

Original Research Article

A randomized controlled trial comparing repeated ultrasound guided aspiration versus suction catheter drainage in breast abscess

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ABSTRACT

Background: Among different comorbidities in lactating women, breast abscess is most dreaded and common. It is more prevalent in developing world, etiology implicated to malnutrition, poor hygiene and health conditions. In era of technical advances management of breast abscess has shifted to minimally invasive and painless techniques which are more patient friendly.

Methods: Hospital based randomized controlled trial was conducted at Department of Surgery, and Department of Radiodiagnosis, King Georges Medical University, Lucknow UP.

Results: In our study total 80 patients were analysed, 40 randomized into USG guided needle aspiration group and other 40 into suction catheter placement group. Incidence of breast abscess was higher in lactating group and most common organism was *Staphylococcus aureus*. It was found that majority of women in both groups were lactating and mean age was 30 years. Same degree of fever was experienced in lactating group as in non-lactating. Amount of pain and scar volume was significantly higher in USG guided needle aspiration group.

Conclusions: It seems that two treatment modalities have same effect in terms of fever and residual volume but pain and scar volume was significantly higher in group with USG guided needle aspiraton.

Keywords: Breast abscess, Needle aspiration, Incision and drainage

INTRODUCTION

Breast abscess is most dreaded complication of mastitis more common in lactating mothers. The etiology behind mastitis to convert into breast abscess occurs in the setting of the breastfeeding problems which typically result in prolonged engorgement or poor drainage.¹ The reported incidence of breast abscess in lactation mastitis is 0.4%-11%.^{2,3}

Till date incision and drainage considered to be novel technique for drainage, which increase patients'

morbidity and hospital burden. Breast abscesses can also be treated by repeated needle aspiration with or without ultrasound guidance and percutaneous drain placement.⁴⁻⁶

There is no data available to compare the outcome of breast abscess treatment when using ultrasound guided needle aspiration versus percutaneous drain placement. The aim of this study was to determine whether US-guided needle aspiration against percutaneous placement of drain can be a feasible alternative treatment option for breast abscesses.

METHODS

This study was prospective, non-blinded, randomized controlled trial with two parallel arms: Ultrasound guided needle aspiration versus percutaneous suction drain placement. The study was carried out over the study period of 2 years from August 2014 to September 2016, in Department of General Surgery and Department of Radiodiagnosis, King Georges Medical University, Lucknow, UP, India after getting the ethical clearance.

As per the study design a total of 80 patient of breast abscess (40 in each arm) seeked to the department of General Surgery, KGMU, Lucknow and Outpatient of Department of Obstetrics and Gynecology, KGMU, Lucknow.

The study included all female patients aged 14 and above (lactating and non-lactating) and breast abscess with a diameter of up to a maximum of 5 cm by ultrasound. Patient previously treated with incision and drainage, inflammatory breast cancer, chronic abscesses (defined as an abscess associated with tuberculosis sepsis, lymphangitis osteomyelitis, or cellulitis extending beyond the abscess cavity and surrounding indurations) and noncompliant patients were excluded.

Clinical diagnosis was made based on the presence of breast tenderness swelling, fever and presence of a fluctuant tender breast swelling. Patients diagnosed clinically were subjected to ultrasound scan (high frequency linear transducer of 7.5 MHZ) in the department of Radiodiagnosis KGMU, Lucknow.

The diagnosis was confirmed sonographically by the presence of a thick walled echo complex mass (hypo echoic or anechoic), predominantly cystic with internal echoes and septations. The size of the abscess and volume was estimated. In this study, healing was defined as achieving breast abscess resolution that means clinically no breast tenderness, swelling or wound at the previous site of the abscess and sonographically complete absence of fluid collection, normal breast glandular and fibro-fatty tissue with no edema.

Randomization

The patients were randomized to either USG guided needle aspiration or suction catheter placement arm using computer-generated numbers. The study was done in non-blinding manner however third party auditor was use to assess the overall outcome.

Treatment procedure and follow up

Percutaneous placement of suction catheter

Under aseptic condition, local anesthesia 2% xylocaine was given at the point of insertion and exit of trochar and at 3cm above the palpable margin of abscess. A 14

French trochar of suction drainage was inserted at upper edge and brought out through the cavity, which was connected to the drain (Figure 1). Tube was adjusted as per the size of cavity and connected to drain. Amount of pus was documented and pus culture and sensitivity was send. The drain was fixed by silk 2-0 suture. Daily output was noted and written. A single dose of antibiotic was given with analgesic daily dressing of drain to be advised. If the pus discharge more than 10ml for more than 14 days then it was regarded as failure and open drainage was done.



Figure 1: Percutaneous placement of suction catheter.

Ultrasound guided needle aspiration

Patients under the needle aspiration arm were managed in the Department of Radiodiagnosis Ultrasound room as outpatient cases. Under aseptic condition, a small area of skin adjacent to the abscess was anaesthetized by 1% xylocaine. Aspiration was done under ultrasound guidance using a 16 G needle and a 20 ml syringe. Initial aspirated pus was sent for culture and sensitivity. Aspiration was done until there was no significant residual pus. After the procedure the patient was discharged on antibiotics and analgesics.



Figure 2: USG guided aspiration.

In order to minimize non-compliance to treatment in both arms, drugs were provided by the principal investigator to the patients who could not afford buying the drugs. In both arms, lactating patients were advised to resume breast-feeding on both breasts as soon as possible as.

Follow up

The patient's follow up was done at the OPD by the principal investigator on day 7 and day 14. At every follow up, clinical assessment of symptoms and signs was done to assess resolution of the abscess. Ultrasound scan was done to assess radiological resolution of the abscess. In situation where the abscess persisted in case of ultrasound guided needle aspiration, re-aspiration was done on day 7, if it still persisted after 4 weeks it was considered treatment failure and hence converted to the traditional incision and drainage. Breast abscess recurrence and acceptance were assessed at the last visit (day 14).

Statistical analysis

The results are presented in mean±SD and percentages. The Chi-square test was used to compare the categorical variables between the groups. The normally distributed variables were compared by unpaired t-test between the groups and non-normal variables were compared by Mann-Whitney U test. The $p < 0.05$ was considered significant. All the analysis was carried out on SPSS 16.0 version (Chicago, Inc., USA).

RESULTS

A total of 88 patients with breast abscesses were seen during the study period, of which 80 patients met the

inclusion criteria and consented for the study. Eight patients were excluded due to their abscesses being already draining pus and others having clinical features of immune suppression. Of the 80 patients, 40 patients were randomized into suction drain group and 40 patients into aspiration group. There was no abscess converted to Incision and drainage in the USG guided needle aspiration group.

The median age in each group was 30 years and 90% (72/80) of the patients were lactating.

Majority of the women in both the groups were lactating. There was no significant ($p > 0.05$) difference in the fever between Group 1 (99.58 ± 1.54) and Group 2 (99.08 ± 1.67). The fever was higher among lactating women than non-lactating women. There was significant ($p = 0.02$) higher pain in Group 1 (4.48 ± 1.35) compared to Group 2 (3.50 ± 1.32). The scar volume was present in 77.5% patients in Group 1 and 40% in Group 2 and the difference was statistically significant ($p = 0.001$). There was higher residual volume in Group 1 (22.58 ± 10.65) compared to Group 2 (19.84 ± 14.87), but the difference was statistically not significant ($p > 0.38$).

On culture, the most common isolated pathogen was *Staphylococcus aureus* (76.7%, 61/80). Pain, as per visual analogue scale persisted for longer duration in group I as compared to group II (4.48 ± 1.35 VS 3.50 ± 1.32 , $p = 0.002$). Scar formation was observed in 77.5% (31/40) of the patients in group I in comparison to of 40% (16/40) in group II ($p = 0.001$). In our study we found statistically no significant difference in term of fever, lump and residual volume, but significant difference was seen in pain and scar.

Table 1: Statistical analysis of the two study arms at different variables.

Variables	Group 1 (n=40)	Group 2 (n=40)	P value
Lactating N (%)	n=36 (90%)	n=36 (90%)	1.0
Non lactating N (%)	n=4 (10%)	n=4 (10%)	
Fever	99.58 ± 1.54	99.08 ± 1.67	0.16
Fever	Lactating	99.60 ± 1.58	0.15
	Non lactating	99.47 ± 1.24	0.18
Pain score (VAS)	4.48 ± 1.35	3.5 ± 1.32	0.002
Scar N (%)	Present	16 (40)	0.001
	Absent	9 (22.50)	
Residual volume (ml)	22.58 ± 10.65	19.84 ± 14.87	0.38

DISCUSSION

Treatment of breast abscess traditionally has been incision and drainage however; this has been found to be associated with possible unsatisfactory cosmetic outcome, difficult in breast feeding and needs general anesthesia, prolonged healing time, and regular dressing.⁷

Two minimal invasive technique - repeated aspiration with ultrasound guidance and suction drain placement has been found to be another treatment option for breast abscess and this has been reported to be associated with less recurrence, excellent cosmetic result and has less costs.^{4,6,8} This study was conducted to establish whether ultrasound guided needle aspiration is a feasible

alternative against suction drain placement as treatment option for the breast abscess.

It was observed that 90% (72/80) patients were lactating and 18% (8/80) were non lactating. This is in agreement with Kataria et al, stated that 90% of the patient developed breast abscess during lactation and more common at 32 week of gestation.⁹

The mean pain score on visual analogue scale (VAS) was statistically high in needle aspiration group when compared to suction drain ($p=0.002$) (Mean \pm SD in aspiration group is 4.48 and in suction drain is 3.50) perhaps this was because, the skin was pierced at 2 point in group 1 which was much more wider in 14 french trochar in drain group. Our finding were in similar to previous work done by Tewari et al who observed no pain till 8 day of drain placement.¹⁰

Significant difference was observed in scar formation between group I and group II, 77% (31/40) in group I and 40% (16/40) in group II which was found to statistically significant ($p=0.001$), similarly a recent study by Odiya et al 2016 has concluded that there was no scarring or distortion of breast parenchyma in breast abscess patients treated with percutaneous suction drain placement.¹¹

Residual volume, in both the groups on 14th day was minimal and statistically non-significant (p value=0.38) Mean \pm SD of 22.58 ml patient in suction drain group and Mean \pm SD of 19.84 ml in aspiration group. In case of drain placement on 14th day, maximum number of patients showed no residual volume but 1 patient presented with persistent discharge and turned into incision and drainage. A recent study by Chandika et al was conducted which states that USG guided aspiration is better technique than incision and drainage in terms healing rate, scar, duration of hospital stay with the follow up of 6 days and repeated aspiration was not done. Patient showed complete resolution of abscess cavity on 7th day and repeated Ultrasound guided aspiration done with a success rate of 75% (30/40) with single aspiration.²

In recent study conducted by Wei et al, in which 30 patients studied for negative suction drain placement through a mini periareolar incision for the treatment of lactational breast abscess concluded that, this procedure reduces postoperative hospital stay and increases breastfeeding rates. They observed the patient for 7 days and breast feeding initiated after 24 hour. However similar results was found in our study regarding breast feeding which was more comfortably done by group 1 patients compared to group 2.¹²

CONCLUSION

Concluding this study, it seems clear that the both the treatment modality have same outcome in term of fever

and residual volume, however statistically significant difference was there in pain and scar.

Various clinical features were studied as age, lactation relation to abscess, quadrant of the breast involved, pain, fever, residual volume, scar (nodule, puckering of skin, hyperpigmentation, redness and distortion of breast architecture) and healing rate. Moreover the study was a randomized controlled trial hence elimination of bias was there. Adequate sample size of this study has put forward data for future studies.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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