PGY-3

**Critical Review Form**

**Therapy**

[Ro HS, Shin JY, Sabbagh MD, Roh SG, Chang SC, Lee NH. Effectiveness of aspiration or deroofing for blister management in patients with burns: A prospective randomized controlled trial. Medicine (Baltimore). 2018;97(17):e0563.](http://pmid.us/29703044)

**Objectives: “To assess the effectiveness and the advantages of different management options of burn blisters; aspiration and deroofing.” (p 2)**

**Methods: From March 2016 thru September 2016 three Plastic Surgeons at Chonbuk National University Hospital in Korea conducted a parallel-group randomized controlled trial of adults with acute burn blisters >6 mm arriving in the emergency department or outpatient clinic. Exclusion criteria included age <18 years, severe pre-existing systemic disease or psychotic disorders (both undefined), or a blister that had ruptured at the time of initial treatment at Chonbuk Hospital.** [**Randomization**](http://pmid.us/7474192) **occurred via coin flip to either blister aspiration or deroofing. Post-procedure “the dressing of each group was matched with antibacterial ointment, anti-adhesive material, and gauze dressing”. (p 2)**

**The authors do not report a primary outcome or** [**sample size estimation**](http://pmid.us/12954688)**, nor do they cite or report adherence to the** [**EQUATOR Network’s CONSORT reporting standards**](https://www.equator-network.org/reporting-guidelines/consort/) **for randomized controlled trials. They assessed four outcomes.**

**Wound healing was assessed by an experienced Plastic Surgeon as judged by absence of oozing at the time of dressing change. The unit of analysis was number of days until complete re-epitheliazation (as judged by the lack of oozing). Dressing changes occurred on days 1, 3, 7, and 14.**

**Functional and aesthetic outcomes were assessed using the Patient and Observer Scar Assessment Scale (POSAS, validated by** [**van de Kar 2005**](http://pmid.us/16079683) **and** [**Truong 2007**](http://pmid.us/17230080)**) in which 1 is normal skin and 10 is “worst scar imaginable”. POSAS scores were obtained from patients and investigators at 4 weeks, 3 months, 6 months, and 1 year. The burn scars in each group were measured independently of each other by board-certified blinded Plastic Surgeons.**

**Patient’s pain during dressing was measured on days 1, 3, 7, and 14 using a** [**visual analog scale**](http://pmid.us/10870749) **from 0 (no pain) to 5 (worst imaginable pain).**

**Bacterial cultures were obtained from both groups. At the first treatment in the aspiration group “the lumen of the blister was swabbed and a bacterial culture was performed.” Whereas at the first treatment “in the deroofing group, the blister was debrided and then the wound bed was swabbed”. Both groups also had their wound beds cultured on days 3, 7, and 14 as well. (p 2)**

|  |  |
| --- | --- |
| **Critical Review Form: Therapy** | |
| Guide | Comments |
| **Are the results valid?** | |
| **Did experimental and control groups being the study with a similar prognosis?** | |
| Were patients randomized? | Yes. “Randomization was performed by block randomization and the coin tossing method”. (p 2) |
| Was allocation concealed? Was it possible to subvert the randomization to ensure a patient would be “randomized” to a particular group? | Yes. The investigators report “a parallel-group randomized controlled trial with concealed allocation”. (p 2) |
| Were patients analyzed in the groups to which they were randomized? | Uncertain – no clear statement of [intention to treat](http://pmid.us/12242181), but also not reports of crossovers. |
| Were patients in the treatment and control groups similar with respect to known prognostic factors? | Yes, as noted in Table 1 (p. 3) no statistically significant differences were found between the two groups in terms of age, gender, burn etiology, percent body surface area, burn location, or bullae size. |
| **Did experimental and control groups retain a similar prognosis after the study started?** | |
| Were patients aware of group allocation? | Yes. Although “patients were treated without being informed of whether they were undergoing aspiration or deroofing” (p 2) they would have been aware simply by observing the procedure. |
| Were clinicians aware of group allocation? | Yes, the treating clinicians had to be aware of the treatment group because they performed the intervention. |
| Were outcome assessors aware of group allocation? | No. “Three board-certified plastic surgeons assessed the treatments while blinded to the patient and group information.” (p 2) |
| Was follow-up complete? | No. As demonstrated in Figure 1 (p 3) three patients in the aspiration and three patients in the deroofing groups were lost to follow-up. No sensitivity analysis was reported with those lost to follow-up. |
| **What are the results?** | |
| How large was the treatment effect? | * 40 patients (20 in each group) enrolled with median age 48-50 and more females than males. The majority of burns were scalding injuries with equal distributions across head/face, trunk, and arm. Palms/soles and legs were less frequently involved. * No difference in healing rates with mean days to complete epitheliazation: 12 in the aspiration group and 12.5 in the deroofing group (p = 0.959). * Three patients required surgery due to non-healing wounds. One in aspiration group underwent escharectomy and two in the deroofing group had skin graft + escharectomy. * Patients rated wound appearance worse in both groups than did Plastic Surgeons. Patients also rated deroofing appearance worse than aspiration at each time point. * Wound maturation and remodeling occurred primarily in the first 1-3 months, although remodeling continued beyond 1-year in some cases. * Pain scores were higher in the deroofing group on days 1 and 3, but not statistically significant (Figure 3, page 5) * Bacterial colonization was lower in the aspiration group (15% vs. 40%) but this was not statistically significant (p – 0.15). |
| How precise was the estimate of the treatment effect? (i.e. what 95% CIs were associated with the results?) | No [confidence intervals](https://www.cmaj.ca/content/171/6/611.long) are reported. |
| **How can I apply the results to patient care?** | |
| Were the study patients similar to my patient? | Probably, although presumably 100% Korean. Also, uncertain what proportion went to ED vs. Plastic Surgery clinic which could limit [external validity](http://pmid.us/15639683). |
| Were all clinically important outcomes considered? | No, understanding ED length of stay and procedural sedation requirements/adverse events would also be important. |
| Are the likely treatment benefits worth the potential harm and costs? | Uncertain based on this analysis. |

**Limitations:**

1. **No clear adherence to** [**CONSORT**](https://www.equator-network.org/reporting-guidelines/consort/) **reporting standards.**
2. **No primary outcome or** [**sample size**](https://emj.bmj.com/content/20/5/453.long) **calculation (so possibility of** [**Type II error**](https://jamanetwork.com/journals/jama/article-abstract/195126) **likely).**
3. **Uncertain** [**external validity**](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(04)17670-8/fulltext) **of Korean patients and Plastic Surgery compared with more ethnically diverse US population and emergency medicine care.**

**Bottom Line:**

**Randomized controlled trial without any *a priori* sample size calculation reporting no significant differences in wound healing rates, appearance, patient discomfort, or infection rates between deroofing or aspirating burn blisters larger than 6mm in adults. However, the small sample size (40 patients) increases the risk of a** [**Type II error**](https://en.wikipedia.org/wiki/Type_I_and_type_II_errors) **(significant difference present but sample size inadequate to detect). A trend favoring aspiration (less immediate pain, greater patient satisfaction with wound appearance, lower rates of bacterial colonization) was identified and merits consideration in** [**shared decision making**](https://onlinelibrary.wiley.com/doi/full/10.1111/acem.12703) **discussions with patients.**