Stop Packing Abscess: A Randomized Clinical Trial Comparing Packing with Non-packing of the Abscess Cavity

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ABSTRACT

Background and Objective(s): Conventionally, it was a routine practice to place packing in the abscess cavity following incision and drainage (I and D), but this concept is changing. This study was conducted to determine more systematically whether routine packing of skin and soft tissue abscess following I and D confers any benefit over I and D followed by simple absorbent dressing alone.

Materials and Methods: Subjects were randomized to either packing or non-packing groups. Treatment failure was assessed at 48-h follow-up by a masked observer who rated it as major (repeat I and D or reexploration or packing the cavity) or minor (further follow-up needed). Pain scores were assessed before the procedure, after the procedure and at 48-h follow-up visit. Healing was assessed at weekly interval using Bates-Jensen tool and cosmesis at 1 week using visual analog scale.

Results: A total of 104 subjects were enrolled. There were no significant differences in baseline characteristics and wound cosmesis between the two groups. The risk of minor treatment failure was almost double in packing than non-packing group (80.8% vs. 40.4%, P = 0.001). Patients in packing reported higher pain scores at 48-h follow-up (mean difference = 1.361 cm; P = 0.001, 95% CI = 1.095–1.628 cm). Wound healing was faster in non-packing than packing group at both 1 week (mean difference = 4.46; P = 0.001, 95% CI = 2.289–5.966) and 2 weeks (mean difference = 1.18; P = 0.049, 95% CI = -0.418-1.921).

Conclusion: Non-packing of abscess cavity significantly reduced minor treatment failure rate and pain perceived.

Key words: Incision and drainage, non-packing, packing, treatment failure

INTRODUCTION

An abscess is a localized collection of pus in a pathological space lined by granulation tissue. The first known use of the term "abscess" was in 1615.^[1] The term "abscess" has been derived from the Latin, abscessus, literally, act of going away.^[1] An abscess is formed from tissues broken down by white blood cells (leukocytes) in response to inflammation. The incidence of cutaneous abscess in general practice is believed to be significant but is not well reported.^[2]

Skin and soft tissue abscesses are frequently managed by opening them with a procedure called "Incision and drainage" (I and D). Conventionally, it was a routine practice to place packing in the abscess cavity to promote better healing and limit the abscess recurrence.^[3] However, the wound cosmesis after healing is compromised.^[4] Several authors have challenged the convention of packing

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abscesses, and none have credited the routine packing of an abscess with any improvement in outcomes.^[5]

In fact, packing may cause harm in the form of increased pain or longer healing times.^[6] Theoretically, it is taught that packing prevents the skin layer from closing prematurely and recreating a potential space for abscess development, but some packing materials actually impede drainage and promote infection through tissue damage. The removal of pack may cause considerable pain and bleeding if it is adherent to tissues. Patients with wound packing usually return to the emergency room or practice setting for multiple "wound checks" and dressing/packing changes which lead to missed days from work or school and utilization of healthcare resources.

Hence, it is important to determine whether packing wound is necessary or even advantageous to patients.

To the best of our knowledge and available literature search, there is no such study done in Nepal. Moreover, no consistency in the results has been found. Due to the inconsistency of previous research reports, we conducted this study to determine whether routine packing of skin and soft tissue abscess following "I and D" confers any benefit over I and D followed by simple absorbent dressing alone.

MATERIALS AND METHODS

Subject

All patients (age \geq 1 year) visiting the Emergency and Surgery Outpatient Department (S-OPD) of BPKIHS with skin and soft tissue abscess.

Study Design

Assessor blinded, randomized, parallel group clinical trial.

Duration of Study

12 months (July 2014–July 2015).

Sample Size Calculation

A sample size was estimated on assumption of overall failure rate of 70% in packed group, based on published data by Kessler *et al.* in 2012.^[7] A sample size of 96 (48 in each arm) was needed to reject null hypothesis at 80% power to detect at least 30% difference between groups in need of intervention at 48 h using an alpha error of 5%.

The above said sample size had been calculated as-

$$N = C \frac{(PcQc) + PeQe}{d2} + \frac{2}{d} + 2$$

Here, Pc = overall failure probability in packed group = 0.7 Qc = 1-Pc = 0.3 Pe = overall failure probability in non-packed group = 0.4 Qe = 1-Pe = 0.6 d = difference between the two groups = 0.3 C = constant = 7.85 for alpha level 5%

Hence,

N = 7.85
$$\frac{(0.7 \times 0.3) + (0.4 \times 0.6)}{0.3 \times 0.3} + \frac{2}{0.3} + 2$$

= 47.8

= around 48 patients in each group.

However, considering 10% to the sample for non-response error, a total of 104 patients (52 in each group) were considered for the study.

Inclusion Criteria

Individuals with age ≥ 1 year, of either sex, with skin and soft tissue abscess were included in the study.

Exclusion Criteria

- Age <1 year.
- Pregnant.
- Post-operative abscess.
- Immunocompromised.
- Multiple abscesses requiring drainage.
- Recurrence of the same abscess.
- Bartholin's abscess, facial abscess, and neck abscess.
- Abscess in intermuscular plane.
- Not giving consent.

Ethical Clearance

The study protocol was performed in accordance with the principle of the declaration of Helsinki and was approved by the Institutional Ethical Review Board on July 22, 2014.

Enrollment of Patients

Patients with the final diagnosis of skin and soft tissue abscess attending the S-OPD and Emergency of BPKIHS, Dharan, were enrolled in the study. A prior printed information sheet was provided in Nepali language along with pictorial and verbal explanation about the abscess, its current mode of treatment as I and D and the equipoise in the mind of surgeon, whether to pack or not to pack the abscess cavity. The patient and relatives were then requested to take part in this randomized controlled trial. The nature of study, interventions as two treatment groups, possible complications, and outcomes were explained in detail. Those agreed to the study then signed a printed consent form. Eligible patients were randomized to one of the two groups: I and D followed by packing or I and D followed by non-packing. A detailed clinical history and was recorded in a preset pro forma. Ultrasonography was done to measure the size; the extent and the depth of the abscess using a high-frequency linear probe before I and D so that deep-seated intermuscular abscesses were excluded from the study.

Randomization and Allocation Concealment

Once consented, he or she was randomized to be in either packing or non-packing group. A randomization list was generated to produce two parallel groups (1:1) with the help of computer-generated numbers. A sequentially generated number with the treatment group was written in sealed envelope. Each patient was assigned a patient identity number and allocated to receive either packing or non-packing group, depending on the treatment specified in sealed envelope.

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Treatment Specified in the Envelope

Inside the envelope instructions to the treating surgeon on how to perform a standardized I and D were written (using a no. 11 blade scalpel and a full-thickness cut incising the lesion along at least 75% of the wound diameter, and then, fully draining, exploring the wound for loculations, and irrigation with normal saline).

- Instructions for the packing group to loosely pack the abscess cavity with quarter-inch gauze ribbons soaked with normal saline.
- Instructions for the non-packing group to place sterile normal saline soaked gauge over abscess cavity and to apply the pressure dressing to obliterate the abscess cavity.

Supportive Treatments

- Types of anesthesia/analgesia/sedation at the time of I and D were decided by the treating clinician.
- Antibiotics were initially given empirically and were changed after culture and sensitivity report if needed.

Blinding

Only the response assessor was blinded.

Clinical Care, Follow-up, and Outcome Measures

- At the follow-up visit (48 h following the procedure), the treating resident was instructed to remove the wound dressing, including packing if present. The supervising attending surgeon then evaluated the wound unaware of the patient's treatment allocation.
- Outcome measures were judged by the masked surgeon.

Primary Outcome Measures

- Treatment failure at 48 h of I and D based on the need of intervention had been defined as major (if interventions needed were either extension of incision or packing abscess cavity or further probing to breakup loculations or need of hospital admission) and as minor (further follow-up needed).
- Pain scores were assessed using a visual analog scale (VAS) before and after the procedure and repeated at 48-h follow-up visit. For patients younger than 5 years, the parent completed the pain score.

Secondary Outcome Measures

These were measured at subsequent follow-up at 1 week and 2 weeks post I and D.

 Wound healing at various intervals of time (such as 1 week, 2 weeks) following I and D was rated using BATES-JENSEN WOUND ASSESSMENT TOOL. 2. Self-rated visual analog cosmesis scale was used to rate the cosmesis at 1 week.

Operational Definition

A wound following I and D was said to be healed if the cavity had been closed with either intact or partial thickness skin with either indistinct edge or distinct edge but attached to wound base.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed by SPSS 11. Data were analyzed using descriptive statistics for abscess characteristics and patient data, Chi-square or Fisher's exact test to compare categorical data, and Student's *t*-test (if data are normally distributed) or Mann–Whitney *U*-test (if data are not normally distributed) for continuous data.

RESULTS

Baseline Characteristics

A total of 134 patients were enrolled in the study. 30 patients were excluded from the study. Of the remaining 104 patients, 52 were randomized to the packing and 52 to the non-packing group [Figure 1]. No cases were lost on follow-up. The groups were similar with respect to age, sex, duration of illness, abscess size, abscess location, and type of anesthesia given during I and D [Table 1].

Interventions Needed at 48-h Follow-up (Treatment Failure)

A number of 42 (80.8%) patients in the packing group and 20 (38.5%) patients in the non-packing group required further follow-up at 48 h assessment (minor intervention). Only 1 (1.9%) patient in the non-packing group required packing of the cavity at 48 h assessment (major intervention) as shown in Table 2.

To apply statistical analysis tool, 1 (1.9%) patient needing packing of abscess cavity at 48 h evaluation in the non-packing group was included in the category of "further follow-up needed" in the non-packing group.

There was statistically significant difference in the packing and non-packing groups in terms of minor intervention required at 48-h follow-up (80.8% vs. 38.5% + 1.9%=40.4%) (P = 0.00).

Comparison of Pain Perceived in Both Groups

The mean \pm SD (median) for VAS score for pre-procedure pain (baseline) for the packing and non-packing groups were 5.46 \pm 1.290 (5) and 5.10 \pm 1.785 (5), respectively (*P* = 0.234).

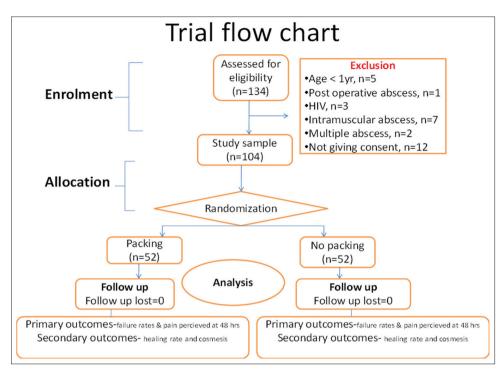


Figure 1: Consort diagram

Table 1: Baseline characteristics

Characteristics	Packing (%)	Non-packing	<pre>7-test*/Chi-square test**</pre>	P value
Age (year)				
Mean±SD (median)	26.29±17.66 (23)	25.35±18.24 (24)	0.268*	0.790
Gender, <i>n</i> (%)				
Male	22 (21.15)	31 (29.80)	3.117**	0.078
Female	30 (28.85)	21 (20.20)		
Duration of illness, (days)				
Mean±SD	10.04±7.73	8.19±6.42	13.57**	0.482
USG size (in mL)				
≤5 mL	17	25	2.556**	0.110
>5 mL	35	27		
Abscess location, n (%)				
Scalp	2 (2)	6 (6)	6.267**	0.617
Extremity	14 (13)	21 (20)		
Axilla	5 (5)	2 (2)		
Back	1 (1)	1 (1)		
Trunk	3 (3)	2 (2)		
Breast	16 (15)	12 (12)		
Buttock	4 (4)	3 (3)		
Perianal	4 (4)	2 (2)		
Groin	3 (3)	3 (3)		
Anesthesia, n (%)				
IVA	36 (35)	24 (23)	7.522**	0.057
Field block	14 (13)	27 (26)		
Regional	1 (1)	1 (1)		
SAB	1 (1)	0 (0)		

SD: Standard deviation

The mean \pm SD (median) for immediate post-procedure pain in the packing group and non-packing groups were

 $0.60 \pm 1.053(0)$ and $0.62 \pm 1.360(0)$, respectively (*P*=0.936). Although statistically not significant, slight increase

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in mean pain in the non-packing group at immediate post-procedure period may be because of the fact that relatively majority in the non-packing group operated under field block (51.92%) followed by intravenous anesthesia (46.15%).

The mean \pm SD (median) for pain at 48 h assessment in the packing and non-packing groups were 1.56 \pm 0.725 (2) and 0.21 \pm 0.96 (0), respectively (*P* = 0.001), as shown in Figure 2.

Comparison of Wound Healing using Bates-Jensen Wound Assessment Tool

At 1-week post-procedure, the mean \pm SD (median) for Bates-Jensen wound score in the packing and non-packing groups were 23.29 \pm 4.811 (24) and 18.83 \pm 4.833 (19), respectively (*P* = 0.001).

At 2-week post-procedure, the mean \pm SD (median) for Bates-Jensen wound score in the packing and no packing groups were 15.52 \pm 2.526 (15.5) and 14.34 \pm 2.733 (13), respectively (*P* = 0.049), as shown in Table 3.

Self-rated Visual Analog Cosmesis Score at 1-week Post-procedure

The mean \pm SD (median) for self-rated wound cosmesis VAS in the packing and non-packing groups were 7.56 \pm 0.725 (8) and 7.73 \pm 1.031 (8), respectively, as shown in Table 3 (*P* = 0.325).

DISCUSSION

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Several theories regarding packing of abscess cavity have been put in surgery texts, but none of them have been demonstrated in the scientific way.^[8]

Table 2: Treatment failure characteristics						
Intervention	Packing (n=52)	Non-packing (n=52)				
Major	0 (0)	1 (1.9)				
Packing abscess cavity						
Minor						
Follow-up needed	42 (80.8)	20 (38.5)				
None	10 (19.2)	31 (59.6)				
Total	52 (100)	52 (100)				

Age Distribution

The age of the patients in the packing group ranged from 1 to 75 years with a mean age of 29 ± 17.66 (23) years, whereas the age of patients in the non-packing group ranged from 1 to 74 years with mean age of 25.35 ± 18.24 (24) years. This result was in corroboration with the study done by O'Malley *et al.*, in 2009, where the mean age was 29.70 years in the packing group and 30.48 years in the non-packing group.^[9]

The result showed consistency in mean age in studies done in various geographical locations, suggesting that the middle-aged patients probably due to more involvement in both indoor and outdoor activities are predominantly affected with skin and soft tissue abscess.

Sex Distribution

In the packing group, there were 22 (21.15%) males and 30 (28.85%) females. In the non-packing group, there were 31 (29.8%) males and 21 (20.20%) females. We observed that males had slightly higher preponderance of skin and soft tissue abscess with the ratio of 1.04:1. The study conducted by Kessler *et al.*, in 2012, had male:female ratio of 2.06:1.^[7]

The slightly higher prevalence among males in our study could probably be due to more involvement of males in outdoor activities than females and also may be due to less number of females in the study.

Duration of Illness

The duration of illness ranged from 3 days to 40 days in the packing group and 3 days to 30 days in the non-packing

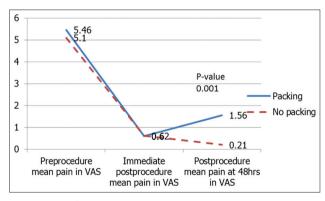


Figure 2: Pain characteristics

Table 3: Healing and wound cosmesis characteristics

Parameter	Packing	Non-packing	P value
Bates-Jensen score			
At 1 week (mean±SD)	23.29±4.811	18.83±4.833	0.001
At 2 weeks (mean±SD)	15.52±2.526	14.34±2.733	0.049
Visual analog cosmetic score (mean±SD)	7.56±0.725	7.73±1.031	0.325

group. Mean duration of illness in the packing group was 10.04 \pm 7.73 (7) days, and in the non-packing group, it was 8.19 \pm 6.42 (5) days. The mean duration of illness was 5 days in the packing group and 5 days in the no packing group in the study conducted by Kessler *et al.* in 2012.^[7]

The longer duration of illness in our study may be due to the fact that patients are very often reluctant to visit clinics regarding their problem and many patients first consult nearby local health practitioner before visiting the tertiary healthcare center like ours.

Size of Abscess Cavity

Among the patients included in the study, 42 (40.38%) patients were found to have abscess cavity of size \leq 5 mL and 62 (59.62%) patients were found to have abscess cavity of size >5 mL.

Abscess Location

Of 104 patients, 35 (33.65%) had abscess on extremities and 28 (26.93%) had breast abscess. Remaining had abscess on scalp (8%), axilla (7%), back (2%), trunk (5%), buttock (7%), perianal region (6%), and groin (6%). In the study conducted by Kessler *et al.*, in 2012, 14 (28.57%) patients had abscess on the extremities.

Type of Anesthesia

In majority of patients, I and D was carried out under intravenous anesthesia (58%), followed by field block (39%), regional block (2%), and SAB (1%).

Geographic Distribution of Patients with Abscess Who Visited BPKIHS

A number of 58 (55.76%) out of 104 patients in our study were from Sunsari district. This is obvious because the tertiary center in which the study was conducted is situated in Sunsari district of Nepal.

Failure Rates (Intervention Needed at 48 h) Among the Patients Receiving Packing and Non-packing Following I and D of Skin and Soft Tissue Abscess

A number of 42 (80.8%) patients in the packing group and 20 (38.5%) patients in the non-packing group required further follow-up at 48 h assessment (minor intervention). Only 1 (1.9%) patient in the non-packing group required packing of the cavity at 48 h assessment (major intervention).

None in the packing group required any form of major intervention at 48-h follow-up. Hence, it was found that packing unnecessarily increased the minor failure rate as compared to the non-packing. This result was in corroboration with the study conducted by Kessler *et al.*, in 2012, in which 19 (70%) out of 27 subjects in the packed group needed an intervention at 48 h compared with 13 (59%) out of 22 subjects in the non-packing group who needed an intervention.^[7]

The likely explanation for the packing causing higher need minor intervention at 48 h assessment could be because patients in packing group had to visit the health center repeatedly for change of the packing materials and for associated more pain. Moreover, those in the non-packing group were able to do self-dressing unlike those in the packing group.

Pain Perceived

The mean \pm SD (median) for immediate post-procedure pain in the packing group and non-packing groups were 0.60 ± 1.053 (0) and 0.62 ± 1.360 (0), respectively. Although statistically not significant, slight increase in mean pain in the non-packing group at immediate post-procedure period may be because of the fact that relatively majority in the non-packing group operated under field block (51.92%) followed by intravenous anesthesia (46.15%).

Post-procedure pain at 48 h of I and D was found to be significantly less in the non-packing group.

In the study conducted by O'Malley *et al.*, in 2009, there was no significant difference in pre-procedure reported pain scores between the packing and the non-packing group (difference of means = 10.25 mm, 95% CI = -7.5-27.9 mm, P = 0.26). Post-procedure pain scores were significantly higher in the packing group (difference of means = 23.8 mm, 95% CI = 5-42 mm, P = 0.014) in the immediate post-procedure period. Subjects in the packing group also reported significantly higher average pain scores at 48-h follow-up (difference of means = 16.4 mm, 95% CI = 1.6-31.2 mm, P = 0.03).

For patients younger than 5 years, the parent completed the pain score. This may be a limitation of this study.

Wound Healing using Bates-Jensen Wound Assessment Tool

Wound healing was significantly faster in the nonpacking than packing group at both 1 week and 2 weeks assessment. However, the difference in wound healing was more at 1 week evaluation between the groups because subsequent packing of the abscess cavity was done if needed in the two groups only for few days in the 1st week following I and D and not always. None of the patients irrespective of their group allocated needed packing of abscess cavity in the 2nd week post-procedure.

In the study conducted by Kessler *et al.*, 2012, no significant difference in healing at 1 week was noted between the two groups.^[7]

Self-rated Visual Analog Cosmetic Score at 1-week Post-procedure

No significant difference in wound cosmesis at 1-week post-procedure was noted between the two groups.

In the study conducted by Kessler *et al.*, 2012, no significant difference in cosmesis at 1 week was noted between the two groups.

CONCLUSION

Non-packing of abscess cavity significantly reduced minor treatment failure rate by decreasing the need of further follow-up in comparison to packing of the abscess cavity. Non-packing of the abscess cavity significantly decreased pain perceived post I and D and improved healing. Nonpacking of abscess has advantage of reduced patient discomfort associated with frequent cavity dressing change, in addition to saving community resources.

This study had a few limitations like short-term follow-up, parent scoring VAS in case of children, an assessor blinded and single center-based study.

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