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Original Article / Özgün Araştırma

Cabergoline and Low-Dose Steroid Therapy İn Idiopathic Granulomatous Mastitis

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Abstract

Introduction: Idiopathic granulomatous mastitis(IGM) is a rare, chronic granulomatous inflammatory disease of the breast. It is mostly seen in young women with a history of breastfeeding. It typically presents as a painful lump in the breast, erythema, focal abscess formation, skin ulceration, or fistula. The etiology and pathogenesis of IGM could not yet be well understood. It is thought to be caused by a localized autoimmune response against fat and protein-rich secretions leaking from the lobules due to previous hyperprolactinemia. There is no definite treatment protocol defined for IGM. Pharmacological agents and surgical interventions are used alone or in combination in the treatment. In this study, we aimed to examine the results of patients who were treated with cabergoline and low-dose steroids for IGM in our center.

Methods: In this study, the files of patients who were treated with cabergoline and steroids for idiopathic granulomatous mastitis in our clinic were reviewed retrospectively. 36 patients were included in the study. The patients were invited to the outpatient clinic for the final examination. Demographic characteristics of the patients, symptoms at presentation, examination findings, laboratory tests, radiological imaging, tru-cut biopsy results, microbiological culture results, treatment doses and durations, remission times, surgery requirements, and recurrence were recorded.

Results: All 36 patients included in the study were women of childbearing age. The most common presenting complaint was a palpable painful mass. Abscesses were present in 12 patients. Ulcers were observed in 9 patients and fistulas were observed in 4 patients. The most common involvement was in the lower outer quadrant. S.aureus was detected in the culture of 1 patient. Complete recovery was observed in 20 of 36 patients as a result of the treatment. The mean duration of remission was 2.85±2.54 months. The treatment of 29 (74.3%) patients was completed medically. Surgical excision was performed in 7 patients with a residual lump. No recurrence was observed during the follow-up period of 27.88 ± 8.21 months.

Conclusion: The treatment of IGM is still controversial. The fact that cabergoline and low-dose steroid therapy provides remission in a short time, minimizes the need for surgery, and does not relapse in medium-term follow-up shows that it is a successful option in IGM treatment.

Keyword: Idiopathic granulomatous mastitis, cabergoline, steroid

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İdiyopatik Granülomatöz Mastitte Kabergolin ve Düşük Doz Steroid Tedavisi

Öz

Giriş: İdiyopatik granülomatöz mastit (IGM), memenin nadir görülen, kronik granülomatöz enflamatuar bir hastalığıdır. Daha çok emzirme öyküsü olan genç kadınlarda görülür. Tipik olarak memede ağrılı bir şişlik, eritem, fokal apse oluşumu, cilt ülserasyonu veya fistül şeklinde kendini gösterir. İGM'nin etiyolojisi ve patogenezi henüz tam olarak anlaşılamamıştır. Daha önceki hiperprolaktinemi nedeniyle lobüllerden sızan yağ ve proteinden zengin sekresyonlara karşı lokalize bir otoimmün yanıtın neden olduğu düşünülmektedir. İGM için tanımlanmış kesin bir tedavi protokolü bulunmamaktadır. Tedavide farmakolojik ajanlar ve cerrahi girişimler tek başına ya da kombinasyon halinde kullanılmaktadır. Bu çalışmada merkezimizde İGM nedeniyle kabergolin ve düşük doz steroid tedavisi uygulanan hastaların sonuçlarını incelemeyi amaçladık.

Yöntemler: Bu çalışmada kliniğimizde idiyopatik granülomatöz mastit nedeniyle kabergolin ve steroid tedavisi uygulanan hastaların dosyaları retrospektif olarak incelendi. Çalışmaya 36 hasta dahil edildi. Hastalar son muayene için polikliniğe çağrıldı. Hastaların demografik özellikleri, başvuru semptomları, muayene bulguları, laboratuvar testleri, radyolojik görüntüleme, tru-cut biyopsi sonuçları, mikrobiyolojik kültür sonuçları, tedavi dozları ve süreleri, remisyon süreleri, cerrahi gereksinimleri ve nüks durumları kaydedildi.

Bulgular: Çalışmaya dahil edilen 36 hastanın tümü doğurganlık çağındaki kadınlardı. En sık başvuru şikayeti ele gelen ağrılı kitle idi. 12 hastada apse mevcuttu. 9 hastada ülser, 4 hastada fistül görüldü. En sık tutulum alt dış kadrandaydı. 1 hastanın kültüründe S. aureus üremesi oldu. Tedavi sonucunda 36 hastanın 20'sinde tam iyileşme gözlendi. Ortalama remisyon süresi 2,85±2,54 ay idi. 29 (%74,3) hastanın tedavisi medikal olarak tamamlandı. Rezidüel odak kalan 7 hastaya cerrahi eksizyon uygulandı. 27,88±8,21 aylık takip süresinde nüks gözlenmedi.

Sonuç: İGM tedavisi halen tartışmalıdır. Kabergolin ve düşük doz steroid tedavisinin kısa sürede remisyon sağlaması, cerrahi gereksinimi en aza indirmesi ve orta süreli takipte nüks gözlenmemesi IGM tedavisinde başarılı bir seçenek olduğunu göstermektedir.

Anahtar kelimeler: İdiyopatik granülomatöz mastit, kabergolin, steroid.

INTRODUCTION

Idiopathic granulomatous mastitis (IGM) is a rare, chronic granulomatous inflammatory disease of the breast. It was first described by Kessler and Wolloch in 1972[1]. It constitutes 1.8% of benign breast diseases[2]. It is mostly seen in a parous woman, which has a story of breastfeeding[3].

The disease often begins as bacterial mastitis. It is a chronic inflammatory condition following abscess and sinus formation. It typically presents as a painful or painless lump in the breast, erythema, focal abscess formation, ulceration or fistula on the skin[2,4].

The disease is characterized by a local invasive course and high recurrence. The ratio of recurrence is reported between 5%to 50%[2,5,6]. IGM often mimics carcinoma of the breast clinically and radiologically[3,7]. The definitive diagnosis is made by tissue biopsy.

The etiology and pathogenesis of IGM could not yet be well understood. It is accepted as idiopathic. It is thought to be caused by a localized autoimmune response against fat and protein-rich secretions leaking from the lobules due to previous hyperprolactinemia[2,8]. Tuberculosis, sarcoidosis, polyarteritis nodosa, pregnancy history, breast trauma, hyperprolactinemia, autoimmune diseases, infective causes, alpha 1 antitrypsin deficiency, and oral contraceptive use are other causes thought to be associated with the disease9. Among infective causes, corynebacterium kroppenstedtii is the pathogen most commonly associated with granulomatosis mastitis[10]. But not proven. Bacterial culture and histochemical staining results are usually negative[11].

It has been reported that lactation change due to hyperprolactinemia increases the risk of granulomatous mastitis[12]. In the literature, drug-induced hyperprolactinemia and pituitary prolactinoma-associated granulomatous mastitis cases have been reported[13,14].

IGM is characterized by non-caseified granulomatous lobulitis. In hİstopathology, granulomas consisting of epithelioid histiocytes, langhans giant cells accompanied by lymphocytes, plasma cells, and rarely eosinophils are found in and around the lobules. These findings support the theory of cell-mediated reaction of lobular cells to one or more substances in mammary secretions[15,16].

There is no definite treatment protocol defined for IGM. Antibiotics, immunosuppressive agents, steroids, and surgical excision options are used alone or in combination in the treatment.

Cabergoline is an ergot derivative, a potent dopamine receptor agonist used in the treatment of hyperprolactinemia-related diseases such as prolactinomas, lactation suppression, amenorrhoea, oligomenorrhea, anovulation, extra-postpartum mastitis, and galactorrhea.

In this study, we aimed to examine the follow-up and treatment results of patients who were treated with cabergoline and low-dose steroids for IGM in our center.

METHODS

The files of patients who were treated for idiopathic granulomatous mastitis in our clinic between January 2020 and December 2021 were reviewed retrospectively. The patients whose diagnosis of granulomatous mastitis was confirmed by tru-cut biopsy were included in the study. Patients with a history of malignancy, patients with a history of diseases that may cause granulomatous diseases such as tuberculosis, sarcoidosis connective tissue diseases, and chronic infectious diseases were excluded from the study. Finally, 36 patients were included in the study. The patients were invited to the outpatient clinic for the final examination. The final examination findings were recorded. The research was carried out in accordance with the Helsinki Declaration. Informed consent was obtained from all patients.

Demographic characteristics of the patients, symptoms at presentation, examination findings, laboratory tests, radiological imaging, tru-cut biopsy results, microbiological culture results, treatment doses and durations, remission times, surgery requirements, and recurrence were recorded.

Bilateral breast axillary ultrasonography (USG) and, if necessary, breast magnetic resonance imaging (MRI) was performed in all patients. Patient follow-ups were made with clinical finds and USG controls. All patients underwent tru-cut biopsy for pathological examination. Abscess contents were aspirated in patients with abscess clinic. Gram stain, bacterial culture and Ziehl-Neelsen staining were performed to rule out possible bacterial infections, tuberculosis, and fungal infections. Chest X-ray and Purified Protein Derivative (PPD) skin test were performed on all patients, and they were consulted by a pulmonologist. During the follow-ups, the patients were evaluated with echo by a cardiologist.

Treatment modalities

Cabergoline 0.5 mg and methylprednisolone 16 mg/day combined treatment was started in patients diagnosed with IGM. Cabergoline 0.5 mg tablet was given orally twice a week. The dose was reduced to one tablet per week in patients who had remission according to clinical examination findings in their follow-ups. Proton pump inhibitor was started and salt restriction was applied to all patients who were started on methylprednisolone. The patients were called for clinical examination every 15 days. The dose of methylprednisolone was administered orally, in two equal daily doses. During the follow-ups, the clinical examination findings of the patients were evaluated and the drug dose was gradually reduced. Patients with residual lumps after medical treatment underwent limited surgical

excision or were followed up without medication. The treatment modalities were wait and watch or surgical intervention after medical treatment was completed. In clinical follow-ups, regression of signs of inflammation, and healing of skin lesions, fistulas, and abscesses were considered as remission. The occurrence of a new lesion in the same region or in a different quadrant of the same breast during or after the treatment, and relapse of the symptoms, were considered as recurrence.

The study was approved by the ethics committee of Memorial Şişli Hospital. Ethics committee meeting date and decision number: 24.12.2021/008

Statistical Analysis

Data were analyzed using the Statistical Package for Social Sciences version 21.0 (SPSS Inc., Chicago, IL). The variables were described using mean values with standard deviations, median values with minimum and maximum values, or numbers with percentages as appropriate. Paired t-test was used for statistical analysis. The p-value <0.05 was accepted as significant.

RESULTS

All 36 patients included in the study were women of childbearing age. The median age of the patients was 35 (24-46) years. All patients, except one, had a history of childbearing and lactation. However, none of the patients included in the study had breastfeeding or pregnancy during treatment. None of the patients included in the study had a history of additional diseases that could cause granulomatous inflammation such as tuberculosis, sarcoidosis, or connective tissue disease. The median follow-up period in our study was 29.5 (15-36) months.

According to the site of involvement, 17 patients had right breast, 18 patients had left breast, and 1 patient had bilateral involvement. The most common involvement was in the lower outer quadrant (38.6%). This was followed by the upper outer quadrant (25%), lower inner quadrant (22.7%), and upper inner quadrant (13.6%), respectively. Retroareolar involvement was observed in 6 patients. Periareolar involvement was present in 10 patients.

The most common presenting complaint was a palpable painful mass in 23 patients (63.8%). The median mass size measured with USG was 3cm (range 1- 8). Mastitis findings were prominent in other patients. Nipple retraction was present in 5 patients. Abscesses were present in 12 patients. Ulcers were observed in 9 patients and fistulas were observed in 4 patients. There was hyperemia in 11 patients, edema in 7 patients, and purulent discharge in 12 patients.

As a result of histopathology, it was reported as chronic granulomatous mastitis with abscess in 6 patients, necrotizing granulomatous mastitis in 1 patient, and granulomatous mastitis in the remaining patients.

The mean prolactin level of patients was 14,8±5,8.

Patient treatments

Oral prednisolone and cabergoline were started in all patients. The dose was gradually reduced in patients who had remission in their follow-ups (Figure 1). The mean duration of remission was 2.85±2.54 months. None of the patients required drug discontinuation due to drug reaction or erythema nodosum.

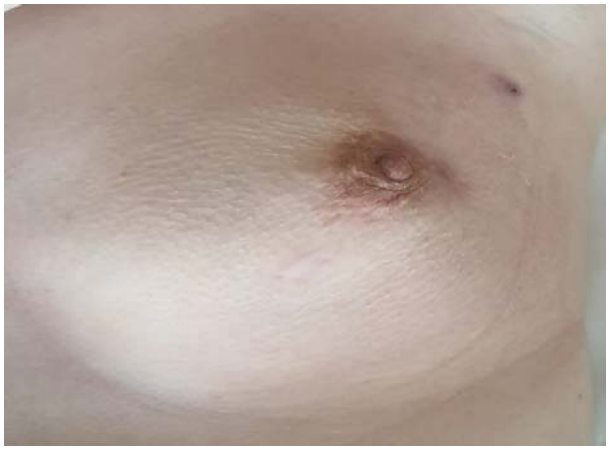

Figure 1: The patient had remission in follow-up.

Abscess drainage was performed at the beginning of the treatment in 4 of 12 patients who presented with an abscess clinic. Gram staining, bacterial culture, and Ziehl-Neelsen staining were performed to rule out infectious causes and tuberculous mastitis in patients who had abscess drainage. As a result of culture, s.aureus was isolated in 1 patient. There was no bacterial growth in the remaining 3 patients. In other patients with small abscess foci who did not require surgical drainage, broad-spectrum oral antibiotics were added at the beginning of the treatment.

The treatment of 29 (74.3%) patients was completed medically. Complete recovery was observed in 20 (55.6%) of 36 patients. No residual lesions were detected in the USG controls of these patients. No recurrence was found in these patients during their follow-ups (Figure 2). Reduction in lesion size was observed in the remaining 16 (44.4%) patients (Figure 3). While the mean mass size measured by USG before the treatment was 33.6 ± 16.4, it decreased to 14.6 ± 8.3 after the treatment ($p < 0.001$).

Figure 2: The treatment of the patient was completed medically. No recurrence was found during follow-ups.

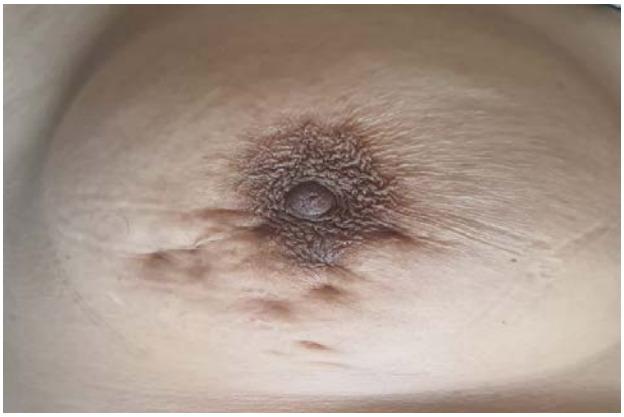

Figure 3: The patient had a reduction in lesions; with an abscess drainage incision scar.

Surgical excision was performed in 7 patients with a residual lump (Figure 4). The median operation time of these patients was 8.6 (4-16) months. 9 patients kept on clinical follow-ups. The patients who underwent surgical excision recovered completely. No treatment was given to the patients who underwent clinical follow-up. No recurrence was observed during the follow-up period.

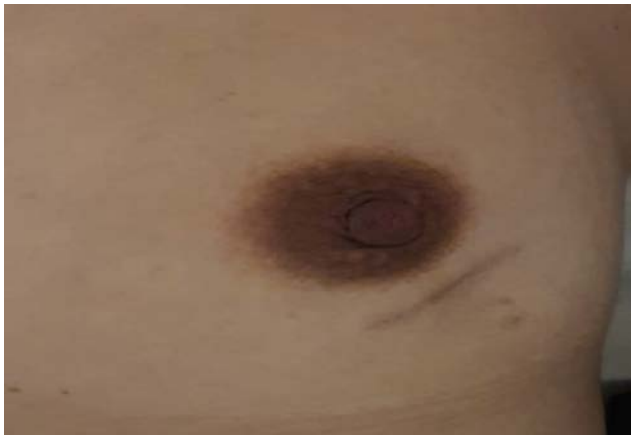

Figure 4: Surgical excision was performed in patient with a residual lump.

DISCUSSION

Idiopathic granulomatous mastitis is a chronic granulomatous inflammatory disease of the breast[1]. Although it has been described for more than 50 years, there is still no consensus on its etiology and treatment. Although the etiology is not clearly known, autoimmunity, infective causes, oral contraceptive use, alpha-1 antitrypsin deficiency, hyperprolactinemia, trauma, breastfeeding, and pregnancy are accepted as risk factors[9]. The disease often affects young women of childbearing age. It is reported that approximately 80% of the patients have a history of pregnancy in the last five years[16,17]. In our study, consistent with the literature, all patients except one were young women with a history of childbearing and breastfeeding. This patient was a young, single woman with no pregnancy history. An unexplained slight increase in prolactin level was detected in her examinations.

Patients often present with breast mass, pain, and skin lesions[18]. It progresses to ulcers, abscesses, fistulas, and nipple retraction over time[1,2,19]. Diagnosis is usually confirmed by histopathological examination of the specimen taken with a core needle biopsy.

Characteristic pathological findings include chronic granulomatous lobulitis with caseous necrosis and micro-abscess[20].

Inflammatory breast cancer, and tuberculous mastitis should be kept in mind in the differential diagnosis of IGM[11]. Although the presence of caseating necrosis and isolation of acid-fast bacilli are the most important pathological diagnostic criteria in tuberculosis patients, the absence of caseating necrosis does not rule out tuberculosis[11,21]. PPD skin test and chest X-rays were performed on all of the patients included in our study, and the patients were evaluated by a pulmonologist. One male and one female patient diagnosed with tuberculous mastitis were excluded from the study. No signs of tuberculosis were detected in the remaining patients.

Although some recent studies have reported cases of igm-associated corynebacterium spp isolated in their cultures, the infective etiology of the disease has still not been proven[22]. Microorganism cultures and staining are generally negative[11]. In our study, s.aureus was isolated in only 1 patient. In the remaining patients, bacteria could not be demonstrated by Gram staining and bacterial cultures were negative.

The positive response of the disease to immunosuppressants and steroids supports the autoimmune etiology of the disease[16].

In the etiopathogenesis of IGM, it is thought that after ductal epithelial damage, the transition of ductal secretions to the lobular connective tissue, local inflammation in the connective tissue, lymphocyte and macrophage migration to the region, and local granulomatous inflammatory response occurs[16,23].

Although the cause of ductal epithelial damage is unknown, it is assumed to result from a localized immune response to fat and protein-rich secretions that are retained or extravasated in the mammary ducts[8].

The fact that IGM is seen at childbearing age and with a history of pregnancy in the last five years

supports that hormones and secretion theory have an important role in the pathophysiology[3].

Although prolactin is thought to be a stimulus that causes granulomatous inflammation in the breast tissue, the mechanism is not fully understood[11]. Lactational changes caused by hyperprolactinemia are thought to cause the development of granulomatous mastitis[12]. In our study, prolactin levels of all patients were within normal limits, except for one patient with hyperprolactinemia of unknown cause. Ergin et al. reported a case of granulomatous mastitis that developed 10 years after the use of antipsychotics[11]. This situation was evaluated as a late reaction to the effect of prolactin, which increased due to the use of antipsychotics. The same situation is thought to be valid for the history of pregnancy and lactation.

No new treatment modality has been identified when comparing the most recent publications on IGM with older studies. The best treatment for the disease is still unclear6. Management and Treatment Options for IGM typically involve clinical observation, medical therapy, surgical interventions, or a combination of surgery and medical therapy. Medical therapy is often the first-line treatment for IGM and may include antibiotics, corticosteroids, and immunosuppressive agents. The success rate of treatment options varies.

IGM is an inflammatory disease with mostly negative bacterial culture results. Therefore, antibiotic therapy often fails[24].

Lai et al. reported that patients with a mild course may regress spontaneously when they are followed up without treatment[25].

In the study of Tang et al. in 2020 comparing intra-lesional steroid administration and observation, it was argued that the injection shortened the duration of the disease in selected cases when compared with observation alone[26].

Oral prednisolone is preferred for corticosteroid therapy. Treatment success and recurrence rates differ in studies. Up to 85% success has been reported with corticosteroid treatment. However, a recurrence rate of 0% to 40% has been reported after stopping the therapy[27,28]. In the case of rapid tapering and discontinuation of the steroid dose, the recurrence rate reaches 78%[29]. For this reason, it is recommended to extend low-dose steroid therapy for up to 6-12 months[28].

The success of methotrexate (MTX) therapy is controversial. Tian et al. reported that 75.3% complete remission was achieved by adding MTX to the treatment in patients who failed corticosteroid treatment[30]. Néel et al. reported that MTX had no significant effect in their study. They reported that three out of four patients who were given MTX treatment had recurrence under the treatment. These findings are supported by data from Hugon et al., who reported that four out of five patients relapsed under the treatment[28,29].

There are case reports in the literature demonstrating successful treatment of IGM with cabergoline. Nikolaev et al. presented four cases in their study, which showed the coexistence of IGM and hyperprolactinemia. The authors recommended evaluating prolactin levels during the examination of patients with granulomatous mastitis when no other identifiable etiology is found[13].

In our study, we used a combination of cabergoline and low-dose steroid therapy. The treatment of 29 (74.3%) patients was completed medically. Seven (19.44%) patients with a residual focus were treated with surgical interventions. Surgical excision was applied to patients whose clinical findings improved but nodular lesions persisted in the follow-up after medical treatment was completed.

The most important dilemma in surgical treatment is aesthetic problems after wide

excision and recurrences after limited excision. Although granulomatous mastitis is a benign disease, its tendency to recurrence poses difficulties in its treatment. The recurrence rate is reported as 5%-50%[2,5,6].

In the case of surgical excision as the first choice in the treatment of IGM, it has been reported that 80% of the recurrence rates are observed in long-term follow-ups[28]. Prasad et al. reported wide excision/lumpectomy as the most effective treatment option with the lowest recurrence rate in their study[16]. However, wide excision brings with it an increase in complications and post-operative aesthetic problems. Deng, et al. reported that the recurrence rate in patients who underwent surgical treatment combined with medical treatment was not lower than in those treated with medical treatment alone[2].

In our study, a limited number of patients needed surgery after the medical treatment. Wide surgical excision was not required in patients who were operated on after medical treatment, and thus the treatment was completed without any serious deterioration in breast aesthetics. No recurrence was observed in these patients during the follow-up period. No drug reactions or side effects were observed in the patients during the medical treatment.

In our study, no recurrence was observed during the follow-up period of 27.88 ± 8.21 months. Therefore, we recommend a pharmaceutical treatment approach first; however, surgery may be recommended in patients with nodular lesions remaining after medical treatment or in patients with recurrence.

The study has certain limitations. Firstly, it is based on a retrospective design. Additionally, the study includes a relatively small number of patients and has a limited sample size. Furthermore, the follow-up duration of the study is relatively limited.

CONCLUSION

In our study, the fact that treatment with cabergoline and low-dose steroid provided remission in a short time and no recurrence was observed in the medium-term follow-up period indicates that it is a successful option in the treatment of IGM. The treatment we apply has also minimized the need for surgery. Since extensive surgical resection is not required in patients undergoing surgery, it has provided good postoperative cosmetic results. However, studies with larger patient groups are needed to support this treatment method.

Ethics Committee Approval: The study was approved by the ethics committee of Memorial Şişli Hospital. Ethics committee meeting date and decision number: 24.12.2021/008

Conflict of Interest: The authors declared no conflicts of interest.

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