

Comparison of surgery and surgery plus corticosteroid therapy in idiopathic granulomatous mastitis, prospective randomized study

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Abstract

Aim: To compare therapeutic effectiveness of surgery alone with surgery plus corticosteroid in patients with granulomatous mastitis.

Material and Methods: The study included 30 patients aged 23-60 years. The patients were randomly assigned into two groups by lot. In-group 1, the patients received 375 mg ampicillin-sulbactam (twice daily, p.o.) for a week; than 32 mg prednisolone was started which was gradually tapered (biweekly by 8 mg) over 8 weeks. Surgery was performed 2 weeks after tapering. In-group 2, the patients received 375 mg ampicillin-sulbactam (twice daily, p.o.) for a week and underwent surgery. During 2-years follow-up, all patients were assessed for etiological factors and recurrence.

Results: No significant differences was found in demographic characteristics, smoking habits, oral contraceptive use, presenting complaints, physical examination findings, localization and diagnostic tools used between groups. During follow-up, recurrence was seen in one patient (6.7%) in surgery group and in 3 patients (20%) in steroid group but no significant difference was detected between groups ($p>0.05$).

Conclusion: In patients with granulomatous mastitis, systemic steroid therapy is an effective modality in patients unresponsive to antibiotic therapy after ruling out tuberculosis.

Keywords: Granulomatous mastitis; steroid therapy; surgical treatment; recurrence

INTRODUCTION

Idiopathic granulomatous mastitis (IGM) is a rare, chronic, inflammatory disease of breast. It was first defined by Kessler and Wolloch in 1972 (1,2). The granulomatous mastitis (GM) is generally seen in middle-age women (third and fourth decades) at reproductive age and it manifests as unilateral, isolated mass lesion with skin lesions suggesting inflammatory carcinoma within a few years after delivery (3-6). The IGM accounts for 24% of all inflammatory disorders of breast. The annual incidence has been reported as 2.4: 100,000 women. Although its prevalence is not fully known in Turkey, it is thought that prevalence rate is higher than USA. Although IGM is a

benign disease, it mimics breast cancer both clinically and radiologically (3,4,7). The IGM etiology has not been fully elucidated (8). However, many factors such as autoimmune disorders, hormonal derangements, trauma or local immune response, local irritants, undiscovered organisms, viruses, hyperprolactinemia, diabetes mellitus, alpha-1-antitrypsin deficiency, smoking, ductal ectasia and oral contraceptive use have been implicated in the etiology (8,9). In addition, sarcoidosis, tuberculosis, foreign body and *Corynebacterium* infections were also implied in the etiology of IGM (3-5,10,11). Moreover, pregnancy, lactation, hyperprolactinemia associated with galactorrhea is other factors proposed in the etiology. However, previous studies showed that only one-third of

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patients had history of oral contraceptive use. In addition, no relationship with pregnancy was reported in some cases (12). The IGM is generally seen in one breast but it may involve all quadrants. It is extremely rare at subareolar region. Both breasts can be involved with equal frequency and it may be bilateral in 25% of cases (6). Clinically, it presents with painful or painless mass lesion in one breast, large induration, discoloration, discharge from fistulas that frequently seen in chronic cases, abscess and ulceration. Mass formation mimicking cancer may cause deformation, nipple retraction and nipple discharge (2,13,14). In the IGM, treatment is controversial and there is no universally accepted treatment strategy. Antibiotics, local and systemic corticosteroids are most commonly used agents in medical treatment. In addition, successful outcomes were reported with methotrexate, azathioprine, glucocorticoid, bromocriptine and colchicines (15-17). The surgical treatment includes abscess drainage, local and wide excisions and mastectomy (18-22). Better outcomes have been reported by adding steroid to surgical therapy (20-23). In the IGM, recurrence can be seen despite wide surgical excision and medical treatment. In the literature, recurrence rate has been reported as 5-50% in different studies (13-15). Here, we aimed to compare therapeutic effectiveness of surgery and surgery plus steroid combination in the treatment of IGM, a challenging disease that is frequently seen in our country; progresses to chronic disorder due to insufficient diagnostic and therapeutic options; impairs quality of life; is complicated secondarily by biopsies. We attempted to establish an algorithm for diagnosis and management. This is the first prospective, randomized study in this field.

MATERIAL and METHODS

In this study, we evaluated data from 60 patients who presented to General Surgery Breast and Endocrine Disorders outpatient clinics of Erciyes University, Medicine School after 26-months follow-up. The study was approved by the ethics committee of Erciyes University Faculty of Medicine (Date; 30.04.2014 No; 96681246/133). Informed consent form was obtained from patients included in the study. Screening studies for specific etiology was performed after ruling out simple mastitis in 30 patients presented to General Surgery Breast and Endocrine Disorders outpatient clinics with mastitis. Among 60 patients screened, 30 patients (aged 23-63 years) who were diagnosed as GM and had complete radiological studies at time of diagnosis and follow-up data were included to the study. In all patients, breast sonography, breast magnetic resonance imaging (MRI) and mammography were performed following physical examination. In the biopsy samples, IGM was diagnosed by histological evaluation including Hematoxylin-Eosin, Ziehl-Neelsen and Periodic Acid Schiff (PAS) staining. Gram staining and culture studies were performed in all samples. The patients were consulted to Chest department regarding tuberculosis. The patients were randomly assigned into either surgery or surgery plus steroid groups by lot. The data were prospectively retrieved from patient files. The

patients with missing data during follow-up, patients with incompletion to treatment, those not attending to follow-up visits, those not requiring surgery, patients aged <18 years or >65 years, and those without definitive diagnosis were excluded. In the steroid plus surgery group, the patients received 375 mg ampicillin-sulbactam (twice daily, p.o.) for a week; than 32 mg prednisolone (Prednol ®; Mustafa Nevzat) was started which was gradually tapered (biweekly by 8 mg) over 8 weeks. Surgery was performed 2 weeks after tapering. In the surgery group, the patients received 375 mg ampicillin-sulbactam (twice daily, p.o.) for a week and underwent surgery. During follow-up, physical examination and sonography were performed by 3-month interval while MRI studies were performed by 6-month interval. The mammography was performed when indicated. After 2-years follow-up, patients were assessed regarding patient satisfaction and etiological factors.

Statistical analysis

Statistical Package for the Social Sciences (SPSS 21 Inc., Chicago, IL, USA) computer software was used for statistical analyses. Mean values were given with standard deviation and median values were given with minimum-maximum values. Student t test, analysis of variance, Chi square test were used for statistical analysis.

RESULTS

The study was conducted by reviewing data from 30 women (aged 23-63 years) who were diagnosed as GM and underwent surgery following medical treatment. Mean follow-up was 25.6 months. Mean age was 35.5±13.6 years in surgery group whereas 34.7±10.3 years in steroid plus surgery group, indicating no significant difference ($t=0.182$; $p>0.05$). When residence was assessed, it was found that 4 patients (26.7%) in the surgery group and 2 patients (13.3%) in the steroid plus surgery group were living in rural areas, indicating no significant difference ($t=0.361$; $p<0.05$). When education level was assessed, it was found that 11 patients (73.3%) in surgery group and 12 patients (80.0%) in steroid plus surgery group were graduated from primary or secondary school, indicating no significant difference ($t=0.952$; $p>0.05$). It was seen that there were six active smokers (40.0%) in surgery group whereas four active smoker (26.7%) in steroid plus surgery group, indicating no significant difference ($t=0.439$; $p>0.05$). No significant difference was found between groups regarding presenting complaints including mass, pain, discharge or erythema ($p>0.05$; Table 1).

Table 1. Application complaints of patients

| | Surgery | | Steroid | | X ² | p |
|-----------|---------|------|---------|------|----------------|-------|
| | Patient | % | Patient | % | | |
| Mass | 11 | 73.3 | 8 | 53.3 | 1.292 | 0.256 |
| Pain | 9 | 60.0 | 13 | 86.7 | 2.727 | 0.099 |
| Discharge | 1 | 6.7 | 0.0 | 0.0 | 1.034 | 0.309 |
| Erythema | 1 | 6.7 | 2 | 13.3 | 0.37 | 0.543 |

No significant difference was found between groups regarding physical findings including palpable mass lesion, abscess and fluctuation, skin fistula or axillary lymph nodes ($p>0.05$) (Table 2). Bilateral mastitis was seen in one patient (6.7%) in the surgery group while no bilateral involvement was observed in surgery plus steroid group. The most common localization was found to be superior outer quadrant. Right superior lateral quadrant involvement was observed in 4 patients (26.7%) in each group while left superior lateral quadrant involvement was observed in 2 patients (13.3%) from surgery group and 5 patients (33.3%) from surgery plus steroid group. No significant difference was detected between groups ($p>0.05$) (Table3).

Table 2. Physical examination findings of patients

| | Surgery | | Steroid | | X ² | p |
|------------|---------|------|---------|------|----------------|-------|
| | Patient | % | Patient | % | | |
| Mass | 11 | 73.3 | 11 | 73.3 | 0.0 | 1 |
| Abscess | 6 | 40.0 | 6 | 40.0 | 0.0 | 1 |
| Fistula | 2 | 13.3 | 1 | 6.7 | 0.37 | 0.543 |
| Lymph node | 0 | 0.0 | 1 | 6.7 | 1.034 | 0.309 |

There were history of oral contraceptive use in 3 patients (20.0%) in surgery group and in one patient (6.7%) in surgery plus steroid group, indication no significant difference ($t=0.283$; $p>0.05$). During diagnostic workshop, breast sonography and MRI study was performed in all patients while mammography was performed based on patient's age. All patients were consulted to Chest department for tuberculosis. During follow-up, recurrence was detected in one patient (6.7%) in surgery group whereas in 3 patients (20%) in surgery plus steroid group, indicating no significant difference between groups ($t=0.283$; $p>0.05$). In surgery group, the recurrence was observed in same breast on month 5, which manifested as fistula formation. The patient received antibiotic therapy without need for re-operation. In surgery plus steroid group, recurrence was observed in the same breast in 3 patients on months 7, 9 and 10, respectively. The recurrence manifested as fistula formation and pain in 2 patients whereas induration and erythema in the other patient. These patients also received antibiotic therapy. When biopsy techniques were assessed, it was found that the diagnosis was made by fine-needle biopsy in 5 patients (33.3%) from surgery group and in 3 patients (20.0%) from surgery plus steroid

Table 3. Lesion localization

| | Surgery | | Steroid | | X ² | p |
|----------------|---------|------|---------|------|----------------|-------|
| | Patient | % | Patient | % | | |
| Right superior | 4 | 26.7 | 4 | 26.7 | 0.0 | 1 |
| Left superior | 2 | 13.3 | 5 | 33.3 | 1.677 | 0.195 |
| Right inferior | 3 | 20.0 | 1 | 6.7 | 1.154 | 0.283 |
| Left inferior | 1 | 6.7 | 3 | 20.0 | 1.154 | 0.283 |
| Central | 4 | 26.7 | 3 | 20.0 | 0.186 | 0.666 |
| Multiple | 1 | 6.7 | 0 | 0.0 | 1.034 | 0.309 |

group ($t=0.409$; $p>0.05$). True-cut biopsy was used for diagnosis in 10 patients (66.7%) in the surgery group whereas in 11 patients (73.3%) in the surgery plus steroid group ($t=0.690$; $p>0.05$). No significant difference was found between groups. Moreover, excisional biopsy was used in 2 patients from surgery group and 4 patients from surgery plus steroid group ($t=0.361$; $p>0.05$).

DISCUSSION

The IGM is a rare, inflammatory disease of breast with unclear etiology. Despite many studies on clinical and radiological findings and treatment modalities in the IGM, there is no established diagnostic and therapeutic protocol. In patient's perspective, the disease appears as a multi-factorial disorder where recurrences mimic breast cancer. The clinicians and patients deal with a challenging situation due to lack of established diagnostic and therapeutic algorithm and questions about departments that will involve in the management

of the disease requiring long-term follow-up. The quality of life is negatively affected in the patients, making its management more challenging.

In the literature, there is increasing number of studies about IGM, suggesting an increase in the number of IGM cases. In our study, the fact that 60 patients were included to the study during 10-months period favors that either IGM is underestimated in our country or there is an increase in the IGM incidence. In our study, we reviewed data from 60 women (aged 23-63 years) who were diagnosed as IGM. Mean follow-up was found as 25.6 months. Mean age was 35.5 years in the surgery group whereas 34.7 years in the surgery plus steroid group. Moreover, mean age was 35.1 years in the study population. Together with literature data, it is seen that IGM is mainly seen during decades 3 and 4 among women at reproductive age. When etiological factors were assessed, it was found that overall 6 patients (25%; 4 patients in surgery and 2 patients in surgery plus steroid

group) were living in rural areas. This finding suggests that residence may have role in etiology, which must be supported by further studies. When educational level was assessed, it was found that overall 23 patients (11 patients in surgery and 12 patients in surgery plus steroid group) had primary or secondary school degree. Although there is no data on educational level in the literature, the finding of 76% of patients had primary or secondary school degree suggests that educational level and sociocultural status may be involved in the etiology. Bani-Hani et al. (6) emphasized that largest series in granulomatous mastitis were reported from developing countries. Future studies may provide more comprehensive data about role of ethnicity and sociocultural status in etiology and epidemiology of IGM. Presence of birth and lactation history in all patients without significance difference between groups supports that birth and lactation have no role in the etiology. Smoking, one of the factors implied in the etiology, was noted in 6 patients in the surgery and 4 patients in the surgery plus steroid group. Although there was no significant difference between groups, smoking rate up to 33% suggest that it may have role in the etiology. In a study, Al-Khaffaf et al. (8) found no relationship with smoking. In our clinic, culture tests are routinely performed in patients diagnosed as IGM and the antibiotic therapy is implemented after obtaining culture tests. No pathogen could be isolated in patients included. The fact that disease control could be achieved in some patients excluded; that patients in our study received antibiotic therapy; and that spontaneous regression was reported in some patients in the literature suggests that inflammation caused by microorganisms can play role in the etiology although it could not be shown. In our study population, there was history of oral contraceptive use in 3 patients (10%; 2 patients in surgery and one patient in surgery plus steroid group. Rate of oral contraceptive use was reported as 19.1% by Parlakgümüş et al.(25) and 13.5% by Akcan et al.(26) On contrary to literature, it was found that history of oral contraceptive use was insignificant. Given that oral contraceptive use may show individual hormonal effects, this issue must be addressed more objectively by quantifying hormone levels. Among patients included, there was diabetes mellitus in 2, eczema in one and hypertension in one patients from surgery group whereas diabetes mellitus in one, hypertension in 2, ankylosing spondylitis in one and depression in one patient from surgery plus steroid group. Based on these data, no significant effect of comorbid disorders was found on IGM. We think that results similar to literature will be obtained by increasing number of patient. We think that stress and smoking are important factor in the etiology; however, further studies are needed. When presenting complaints were assessed, it was found that 22 patients (72.6 %); 9 patients from surgery group and 13 patients from surgery plus steroid group presented with pain whereas 19 patients (62.7 %); 11 patients from surgery group and 8 patients from surgery group) presented with palpable mass lesion. The pain and mass lesion were most common presenting complaints. Other presenting

complaints included discharge and fistula, which were seen in 3 patients (one patient from surgery and 2 patients from surgery plus steroid groups. In their study, Mızraklı et al.(27) reported that there was pain 77.6%, erythema 75.5%, wound/discharge (fistula) in 67.3% of patients as presenting complaint while Akcan et al.(26) reported palpable mass lesion in 57.1%, pain in 33.3% of patients. In a study by Parlakgümüş et al.(25), it was reported that presenting complaints included palpable mass lesion in breast 80%, erythema and edema in 29.6% and purulent discharge or fistula formation in 25.4% of patients. In our study, it was found that pain and mass were most common presenting complaints in agreement with literature. The finding that there was fear or suspicion of breast cancer at time of presentation in patients with mass and pain suggests that there is an increasing awareness about breast cancer in Turkish population, allowing early diagnosis of IGM. It is though that early diagnosis led a decrease in patients with fistula development. When physical findings were assessed, it was seen that there was palpable mass in 22 patients (73.3%) 11 patients in each group). Abscess and fluctuation was detected in 12 patients (40%) whereas skin fistula in 3 patients (10%; 2 patients from surgery and one patient from surgery plus steroid groups) during physical examination and axillary lymph node involvement in one patient (6.7%). Akcan et al.(26) reported palpable mass in 60, skin edema and inflammation in 21.5%, axillary lymph node involvement in 13.4% and skin fistula in 9.4% of patients. Moreover, Parlakgümüş et al.(25) reported palpable mass in 80%, skin edema and inflammation in 29.6%, skin fistula in 25.4% and axillary lymph node involvement in 31.8% while Korkut et al.(28) palpable mass in 100% and axillary lymph node involvement in 13% of patients. In our study, the most common physical finding was palpable mass in agreement with literature. One should obtain thorough history and aim to establish diagnosis by physical examination findings and imaging studies. Concerns regarding pain and mass should be clarified as soon as possible. It is important that stress is a trigger in this disease. When lesion localization was assessed, it was found that the lesion was localized to right superior quadrant in 8 patients (26.7%), left superior quadrant in 7 patients (23.3%), right inferior quadrant in 4 patients (13.3), left inferior quadrant in 4 patients (13.3%) in multiple quadrants in one patient (3.3%). In addition, central localization was observed in 7 patients (23.3%). In the literature Akcan et al.(26) reported left breast localization in 62% of patients and Korkut et al.(28) reported equal involvement for right and left breasts. The most common localization was reported as right breast (62%), by Parlakgümüş et al.(25) and left superior quadrant (28%) it could be suggested that the disease is most frequently seen superior lateral quadrant which is most closer quadrant with most intensive breast tissue. In our study, bilateral involvement was seen in only one patient (3.3%). Although imaging modalities are important since lesions mimic breast cancer and radiological findings are non-specific, definitive diagnosis is made histopathological examination. It was concluded there is no specific finding

on imaging studies, which allows diagnosis of GM. When study population was assessed regarding biopsy techniques for histopathological diagnosis, it was found that the diagnosis was made by fine-needle aspiration biopsy in 8 patients (26.6%), by true-cut biopsy in 21 patients (69.9%) and by excisional biopsy in 6 patients (20.0%). In the literature, Al-Jarrah A et al. (29) recommended core-needle biopsy or excisional biopsy rather than fine-needle biopsy for diagnosis. In addition, Öztürk et al. (30) reported that diagnosis was made by excisional biopsy in all patients while Akcan et al. (26) reported that core-needle biopsy or excisional biopsy and fine-needle biopsy were made in 50% of patients for each. Parlakgümüş et al. (25) reported core-needle biopsy in 61.7% of patients. True-cut biopsy provides more definitive results than fine-needle aspiration biopsy since is a cytological method. Percutaneous biopsy should be performed rather than excisional biopsy whenever possible since it is a less invasive method. The treatment of granulomatous mastitis is unclear without an established treatment protocol. Recurrence was detected in 5 patients (one patient in surgery group and 4 patients in surgery plus steroid group during 25.6 months of follow-up. Overall 8 weeks of steroid therapy was given to the patient; initial dose of 32 mg for 2 weeks; followed by 24 mg for 2 weeks, 16 mg for 2 weeks and 8 mg for 2 weeks. It was seen that lesion size was decreased at the end of 8 weeks. In the literature, Lai et al. (19) reported that spontaneous regression is possible in GM patients with mild clinical findings even with clinical follow-up and that oral prednisolone therapy should be preserved to patients with severe clinical findings. Kim et al. (22) proposed that immunosuppressive agents such as methotrexate or azathioprine in refractory cases despite limited response with other supporting studies. Asoğlu et al. (21) reported that wide local excision or even mastectomy can be used in cases unresponsive to medical treatment in the presence of clinical findings such as recurrent abscess or fistula. Akcan et al. (26) reported recurrence rate as 9.5%. In addition same author's recurrence rate as 5.4% in patients underwent surgery alone. In a study on 33 patients, Erözgen et al. (31) reported that steroid therapy (0.5 mg/kg/day) was given with gradual tapering, achieving long-term disease free period. It is major obstacle that there is no routine dose or algorithm in this disease that is attempted to be treated with several doses and combined methods. Lai et al. (19) recommend that strict monitoring can be a treatment model since granulomatous lobular mastitis is a self-limiting disease.

CONCLUSION

This is the first randomized study in GM. The fact that there were some patients who showed spontaneous regression by antibiotic therapy alone or steroid therapy alone emphasized importance of medical therapy. Decreased size of mass lesion in patients with large mass and better cosmetic outcomes with surgery indicated value of steroid and surgical therapy.

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