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Controlling intraoperative hemorrhage during burn surgery: A prospective, randomized trial comparing NuStat® hemostatic dressing to the historic standard of care☆

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ARTICLE INFO

Article history:
Accepted 26 August 2016

Keywords:
Blood loss
Intraoperative hemorrhage
Hemostatic dressings

ABSTRACT

Introduction: One of the primary intraoperative challenges during burn surgery is to adequately excise the burn while avoiding massive hemorrhage. This has become increasingly important, as we see more burn patients that are older and with more medical comorbidities. While adequate excision down to healthy tissues for deep burns is essential for skin graft to take, it also leads to active bleeding that can be a challenge to control. Good hemostasis is imperative as a hematoma is the most common cause of graft loss. Several new products have become available to help control intraoperative hemorrhage. A new hemostatic dressing, NuStat®, is available and approved by FDA in United States.

Methods: A single institution prospective randomized control trial was completed at Regional Burn Center of the University of South Alabama comparing NuStat® with the institutional historic standard of care. Twenty such patients were included in our study. A cost analysis was also completed as part of the study retrospectively.

Results: For dressings used to treat the burn site, blood loss on the side treated with NuStat® was on average less (27 g/100 cm^2) than the side treated with our historic standard of care (31 g/100 cm^2), though it was not statistically significant ($p=0.81$). Similarly, on the donor site, blood loss on the side treated with NuStat® was on average less (14 g/100 cm^2) than the side treated with our historic standard of care (15 g/100 cm^2), but it was also not statistically significant ($p=0.92$). Average total blood loss from both excision and donor sites was also less with NuStat® (10 g/100 cm^2) compared to the historic standard of care (12 g/100 cm^2), but it was also not significant ($p=0.77$). There was no difference in the number of cycles required to achieve hemostasis for either the burn (1.15 NuStat® vs. 1.1 for historic standard of care, $p=0.70$) or the donor site (1 vs. 1, $p=1.0$). When comparing the cost of NuStat® versus the historic standard of care, the actual costs incurred for the wounds was less for the portion treated with NuStat® ($148.43) when compared to the historic standard of care ($186.45) ($p<0.001$).

Conclusions: Based on these findings, NuStat® hemostatic action should be comparable to the historic standard of care, and these newer hemostatic agents evaluated further in burn surgery and bleeding during other procedures such as trauma surgery.

☆ The authors have no conflict of interest to report regarding this manuscript. All authors participated in interpretation of the data analysis.

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http://dx.doi.org/10.1016/j.burns.2016.08.026
0305-4179/

1. Introduction

Burn care has greatly changed in the last twenty five years, from focusing on acute treatment to reduce mortality, to focusing on intermediate- and long-term burn care in terms of reduced morbidity, quality of life measures, overall aesthetics, and minimization of pain [1]. Early excision was brought to the forefront in 1970 by Janzekovich [2], and has been shown to significantly reduce mortality, lower rates of sepsis, length of stay, and reduced costs [3,4]. The initial opponents to early excision cited the increased intraoperative blood loss with this technique. Though minimized thanks to improvements in critical care, this intraoperative challenge has persisted, with recent studies finding that for each percent of total body service area excised, adults will lose between 196 and 269 mL of blood [5]. Controlling hemorrhage to minimize blood loss has become increasingly important as the populations in United States and Europe have begun to age, and burn units are increasingly likely to treat older patients and those with comoribidites, who are at the greatest risk of having a burn [6]. Good hemostasis is imperative, as a hematoma is the most common cause of graft loss [7]. Numerous prior studies have evaluated ways to control intraoperative hemorrhage, including tourniquets, epinephrine tumescence, topical pro-coagulants (i.e. thrombin, fibrin sealant, Arista®), and systemic agents [3,8–14]. Several new products have become available to help control intraoperative hemorrhage. A new hemostatic dressing, NuStat®, is available and approved by FDA in United States. It is a combination of continuous filament silica and bamboo cellulose, which together promote hemostasis by activating the clotting cascade.

The purpose of this study was to assess the efficacy of NuStat® in controlling intraoperative hemorrhage, using blood loss and length of time to hemostasis as primary end points. We hypothesized that the use of NuStat® would be as effective as the historic standard of care, application of epineprhine and thrombin to excised donor and graft sites. Secondarily, we evaluated the costs of using NuStat® relative to the historic standard of care.

2. Methods

A prospective randomized control trial was undertaken to evaluate the difference, if any, between the NuStat® dressing and historic standard of care. All patients were treated at the University of South Alabama's Arnold Luterman Regional Burn Center. The Arnold Luterman Regional Burn Center is located in Mobile, AL and serves south Alabama, northwest Florida, southern Mississippi, and eastern Louisiana. We evaluated adult patients (≥19 years of age) that were not on anticoagulant or antiplatelet therapy sustaining burns who sustained less than 10% total body surface area (TBSA) to the extremities that required excision. Based on operative notes from previous excisions of similar burns (<10% TBSA extremity burns), the mean estimated blood loss was approximately 50 mL/100 cm^2 (~53 g based on a density of 1.06 g/mL). Based on a presumption of a 25% decrease in measured blood loss, we calculated we needed an N of 20 to avoid a type II error. Data was collected prospectively, including age, gender, total body surface area percentage burned, total body surface area percentage treated, study site. Both NuStat® bandages and the material required for the control (epinephrine- and thrombin-soaked non-adherent dressings, saline-soaked laparotomy sponges, and elastic bandage wraps) were weighed pre-operatively. Our historic standard of care consisted of 50 pack of non-adherent dressings soaked in a solution made up of 200 cc normal saline with 20,000 units of thrombin and 4 cc of 1:1000 epinephrine. Non-adherent dressings are placed over the excision or donor site and wrapped with hot packs and elastic bandage wraps for compression. After infiltration of 1:1,000,000 epinephrine solution into the subcutaneous tissues, each graft and donor site was divided into two equal halves by surface area (Fig. 1) and the NuStat® bandage or the epinephrine- and thrombin-soaked non-adherent dressings covered by warm saline-soaked laparotomy sponges and wrapped in elastic bandage wraps were randomized to the proximal and distal aspects of each wound (Fig. 2). The dressings were removed after a five minute cycle and the wound was evaluated for bleeding (Fig. 3). If the wound still showed signs of clinically significant bleeding, the dressings were re-applied for an additional full five minute cycle. This process could occur up to three times to

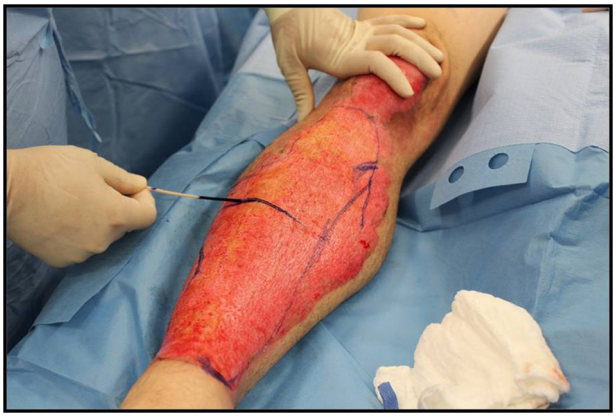

Fig. 1 – Graft and donor site are divided into equal halves by surface area, randomizing the proximal and distal ends to historic standard of care or NuStat.

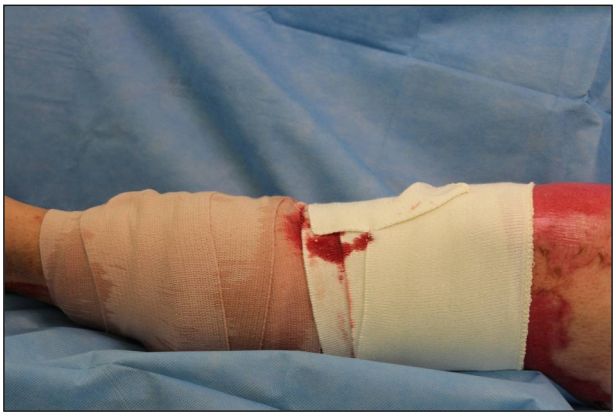

Fig. 2 – Each half is wrapped for a five minute cycle by his randomized dressing.