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): Traditionally, it was a routine practice to place packing in the abscess cavity following I&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&D confers any benefit over I&D followed by simple absorbent dressing alone.

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

Results: Total 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% versus 40.4%, P=0.001). Patients in packing reported higher pain scores at 48 hours follow up (mean difference = 1.361cm; p = 0.001, 95% CI = 1.095 to 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 to 5.966) and 2 weeks(mean difference = 1.18; p = 0.049, 95% CI = -0.418 to 1.921).

Conclusion: Non-packing of abscess cavity significantly reduced minor treatment failure rate andpain perceived

Key words:I&D (Incision and Drainage), Packing, Non-packing, treatment failure.

Conflict of interest: None of the authors is having any conflict of interest.

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 & Drainage"(I & D).Traditionally it was a routine practice to place packing in the abscess cavity in order 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 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.

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

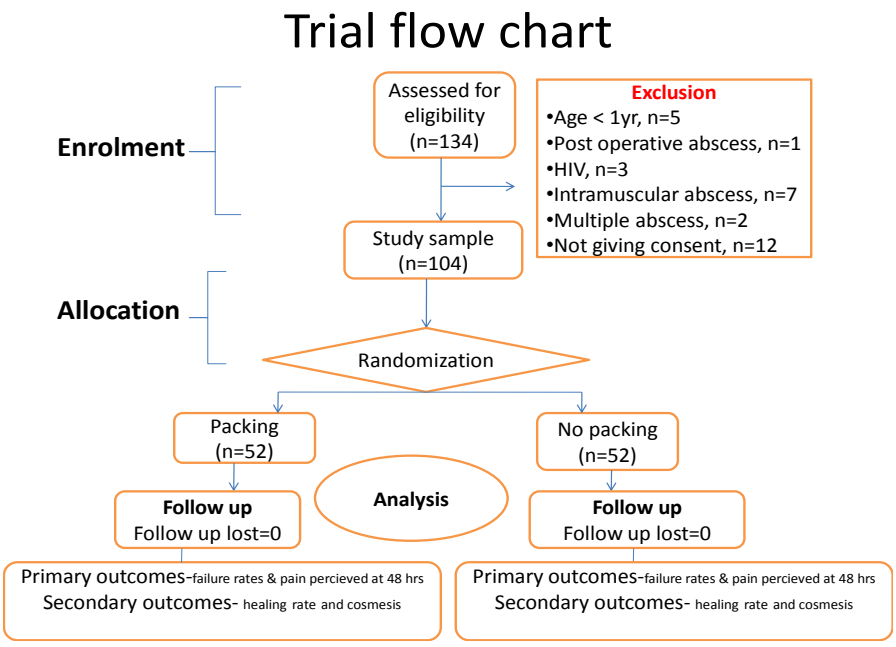

Fig.1- consort diagram

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. Owing to the inconsistency of previous research reports we conducted this study to determine whether routine packing of skin and soft tissue abscess following "Incision and Drainage" confers any benefit over Incision and Drainage followed by simple absorbent dressing alone.

MATERIALS AND METHODS

SUBJECT

All patients (age ≥ 1year) vising the emergency & Surgery Out Patient Department (S-OPD) ofBPKIHS with skin & soft tissue abscess.

STUDY DESIGN

Assessor blinded, randomized, parallel group clinical trial.

DURATION OF STUDY:Twelve months (July 2014 to 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 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 the need of intervention at 48hours 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,

$N=7.85\frac{(0.7X0.3)+(0.4x0.6)}{0.3x0.3} + \frac{2}{0.3} + 2$

=47.8

=around 48 patients in each group.

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

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

ILLUSTRATION 2: Table 1-Baseline characteristics

	Packing	Non packing	T-test*/chi-square test**	p-value
Age (year),mean ± SD(median)	26.29±17.66(23)	25.35±18.24(24)	0.268*	**0.790**
Gender,n(%)				
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)				
≤5ml	17	25	2.556**	**0.110**
> 5 ml	35	27		
Abscess Location,n(%)				
Scalp	2(2%)	6(6%)		
Extremity	14(13%)	21(20%)		
Axilla	5(5%)	2(2%)		
Back	1(1%)	1(1%)	6.267**	**0.617**
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%)		
Anestheisia,n(%)				
IVA	36(35%)	24(23%)		
Field block	14(13%)	27(26%)	7.522**	**0.057**
Regional	1(1%)	1(1%)		
SAB	1(1%)	0(0%)		

INCLUSION CRITERIA

A person of age ≥ 1year, of either sex, with skin & soft tissue abscess

EXCLUSION CRITERIA

- Age<1year
- Pregnant
- Post-operative abscess
- Immunocompromised
- Multiple abscesses requiring drainage
- Recurrence of the same abscess
- Bartholins abscess , facial abscess , Neck abscess
- Abscess in intermuscular plane
- Not giving consent

ETHICAL CLEARANCE

ENROLLMENT OF PATIENTS

Patients with the final diagnosis of skin and soft tissue abscess attending the surgery-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 incision & drainage 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: Incision & Drainage followed by packing or Incision & Drainage followed by non packing.A detailed clinical historyand was recorded in a preset proforma.Ultrasonography was done to measure the size,the extent and the depth of the abscess using a high frequency linear probe prior to Incision & Drainage so that deep seated intermuscular abscesses were excluded from the study.

ILLUSTRATION 3:Table 2- Treatment failure characteristics

Intervention	Packing(n=52)	Non packing(n=52)
Major Packing Abscess cavity	0(0%)	1(1.9%)
Minor Follow up needed	42(80.8%)	20(38.5%)
None	10(19.2%)	31(59.6%)
TOTAL	52(100%)	52(100%)

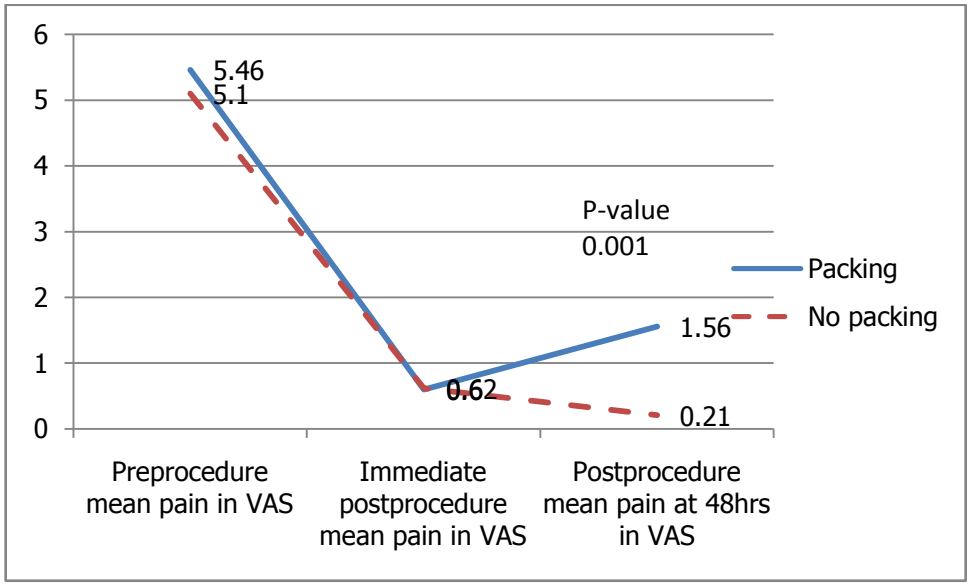

ILLUSTRATION 4: Fig.2- Pain characteristics

RANDOMIZATION AND ALLOCATION CONCEALMENT

Once consented, he or she was randomized to be in either packing or nonpacking 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 upon the treatment specified in sealed envelope.

ILLUSTRATION 5: Table 3- Healing and wound cosmesis characteristics

	Packing	Non packing	p-Value
Betes-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 ±	7.56±0. 725	7.73±1. 031	**0.325**

TREATMENT SPECIFIED IN THE ENVELOPE

Inside the envelope instructions to the treating surgeon on how to perform a standardized Incision & Drainage 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

- Type of anaesthesia/Analgesia/sedation at the time of the I&D were decided by the treating clinician.
- Antibiotics were initially given empirically & was changed after culture and sensitivity report if needed.

BLINDING

Only the response assessor was blinded.

CLINICAL CARE, FOLLOW UP AND OUTCOMEMEASURES

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

Primary Outcome measures

1. Treatment failure at 48 hours of Incision and Drainage based on need of intervention had been defined as *major*(if interventions needed were either extension of incision or packing abscess cavity or further probing to break up loculations or need of hospital admission) and as *minor*(further follow up needed).
2. Pain scores were assessed using a Visual Analogue Scale (VAS) before and after the procedure; and repeated at 48 hours 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 & D.

1. Wound healing at various interval of time (such as 1 week , 2 weeks) following I & D was rated by using BATES-JENSEN WOUND ASSESSMENT TOOL .
2. Self rated Visual Analogue Cosmesis scale was used to rate the cosmesis at one week

OPERATIONAL DEFINITION

A wound following I&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 was entered in Microsoft Excel and analyzed by SPSS 11. Data was analyzed using descriptive statistics for abscess characteristics and patient data, *chi square or Fisher exact test* to comparecategorical data, and student-t test(if data is normally distributed) or Mann-Whitney U test(if data is not normally distributed) for continuous data.

RESULTS

Baseline characteristics

A total of 134 patients were enrolled in the study. Thirty patients were excluded. Of the remaining 104 patients, 52 were randomized to the packing and 52 to the non packing group (fig. 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 Incision & Drainage (table 1).

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

Forty two (80.8%) patients in the packing group and twenty (38.5%) patients in the non packing group required further follow up at 48 hours assessment (minor intervention). Only one (1.9%) patient in the non packing group required packing of the cavity at 48 hour assessment (major intervention) as shown in Table 2.

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

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

Comparison of pain perceived in both groups

The mean ± SD (median) for VAS score for pre-procedure pain (base line) for the packing and non packing groups were 5.46 ± 1.290 (5) and 5.10 ± 1.785 (5) respectively(P-value=0.234).

The mean ± 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 (P-value=0.936). Though 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%).

The mean ± SD (median) for pain at 48 hours assessment in the packing and non packing groups were 1.56 ± 0.725 (2) and 0.21 ± 0.96 (0) respectively (P-value 0.001) as shown in figure 2.

Comparison of Wound healing using Bates-Jensen wound assessment Tool:

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

At 2 weeks post procedure , the mean ± SD (median) for Bates-Jensen wound score in the packing and no packing groups were15.52 ± 2.526 (15.5) and 14.34 ± 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 ± SD (median) for self rated wound cosmesis VAS in the packing and non packing groups were7.56 ± 0.725(8) and 7.73 ± 1.031(8) respectively as shown in table 3(P-value 0.325).

DISCUSSION

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].

AGE DISTRIBUTION:

The age of the patients in the packing group ranged from 1 – 75 years with a mean age of 29±17.66 (23) years, whereas the age of patients in the non packing group ranged from 1–74 years with mean age of 25.35±18.24 (24). 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 andsoft tissue abscess with the ratio of 1.04:1. The study done by Kessler et al in 2012 had male: female ratio of 2.06:1[7].

The slightly higher prevalence amongst 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 group. Mean duration of illness in the packing group was 10.04 ±7.73 (7) days and in the non packing group, it was 8.19±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 done 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 health care centre 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 ≤ 5ml and 62 (59.62%) patients were found to have abscess cavity of size > 5ml.

ABSCESS LOCATION:

Out 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 done by Kessler et al in 2012, fourteen (28.57%) patients had abscess on theextremities.

TYPE OF ANESTHESIA:

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

GEOGRAPHIC DISTRIBUTION OF PATIENS WITH ABSCESS WHO VISITED BPKIHS:

Fifty eight (55.76%) out of 104 patients in our study were from Sunsari district. This is obvious because the tertiary centre in which the study was conducted is situated in Sunsari district of Nepal.

Failure rates (intervention needed at 48 hours) among the patients receiving packing and non packing following Incision and Drainage of skin and soft tissue abscess:

Forty two (80.8%) patients in the packing group and twenty (38.5%) patients in the non packing group required further follow up at 48 hours assessment (minor intervention). Only one (1.9%) patient in the non packing group required packing of the cavity at 48 hour assessment (major intervention)

None in the packing group required any form of major intervention at 48 hour follow up. So 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 done by Kessler et al in 2012 in which 19(70%) out of 27 subjects in the packed group needed an intervention at 48 hours 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 hours assessment could be because patients in packing group had to visit the health centre 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 ± 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. Though 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 hours of Incision and Drainage was found to be significantly less in the non packing group.

In the study done by O'Malley et al in 2009, there was no significant difference in preprocedure reported pain scores between the packing and the non packing group (difference of means=10.25 mm, 95% CI= -7.5 to 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 to 42 mm, P= 0.014) in the immediate postprocedure period. Subjects in the packing group also reported significantalyy higher average pain scores at 48 hours follow up (difference of means = 16.4 mm,95% CI=1.6 to 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 non packing 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 first week following I & D and not always. None of patients irrespective of their group allocated needed packing of abscess cavity in the second week postprocedure.

In study 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 study 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 comparision to packing of the abscess cavity.Non packing of the abscess cavity significantly decreased pain perceived post Incision & Drainage and improved healing.Non packing 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 centre based study.

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