PGY-1

**Critical Review Form**

**Therapy**

[Swain AH, Azadian BS, Wakeley CJ, Shakespeare PG. Management of blisters in minor burns. Br Med J (Clin Res Ed). 1987;295(6591):181.](http://pmid.us/3115367)

**Objectives: To investigate the effects of minor burn blister de-roofing, aspiration, and keeping blisters intact on “bacterial colonization of the blister fluid or surface of the burn and on wound pain”. (p 181)**

**Methods: 202 patients presenting to two ED’s during an unspecified time period with minor (partial thickness) burn injuries averaging <1% of body surface area (BSA) of the arm or leg were managed in one of three ways in non-randomized fashion. During phase-1 blisters were left intact for up to 10 days with aspiration of blister fluid for culture (uncertain when aspiration occurred). In phase-2 “blister fluid was aspirated through a single puncture hole at the first follow-up visit” and “some of the blisters which were aspirated…were actively deroofed”.**

**Patients were asked to follow-up in the next weekday Burn Clinic and 2-3 times weekly thereafter (for undefined duration). The lumen of the blister was swabbed once the during the next 12 days. Patients with aspiration or deroofing were asked at least one day later about any change in pain (increased, no change, or decreased). “Sampling times were comparable in aspirated and exposed burns”, but specific intervals to obtaining fluid specimens are not reported. The culture specimens “were analyzed according to standard bacteriological methods” which are not described further.**

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| **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? | No randomization – this was a two-phase study. |
| Was allocation concealed? Was it possible to subvert the randomization to ensure a patient would be “randomized” to a particular group? | No randomization so no allocation to conceal. |
| Were patients analyzed in the groups to which they were randomized? | Presumably yes, but not explicitly stated whether crossovers occurred. |
| Were patients in the treatment and control groups similar with respect to known prognostic factors? | Uncertain since no demographics reported (% with diabetes or other immunocompromising conditions). |
| **Did experimental and control groups retain a similar prognosis after the study started?** | |
| Were patients aware of group allocation? | Yes, no blinding. |
| Were clinicians aware of group allocation? | Yes, no blinding. |
| Were outcome assessors aware of group allocation? | Yes, no statement of outcome assessor blinding. |
| Was follow-up complete? | Uncertain since no follow-up rates are provided. |
| **What are the results?** | |
| How large was the treatment effect? | In addition to the non-randomized design and incomplete methods reporting that would be impossible to replicate, the reporting of results is confusing. For example, the authors report 202 patients enrolled but the table reports 110 in the “intact” group, 104 in the “aspirated” group, and 102 in the “exposed” group – none of these add up to 202? In addition, they report that 37 patients with deroofed blisters had no pain reduction but their table indicates that 102 patients had exposed (deroofed) blisters. Does one interpret that discrepancy as only 37 deroofed patients were asked about pain reduction? Or that only 37 patients had their blister deroofed?  With those reporting problems noted, the authors note less bacterial colonization of intact blisters (14%) than with aspirated (70%) or exposed/deroofed (76%). They also reported that 0/37 (0%) deroofed patients reported pain reduction (16 increased, 21 unchanged) vs. pain reduction of 23/73 (37%) with aspiration. No confounding variables or adjusted analysis are reported, nor any contemplation of limitations. |
| 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) reported. |
| **How can I apply the results to patient care?** | |
| Were the study patients similar to my patient? | Uncertain since neither patient demographics (age, comorbid illness burden, insurance status) nor healthcare professional attributes (nurse, physician, someone else) are reported. |
| Were all clinically important outcomes considered? | No. Additionally important outcomes would include ED length of stay (presumably longer to aspirate or deroof), wound healing time, analgesic requirement, and patient satisfaction with wound healing. |
| Are the likely treatment benefits worth the potential harm and costs? | Uncertain based on this data which can best be labeled hypothesis-generating to support a controlled trial of no intervention vs. aspiration vs. deroofing. |

**Limitations:**

1. **Not randomized, so multiple potential confounding variables (immunocompromised status, delay to burn care, patient age, depth of burn, topical agents).**
2. [**Decision-making**](http://pmid.us/17112935) **around which patients to deroof unexplained.**
3. **Number of patients in each group illogical.**
4. **Culture methods not reproducible.**
5. **Proportion adherent to follow-up unreported.**
6. **No comparison of pain in the “Intact” group.**
7. **Evidence presented does not differentiate clinically consequential fluid bacteria from contaminant or otherwise asymptomatic colonization.**

**Bottom Line:**

**Non-randomized study with inadequate reporting of either methods or results to support or refute the hypothesis that burn blister aspiration increases fluid bacterial contamination compared with leaving the blister intact. To be conclusive, future research would need to** [**randomize**](http://pmid.us/7474192) **patients in report the methods/results in adherence with** [**CONSORT criteria**](https://www.equator-network.org/reporting-guidelines/consort/) **and then** [**adjust**](http://pmid.us/18175191) **for factors potentially associated with burn wound infection (immunocompromising disorders, delay to burn care, application of topical agents).**