23.7 (SD 8.0) for the minimal debridement group (p=0.24).

Conclusion: Our study found no statistically significant difference in time to healing, patient satisfaction, or cosmetic outcome between the two treatment groups. Aggressive debridement is more time- and cost-intensive and may not offer additional benefits for acute, postoperative wounds.

INTRODUCTION

Wound care represents a major health burden with significant associated costs [1]. In dermatology, post-surgical wounds are either repaired or allowed to heal by second intention, with generally acceptable cosmetic outcomes and low complication rate [2]. Previous studies have shown a positive association between the frequency of debridement and healing rates in chronic wounds, based on the belief that debridement initiates the first stage of wound healing, and transforms chronic wounds into acute wounds [1,3-5]. However, the effect of debridement on acute, post-surgical wounds is not well-described in the literature [6].

Debridement has been shown to hasten wound healing. However, too frequent debridement may unnecessarily strip the wound of healthy substances such as fibrin, platelets, neutrophils, macrophages, fibroblasts, collagen, granulation tissue, and keratinocytes that are valuable for post-surgical wound healing. Additionally, it is not clear whether the presence of fibrinous slough in the wound, which contains both the healthy substances, listed above as well as bacteria and cellular debris, impedes or facilitates the healing of healthy post-surgical wounds that have not become stalled in their healing process.

One retrospective review of debridement and time to healing did include the analysis of surgical wounds and concluded that frequent debridement led to shorter healing times, but no prospective studies have been done investigating whether this subset of wounds shows a propensity to heal as quickly without frequent and aggressive debridement [7]. Both aggressive debridement and minimal debridement are accepted methods of post-operative care for secondary intention wounds. While both methods are practiced at our institution, there is no known, published "standard-of-care" in the literature for such wounds. This is because there have been no randomized controlled trials undertaken comparing efficacy of these two methods.

The goal of this randomized clinical trial was to assess whether frequent and aggressive debridement facilitates or

impedes acute wound healing. Findings of this study may have implications on the number and frequency of follow-up clinical visits for patients, with direct effects on costs to the patient, costs to the healthcare system, opportunity costs to the patient, as well as the availability of wound care appointments for other uses. Optimizing wound care methods in this era of accountable care organizations therefore targets the triple aim of improving patient satisfaction, improving quality of care, and reducing overall system costs [8].

METHODS

Study design

This was a prospective, 2-arm, randomized, registered clinical trial (ClinicalTrials.gov Identifier: NCT03880331). Ethical approval was obtained through the Institutional Review Board of Lahey Hospital and Medical Center before study commencement. All patients provided written and verbal consent to enroll.

Block randomization was used to ensure balanced enrollment in each arm as the trial progressed. Randomization was stratified by anatomic region. The three anatomic regions included: head and neck, trunk and upper extremity, and lower extremity. Randomization sequences were generated in advance using an available web service (Sealed Envelope Ltd. 2015), were kept sealed and blinded to the investigators, and were only revealed after each patient was consented and enrolled in the study.

Patients

Patients were eligible for enrollment if they were older than 18 years, had undergone Mohs or excisional surgery, were able to give consent, had postoperative defects amenable to healing by secondary intention, and were willing and able to return to clinic for all wound care visits.

Patients were excluded from the study if they were unable to give independent consent due to mental status or language barrier, unable to perform daily wound care, unwilling or unable to return for follow-up visits, had more than one active wound, or had baseline venous stasis or pitting edema of the affected limb requiring compression stockings or a compressive bandage such as an Unna boot.

Wound care methods

All patients were instructed to keep the bandage clean and dry for 24-48 hours, then to start daily wound care until their next follow up visit.

Patients allocated to the aggressive debridement group were instructed to clean the wound with mild soap and water, scrub the surface of the wound with a clean washcloth aggressively in order to remove all scab and fibrinous slough from the wound base until they saw pinpoint bleeding, and then to apply petrolatum and a non-stick bandage. Patients were scheduled to be seen in clinic every week until healed. All scab, eschar, and fibrinous slough was debrided from the wound base down to pinpoint bleeding by the clinician at each in-person visit as necessary.

Patients allocated to the minimal debridement group were instructed to clean the wound gently with mild soap and water, to not scrub the wound aggressively, and to apply petrolatum and a non-stick bandage. There was no removal of eschar or fibrinous slough in the wound base by the patient or the clinician at their in-person visits. Only scab was removed by the clinician during the in-person visits. Patients were scheduled to be seen in clinic every two weeks until healed, which was the standard of care in our practice. To ensure balance between the two arms, these patients were contacted by telephone at weekly intervals between their scheduled clinic visits to determine if healing had occurred.

In both arms, patients were instructed to not let a scab form. Silver nitrate was used by the clinician to treat excessive granulation tissue only when the granulation tissue was higher than the level of the surrounding skin.

Photographs were taken of all patients at every visit. All patients were given a handout with standard photographs of the healing stages of secondary intention, including features such as granulation tissue, fibrinous slough, and re-epithelialization, and were asked to record the date they believed their wounds were completely healed.

Assessments

The primary outcome measure was time to complete wound healing. Secondary outcomes included patient satisfaction (as assessed by the Patient Satisfaction Assessment Questionnaire – VSAQ - given to the patient once the wound was completely healed) and cosmetic appearance (as assessed by the Visual Analog Scale – VAS - by two blinded observers using photographs of the final healed wounds). Tertiary outcomes included the number of complications, including pain, bleeding, infection, excess granulation tissue requiring treatment with silver nitrate, tumor recurrence, and any treatment failures as defined as wounds that did not heal by 16 weeks.

We obtained basic demographic data following intervention assignment at patient enrollment. This included the patient's age, sex, and race, as well as pertinent comorbidities that would affect wound healing, including diabetes, venous stasis, immunosuppression, and current tobacco use. Wound defect length, width, and depth was measured at baseline and at every visit. A photograph of the wound was taken at baseline and at every visit.

Statistical analysis

Differences in demographics and wound characteristics between the groups were compared to evaluate balanced randomization. Two-sided *t* tests (alpha=0.05) were performed on the data obtained for the primary and secondary outcome measures for each treatment group to determine statistical significance.

RESULTS

52 patients were screened to enroll a total of 8 patients with 8 surgical sites, 4 in each treatment group. A total of 32 screened patients (61.5%) declined to participate due to time required for return visits (n = 12, 23.1%), travel distance to clinic (n = 8, 15.4%), unwillingness to perform aggressive debridement at home (n = 7, 13.5%), cost of visits such as insurance deductibles and copays (n = 3, 5.8%), not wanting to participate in a study (n = 1, 1.9%), and reason not given (n = 1, 1.9%). 12 patients (23.1%) were excluded due to lower extremity edema requiring compression stockings or Unna Boot (n = 3, 5.8%), inability to perform wound care (n = 3, 5.8%), inability to obtain independent consent due to dementia and language barrier (n = 2, 3.8%), multiple surgical sites (n = 2, 3.8%), and wounds requiring a xenograft (n = 2, 3.8%).

The patient demographics, procedures performed, tumor types, tumor locations, initial wound size, and comorbidities were similar in both treatment groups. Most of the patients enrolled in the study were elderly (Mean age of 75 years, Range 66-88), male (62.5%), and white (100%). Most had undergone Mohs surgery (87.5%), and the most common anatomic location was the lower extremities (62.5%) (Table 1). One patient decided he was mentally unable to perform aggressive debridement at home. He was given guidance on minimal debridement wound care and followed to complete healing. His results were calculated using the intent to treat methodology. Another patient in the aggressive debridement arm was unable to return for in-person visits due to the COVID-19 pandemic but was able to follow the aggressive debridement protocol at home. This patient was followed to complete healing via telehealth visits. No patients were lost to follow-up. Unfortunately, further study recruitment was terminated early due to our hospital's IRB restrictions during the COVID-19 pandemic.

Mean time to healing for the aggressive debridement group was 56.8 days (Range 27-96, SD 29.8) and 61.5 days (Range 35-89, SD 30.0) for the minimal debridement group. The difference was not statistically significant, with a p value of 0.82.

Table 1: Patient demographics and baseline characteristics.

		Aggressive Debridement Group	Minimal Debridement Group
Number of Patients, n		4	4
Age, Mean (Range)		77.5 (70-83)	73 (66-88)
Sex, n	Male	3	2
	Female	1	2
Race, n	White	4	4
Procedure, n	Mohs	3	4
	Excision	1	0
Tumor type, n	BCC	3	3
	SCC	1	1
Tumor Location, n	Head and Neck	2	1
	Lower extremities	2	3
Initial Wound Size, Length x Width	Mean	2.1 x 1.7 cm	2 x 1.6 cm

The mean total PSAQ score was 39.8 (SD 6.9) for the aggressive debridement group and 45 (SD 6.5) for the minimal debridement group. Lower scores indicate better outcomes. This difference was not statistically significant, with a p value of 0.36 (Table 2). No statistically significant differences were found between the PSAQ subcategory scores for appearance, consciousness, satisfaction with appearance, or satisfaction with symptoms.

The mean total VAS score for the aggressive debridement group was 32.3 (SD 12.7) and 23.7 (SD 8.0) for the minimal debridement group. Higher scores indicate better outcomes. This difference was not statistically significant, with a p value of 0.24 (Table 2). No statistically significant differences were found between the VAS subcategory scores for vascularity, pigmentation, acceptability, observer comfort, or contour.

One patient in the minimal debridement group complained of one episode of pain (maximum pain 4/10), which was associated with a post-operative methicillin-sensitive Staphylococcus aureus infection on the lower extremity within the first week post-operatively, and was treated successfully with appropriate antibiotic therapy. Two patients, one in each treatment arm, had brief episodes of bleeding within the first two weeks postoperatively, which were managed successfully with pressure at home. Neither patient required a separate visit or hospitalization. Three patients, one in the aggressive debridement group and two in the minimal debridement group, had episodes of excess granulation tissue rising above the level of the surrounding skin, which were treated successfully with silver nitrate. There were no tumor recurrences nor treatment failures in either group.

DISCUSSION

Our study found no statistically significant difference in time to healing, patient satisfaction, or cosmetic outcome between our two research groups. Furthermore, our study did not identify any significant differences in complication rates between the two groups. In fact, the low rates of complications in our study support the widespread belief that secondary intention healing is a safe wound care method with a low rate of complications, despite the exact secondary intention wound care method employed. Therefore, our findings suggest that frequent or aggressive debridement may not offer added benefit over a gentler, less time- and cost-intensive wound care method for acute, postoperative wounds.

The conclusions of our study are strengthened by the randomized design with allocation concealment, blinded reviewers, and use of validated outcome measure tools. Our 100% follow-up rate diminishes the chance of bias that might occur from patients excluded from analysis. One patient who was uncomfortable performing aggressive debridement was followed to complete healing, and his data was calculated using an intention-to-treat analysis in order to avoid a biased estimate of treatment efficacy.

Limitations of our study include small sample size and the fact

Table 2: Results.

	Aggressive Debridement Group	Minimal Debridement Group	
Primary Outcome: Time to Healing	**Mean, Range (SD)**	**Mean, Range (SD)**	***p* value**
Time to Healing in Days	**56.8, 27-96 (29.8)**	**61.5, 35-89 (30.0)**	**0.82**
Secondary Outcome: Patient Satisfaction (PSAQ)	Mean (SD)	Mean (SD)	*p* value
Appearance Total	17.3 (3.2)	17.5 (4.2)	0.93
Consciousness Total	7.5 (1)	9.3 (1.5)	0.188
Satisfaction with Appearance	10 (4)	13.3 (2.6)	0.35
Satisfaction with Symptoms	5 (0)	5 (0)	N/A
Total	39.8 (6.9)	45 (6.5)	0.36
Secondary Outcome: Cosmetic Appearance (VAS)	Mean (SD)	Mean (SD)	*p* value
Vascularity	6.2 (2.3)	3.7 (1.5)	0.11
Pigmentation	7.1 (1.9)	5.9 (2.3)	0.52
Acceptability	6 (3.3)	4.3 (1.9)	0.32
Observer Comfort	5.9 (3.5)	4.1 (2.2)	0.28
Contour	7.2 (2.1)	5.7 (2.2)	0.41
Total	32.3 (12.7)	23.7 (8.0)	0.24

this study was performed at a single institution. Our sample size was limited due to the COVID-19 pandemic, and this may have resulted in insufficient power to detect a statistically significant difference between the two treatment arms. A larger, multi-institution study is needed to corroborate our results. Patients and providers were not blinded to the nature of the treatments given the nature of our study, and we were unable to measure the degree of debridement performed by patients at home. The minimal debridement group was seen by the clinician every two weeks while the aggressive debridement group was seen weekly, but all patients were contacted by study clinicians at least weekly.

44.2% of patients refused to participate in the study due to factors related to in-person visits, including time, travel, and cost of wound care visits. 13.5% of patients refused to participate due to unwillingness to perform aggressive debridement at home. This suggest patient preferences for less invasive and time intense wound management plans, which may play key roles in influencing patient satisfaction in addition to healing time and scar appearance.

CONCLUSION

Aggressive and minimal debridement wound care methods for post-surgical dermatologic wounds result in similar time to healing, patient satisfaction, and cosmetic outcomes. A larger, multi-center trial is needed to confirm these findings in the larger context of patient preferences, individual and system-based healthcare costs.

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Authorship statement

Sreya Talasila, Kristina Liu, and Jeffrey Tiger contributed to the study conception, design, and material preparation. Data collection was performed by Sreya Talasila and Jeffrey Tiger. Data analysis was performed by all authors. The first draft of the manuscript was written by Sreya Talasila. All authors commented on previous versions of the manuscript and contributed meaningfully to the final manuscript as submitted. All authors read and approved the final manuscript.

Level of evidence

Clinical Trial Registration: ClinicalTrials.gov NCT03880331.

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