

A Randomized Control Trial of Percutaneous Ultrasound Guided Needle Aspirations Versus Incision and Drainage for the Management of Breast Abscesses in the Garhwal Region of Uttarakhand

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Abstract

Objectives: This present study was aimed to compare the clinical outcomes of the two treatment modalities: percutaneous ultrasound guided needle aspirations versus incision and drainage in the management of breast abscesses.

Methods: A total of 50 breast abscess patients were enrolled in this study. All the patients were randomized and allocated into 2 groups of 25 patients each. 25 patients in one group were subjected to percutaneous ultrasound guided needle aspiration (Group A) under local anaesthesia and 25 patients in another group to incision and drainage (Group B) under general anaesthesia respectively. A detailed history and clinical examination was done for all the patients and multiple clinical variables were recorded prospectively to evaluate the differences in the clinical outcomes of the two modalities used for the management of breast abscesses.

Results: Majority of patients 27(54%) were in the age group of 21-25 years. 44% of the patients of group A and 36% patients of group B were found to be febrile. Pain and swelling was universally present in both the groups respectively. Axillary lymphadenopathy in group A was present in 12% patients and in group B in 8% patients. Cracked nipples were seen in 24% patients in group A and 12% patients in group B. Breast feeding was abandoned from the diseased breast in only one patient (4%) of Group A due to failure of therapy and in all the patients of Group B. Only one patient (4%) in Group B developed milk fistula, a known complication and two patients (8%) developed recurrent breast abscesses. 23 patients (92%) were satisfied in Group A and 14 patients (56%) were satisfied in Group B.

Conclusions: Ultrasound guided needle aspiration is a safe and cost effective method that does not require hospital admissions, does not require prompt post operative care, does not hamper breast feeding from the diseased breast, gives an excellent cosmetic result and can be done as a day care procedure with a high rate of success. Thus it is a better alternative to surgical incision and drainage for the management of breast abscesses.

Key words: Breast abscess, Needle Aspiration under Ultrasonographic Guidance, Incision and drainage

Introduction

Breast abscess is a common cause of morbidity in women. Mastitis is commonly seen in a lactating woman but the presence in a non-lactating woman should spur evaluation for an inflammatory breast carcinoma, newly onset diabetes, infection with tuberculosis and other idiopathic causes. The possession of breasts carry a psychological impact on the female and hence care should be taken to ensure that its cosmesis is minimally compromised in order to preserve its value and function. Despite of breast abscess becoming less in developed countries due to improved maternal hygiene, nutrition, standard of living and early use of antibiotics, breast abscess remains a problem among the women in the developing countries [1].

Patients commonly present with a painful swelling of the breast and fever. The most commonly implicated organism in a lactational breast abscess is *Staphylococcus aureus* however non-lactational breast abscess typically consist of mixed flora including anaerobes. Diabetes is strongly associated with incidence and clinical outcomes of non-lactational breast abscesses. High-resolution real-time sonography is a unique means for diagnosing and evaluating the extent, site, size and internal characteristics of breast abscesses.

Traditional treatment of breast abscess is by surgical incision and drainage. This strategy often requires general anesthesia, may leave unpleasant scars, requires extensive postoperative care, and interferes with breastfeeding. In addition, 10%–38% of abscesses recur and need additional surgical drainage [2].

Ultrasound guided serial percutaneous needle aspirations of the purulent collections in breast abscesses is a known alternative to the standard treatment - incision and drainage.

There is no need of general anaesthesia or operation, no in-hospital stay and with no requirement of postoperative dressings. There is minimal discomfort after aspiration therapy as compared to that of incision and drainage. There is also a lower occurrence of the troublesome milk fistulae that often follows incision and drainage [3]. Needle aspiration under ultrasound guidance has thus gained popularity due to its lower rates of complications as compared to incision and drainage and better patient satisfaction. The purpose of this study was to compare the two treatment modalities: percutaneous ultrasound guided needle aspirations versus incision and drainage of breast abscesses and assess the differences in their clinical outcomes.

Materials & Methods

The present study was conducted in the department of Surgery, Veer Chandra Singh Garhwali Government Institute of Medical Sciences and Research (VCSGGIMS&R), Srinagar, Garhwal, Uttarakhand, India between March 2020 to September 2023. All the subjects signed an informed consent approved by the institutional ethical committee, VCSGGIMS&R, Uttarakhand. A total of 50 patients of breast abscesses of age group 15 to 45 years were enrolled in this study who visited the outdoor department or were admitted in the surgical wards of the institute.

Randomization was done using a computer generated randomization table. All the patients were divided into two groups of 25 patients each on the basis of the treatment modality given to them. 25 patients in one group were subjected to ultrasound guided aspirations under local anaesthesia (Group A) and 25 patients in another group were subjected to incision and drainage under general anaesthesia (Group B) respectively. A detailed history of all the patients was taken and general physical examination was done. Routine blood investigations

like hemogram, renal function tests, random blood sugar and coagulation profile was done and a primary ultrasound of the breast was done for assessing the abscess size, location, number and loculations (uniloculated and multiloculated). Multiple clinical variables were recorded prospectively to evaluate the clinical outcomes of both treatment modalities for breast abscesses. Characteristic features of breast swelling were noted which included duration, site and nature. Other associated symptoms such as fever and chills were also noted. The procedure of USG guided percutaneous aspiration was well explained to the patients.

After the initial diagnosis by clinical grounds and ultrasound, all the breast abscesses without any skin changes were treated by serial percutaneous ultrasound guided aspirations. Characteristic features of breast abscesses on ultrasound were round, oval or irregular shaped hypo-echoic lesions with a variable acoustic enhancement. Ultrasound guided needle aspiration was performed under local anaesthesia by using an 18-G needle and a 20-ml syringe in each case.

The total amount of pus aspirated was recorded and some of it was sent for culture and sensitivity. These patients were given oral treatment with tablet Amoxicillin clavulanic acid 625mg tds and tablet Diclofenac 50 mg tds for 7 days. Patients in the incision and drainage group were admitted in the surgical wards and prepared for surgery under general anaesthesia in the emergency operation theatre. Post operatively the patients were put on analgesics and antibiotics. Injection Diclofenac sodium 75 mg i.m.tds and injection Amoxicillin Clavulanic acid 1.2gm iv tds was given to them for a maximum of 7 days.

These patients were discharged when comfortable on tablet Diclofenac 50 mg tds and tablet Amoxicillin clavulanic acid 625 mg tds for a total of 7 days. Antibiotics were changed according to the pus culture and sensitivity report. All the patients were followed up regularly and the healing time, scarring, recurrence rate, patients' satisfaction and complications (if any) were noted. In group A, a maximum number of three aspirations were attempted including the follow up period after which, the incision and drainage was done and the patient was labelled as treatment failure. In this study, healing was defined as achieving breast abscess resolution. Breast abscess resolution was defined as clinically no breast tenderness, swelling or erythema at the previous site of abscess and on ultrasound, complete absence of fluid collection and presence of normal glandular and fibro-fatty tissue of the breast without any edema.

Statistical Analysis

Data was analysed with the help of SPSS software. All data was tabulated. Mean \pm standard deviations were observed. p-value was taken less than or equal to 0.05 for significant differences ($p \leq 0.05$).

Results

In this study, we had included a total of 50 patients with age group of 15 to 45 years. Majority of patients 27(54%) were in the age group of 21-25 years. Out of 50 patients, 25 patients were enrolled in the USG guided aspiration group (group A) and 25 patients were enrolled in the incision and drainage group (group B).

Table1: Age wise distribution

| Age (Years) | USG guided aspiration (group A) n=25 | I and D(group B) n=25 | Total |
|-------------|--------------------------------------|-----------------------|--------|
| 15-20 | 01(4%) | 01(4%) | 02(4%) |

| | | | |
|-------|----------|----------|----------|
| 21-25 | 15(60%) | 12(48%) | 27(54%) |
| 26-30 | 04(16%) | 07(28%) | 11(22%) |
| 30-35 | 01(4%) | 01(4%) | 02(4%) |
| 35-45 | 04(16%) | 04(16%) | 08(16%) |
| Total | 25(100%) | 25(100%) | 50(100%) |

44% patients of group A and 36% patients of group B were found to be febrile. Pain and swelling was universally observed in all the patients of both the groups respectively. Axillary lymphadenopathy was seen in 12% patients of group A and 8% patients of group B. Cracked nipples were seen in 24% patients of group A and 12% patients of group B.

Table2: According to symptoms and sign

| | Variables | Group A | Group B |
|-----------------|---------------------------|----------|----------|
| Symptoms | Swelling | 25(100%) | 25(100%) |
| | Pain | 25(100%) | 25(100%) |
| | Fever | 11(44%) | 09(36%) |
| | Breast swelling | 25(100%) | 25(100%) |
| | Erythema | 25(100%) | 25(100%) |
| Sign | Local rise of temperature | 23(92%) | 25(100%) |
| | Tenderness | 23(92%) | 25(100%) |
| | Axillary-lymphadenopathy | 3(12%) | 2(8%) |
| | Cracked nipples | 6(24%) | 3(12%) |

Majority of the patients in group A and in group B had breast abscess diameter of 3 to 5cm (44% and 56% respectively). The mean diameter was 3.6 cm in group A and 4.7cm in group B. Majority of the patients in both the groups drained less than 60ml pus from the abscesses. The least volume of drained pus was 7 ml, seen in a 45 years old non-lactating patient whereas the largest volume of drained pus was 454ml, seen in a 27 years old lactating mother who underwent incision and drainage procedure. It was observed that the average volume of pus was 45.65 ml in the USG guided aspiration group (range 7-152 ml) and 60.34ml (range 10-454 ml) in the incision and drainage group respectively.

Table3: According to size of abscess and volume of pus

| Size of abscess(cm) | Variables | Group A(n=25) | Group B (n=25) |
|--------------------------|-----------|---------------|----------------|
| | <2 | 2(8%) | 1(4%) |
| | 2 to 3 | 7(28%) | 4(16%) |
| | 3 to 5 | 11(44%) | 14(56%) |
| | 5-10 | 3(12%) | 5(20%) |
| | 10-20 | 2(8%) | 1(4%) |
| Volume of pus(ml) | 20 to 40 | 11(44%) | 10(40%) |
| | 41 to 60 | 8(32%) | 8(32%) |
| | 61 to 80 | 4(16%) | 4(16%) |
| | 81 to 100 | 1(4%) | 2(8%) |
| | >100 | 1(4%) | 1(4%) |

Out of total 25 patients treated in the USG guided aspiration group, one patient during treatment developed skin changes over the breast and was treated subsequently by incision and drainage. One patient in this group had bilateral breast tuberculosis and for which the patient was put on anti-tubercular treatment.

Out of total 25 patients treated in incision and drainage group, two patients developed recurrent breast abscess and were managed by repeat incision and drainage. In another two patients, along with incision and drainage, excision biopsy was done which was reported as a case of carcinoma breast on the histopathological report and were subsequently advised modified radical mastectomy for the same, however they were lost to follow up.

Table4: According to treatment outcome in both groups

| Treatment modality | Cured with respective treatment | Recurrence/failure | Excision biopsy | TB |
|-----------------------|---------------------------------|--------------------|-----------------|-------|
| USG guided aspiration | 23(92%) | 1(4%) failure | 0(0%) | 1(4%) |
| Incision drainage | 21(84%) | 2(8%) recurrence | 2(8%) | 0 |

Majority of the patients in the ultrasound guided aspiration group were treated on an outdoor patient department basis whereas only one patient from this group ended up in hospitalization due to treatment failure and underlying causes whereas all the patients in the incision and drainage group required hospital admissions. The mean healing time in the ultrasound guided aspiration group was 1.98 ± 0.45 weeks excluding those patients in this group whose aspiration had failed whereas in the incision and drainage group, the mean healing time was 3.18 ± 0.57 weeks.

Breast feeding was abandoned from the diseased breast in only one patient (4%) in the ultrasound guided aspiration group due to treatment failure and in all the patients of the incision and drainage group however they were advised frequent milk emptying from the diseased breast. One patient(4%) in incision and drainage group developed milk fistula, a known complication whereas two patients (8%) developed recurrent breast abscesses.

23(92%) patients were satisfied in ultrasound guided aspiration and 14(56%) patients were satisfied in the incision and drainage procedure respectively.

Table5: According to Response to treatment

| Outcome | USG Aspiration | Incision and Drainage | p-value |
|---|-----------------|-----------------------|---------|
| Healing time (weeks) | 1.98 ± 0.45 | 3.18 ± 0.57 | 0.000 |
| OPD/IPD | 24/1 | 0/25 | 0.000 |
| Recurrent abscess | 00 | 2(8%) | 0.000 |
| Breast feeding cessation from diseased breast | 1(4%) | 25(100%) | 0.000 |
| Milk fistula | 00 | 1(4%) | 0.000 |
| Satisfaction | 23(92%) | 14(56%) | 0.004 |

Discussions

Breast abscess is a rare complication of mastitis especially when the treatment is either inadequate or delayed [4]. This condition poses a significant stress to the woman. Whether the abscess is lactational or non-lactational, traditional treatment has been an incision and drainage procedure, but this results in more hospital admissions, raised expenses, need for general anaesthesia, possible unsatisfactory cosmetic outcomes due to scarring, hampers

breast feeding from the diseased breast, prolongs the healing time and needs a prompt post operative care including regular dressings[5].

In the present study, a total of 50 patients with breast abscesses were enrolled which were randomized in two groups of 25 patients each, on the basis of treatment modality given to them. Group A consisted of 25 patients who were subjected to percutaneous ultrasound guided needle aspirations under local anaesthesia and Group B consisted of 25 patients who were subjected to incision and drainage procedure under general anaesthesia. The mean age was 24.86 ± 7.13 in group A and 26.98 ± 8.76 years in group B. Francisco et al Dieter et al [6] also observed similar findings in their study. In this study, swelling, pain over the swelling and local rise of temperature was universally seen in all the patients of breast abscesses in both the groups respectively. 44% patients of group A and 36% patients of group B were found to be febrile. Schwarz et al [7] and Faisal Elagili et al [8] also observed similar signs and symptoms in their study.

The possibility of using ultrasound guided percutaneous aspirations has emerged as a valid alternative to surgical drainage. Karstrup et al [9] first reported the successful use of this technique in 1990, soon followed by other investigators. More recently, Imperiale et al [10] resurrected the local instillation of antibiotics (40–160 mg of gentamicin) after ultrasound guided percutaneous aspirations in 26 patients with non-lactational abscesses in whom systemic antibiotics had failed, with only one failure requiring surgical drainage.

O'Hara et al [11] reported a cure rate of 85% in 22 abscesses, some of them aspirated without ultrasound guidance. Schwarz and Shrestha [12] also reported aspiration without ultrasound guidance plus oral antibiotics in 33 abscesses, with a cure rate of 82%. Their success rate statistically correlated with a mean volume of 4.6 ml pus at the first aspirate compared with failure in abscesses with a mean volume of 21.5 ml pus respectively. Hook and Ikeda [13] reported a 54% cure rate of 13 breast abscesses treated by aspiration and irrigation. The patients in whom treatment failed had an abscess of more than 3 cm in diameter. Dixon [14] however, reported successful aspiration of six lactating abscesses with a mean volume of 26 ml pus.

In the present study, the mean diameter of the abscess as determined clinically was 3.6 cm in group A and 4.7 cm in group B respectively. Similar findings were also observed by A F Christensen et al [15] (3.5 cm), Faisal et al [16] (4 cm) and Alphonse et al [17] (3.49 cm) in their study. In the present study, it was seen that the mean pus volume in group A (range 7-152ml) was 45.65 ml whereas it was 60.34 ml in group B (range 10-454ml). Dixon et al [18] reported successful treatment of breast abscesses by aspiration with mean pus volume of 26ml (range 15-40ml). In the study of Francisco et al [19], the mean volume of the aspirate at the initial aspiration was 28ml (range 1 to 225 ml). Faisal et al [16] observed the mean pus volume at the initial aspiration as 14 ml (range 1- 200ml) in their study. Among the ultrasound guided aspiration patients, the cure rate was 88.57% whereas patients managed by incision and drainage procedure had a cure rate of 93.44%. In the present study, cure rate in ultrasound guided aspiration group was 92% and that in the incision and drainage group was 84%.

O'Hara et al [11] reported an 85% cure rate, some of them aspirated without ultrasound guidance. Garg et al [20] reported a success rate of 84% in their study. Faisal Elagili et al [16] reported a success rate of 83.3% with ultrasound guided aspiration of breast abscesses. Alphonse et al [17] observed a cure rate of 93.1% by ultrasound guided aspirations. Out of 25

patients managed by incision and drainage, two patients(8%) developed recurrent breast abscess within four months of primary surgery. This was consistent with the findings of Srauss et al [22]. The mean healing time in the ultrasound guided aspiration group was 1.98 ± 0.45 weeks while that in the incision and drainage group was 3.18 ± 0.57 weeks which correlates with the study of Markus et al [21]. One patient(4%) in the incision and drainage group had developed milk fistula which correlates with the study by Dr.Saira Saleem et al [23]. Milk fistula healed spontaneously after the cessation of breast feeding in this patient however there was no milk fistula noted in the ultrasound guided aspiration group. In the present study, 96% patients continued breast feeding in the ultrasound guided aspiration group whereas breast feeding was abandoned from the diseased breast in all the lactating females of the incision and drainage group which correlates with the study of Dr.Saira Saleem et al [23]. Satisfaction rate in the patients treated by ultrasound guided aspiration group was 92 % and that in the incision and drainage group was 56% and these findings were in correlation with the study of Dieter et al [6] and Dr.Saira Saleem et al [23]. Cosmetic results in the incision and drainage group were unsatisfactory whereas the cosmesis in the patients in the ultrasound guided aspiration group was found to be excellent.

There are a number of benefits for the patients of breast abscesses who are treated by ultrasound guided needle aspirations as compared to those who are treated by incision and drainage methods. In patients treated by percutaneous ultrasound guided aspirations, there is no need for general anaesthesia or operation, no in-hospital stay, no requirement for prompt postoperative dressings, no prolonged healing time, no possible unsatisfactory cosmetic outcomes due to scarring and overall lesser cost in comparison to those who are treated with incision and drainage methods. The discomfort after aspiration therapy is also lesser as compared to that by incision and drainage. There is also a lower occurrence of the troublesome milk fistulae that often follows incision and drainage procedures. Aspiration therapy does not hamper lactation from the diseased breast unlike incision and drainage procedures. With the increasing concerns for the need of a cost-effective treatment worldwide, the savings following aspiration therapy are considerable, as surgery is eliminated and no postoperative care is needed.

Conclusions

The present study concluded that percutaneous needle aspirations under ultrasound guidance is a safe and effective method that does not require hospital admissions, does not require prompt post operative care, does not hamper breast feeding from the diseased breast, gives an excellent cosmetic result, and can be done as a day care procedure with a high rate of success. Thus it is a better alternative to surgical incision and drainage for the management of breast abscesses.

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