ORIGINAL ARTICLE

Comparison of Usefulness of Topical Capsicum Ointment with Diclofenac Gel in the Treatment of Mastalgia

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ABSTRACT

Objective — *To compare the usefulness of topical capsicum ointment with diclofenac sodium gel in the treatment of mastalgia.*

Study design — *Comparative study.*

Place & Duration of study — *Ward-3 Surgical Unit I, Jinnah Postgraduate Medical Center Karachi, from September 2011 to March 2012.*

Methodology — *Women with mastalgia were assigned into two groups. Group A received topical diclofenac sodium gel while group B received capsicum ointment. Severity of pain was assessed on visual analogue scale (VAS) of 0-10. Chi-square test was applied to compare the outcome of two groups and p-value <0.05 was considered statistically significant.*

Results — *A total of 72 women were enrolled. Each group had 31 participants. The mean age of the patients was 27.47 ± 8.08 year (95% CI: 25.57 to 29.37). Duration of disease was 38.66 + 9.34 months and 39.20 ± 11.12 months in group A and B respectively. Of total study participants, 41(57%) improved with treatment. In diclofenac group more patients reported pain relief than capsicum group (69.4% vessus 44.4%-p-value:<0.001).*

Conclusion — *Topical diclofenac sodium and capsicum ointment both were found effective but diclofenac sodium was more effective in relieving mastalgia.*

Key words — *Mastalgia, Diclofenac sodium gel, Capsicum ointment.*

INTRODUCTION:

Breast pain or mastalgia, is a common symptom experienced by most of the females in the childbearing age.[1] This disorder is broadly grouped into cyclic and non cyclic mastalgia.[2] Majority of these patients only require reassurance for the improvement of their complaint. However a small group of patients need some form of drug therapy for their complaints. Many pharmacological agents both topical and systemic, have been tried to treat mastalgia.[3] The systemic drug therapy includes danazol, bromocriptine, tamoxifen etc. Even diet supplements like vitamin A and E and evening primrose oil are used for the treatment of breast pain. However these medications when taken orally have an increased frequency of adverse effects.[4,5]

Topical application of some pharmacological agents like disclofenac sodium gel has been reported which is found to be quick in action and effective in the relief of the symptoms with minimal or no side effects.[6] Another new drug, capsicum abstract is being used for the topical treatment of mastalgia as well. It has been observed that adverse events from capsicun are mainly at the application site (burning, stinging, erythema), and systemic events are rare. This study was conducted to compare the usefulness of topical capsicum and diclofenac sodium gel in patients with mastalgia.

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METHODOLOGY:

This comparative study was conducted in Ward 3 Surgical Unit I, Jinnah Postgraduate Medical Center Karachi, from September 2011 to March 2012. Considering 92% efficacy of topical capsicum ointment and 64% with diclofenac gel the sample size of 72 was obtained with 90% power and 95% confidence interval. The study participants were assigned into two groups A and B, with 31 women in each group. Women having pain in their breasts of more than four weeks duration with pain score of 4 or more on VAS were enrolled. Women with breast lump, previous surgery, lactating mothers and those who had received any previous treatment for breast pain were excluded.

Group A received diclofenac sodium gel and group B received capsicum ointment for mastalgia for 3 months. The severity of breast pain was assessed on VAS 0-10 scale at the end of treatment for all patients included in this study. Patients were advised to apply small quantity of gel three times a day. A chart was provided to them to assess the compliance for treatment. Patients were followed up weekly in the OPD till the post-treatment three months to assess the final outcome.

SPSS version 17 software was used for data entry and analysis. Continuous data like age and VAS were presented in terms of mean + standard deviation. For categorical data like marital status frequencies and percentages were used. Chi-square test was applied to compare the outcome of treatment between the two groups and p-value <0.05 was considered statistically significant. To control effect modifier, stratification with regards to age, marital status and duration of pain was also done.

RESULTS:

Most of the patients were below 46 year of age. The mean age of the patients was 24.47 ± 8.08 year (95%CI: 25.57 to 29.37). Duration of pain, VAS1, VAS2 and VAS3 are given in table I. The mean age was 13.66 ± 3.74 year and 13.45 ± 3.06 year, and duration of disease was 38.66 ± 9.34 months and 39.20 ± 11.12 months in group A and B respectively. In group A, 23 (63.9%) patients were married while in group B, 20(55.6%) were married. Out of 72 patients 41(57%) improved. This improvement was significantly higher in diclofenac sodium group than capsicum group (69.41% vs. 44.44% - p <0.001 as shown in table II. On comparing improvement between the type of pain, cyclic pain improved more than non-cyclic mastalgia (68.2% vs. 31.7%-p= 0.392) but it was not significant.

DISCUSSION:

Breast pain synonymous with mastalgia or mastodynia is a very common condition in females.[7] This affects most of the women during lifetime and is the most common reason for their referrals to the breast clinic. Majority of the females present with cyclical mastalgia.[8] This is reported more often in the younger age group, as also seen in this study. Most of them need reassurance.

Mastalgia may interfere with sexual, physical and social activities. It is found that majority of women

Table I: Characteristics of the Study Patients (n= 72)

Variables	Mean± SD	95% CI	Median	Max- Min
Age (year)	24.47 ± 8.08	25.57 to 29.37	27.5	45- 16
Duration of Pain (Months)	11.66 ± 5.56	10.35 to12.97	12	20-04
VAS (1st Visit)	6.04 ± 0.95	5.82 to 6.27	06	08-04
VAS (2nd Visit)	3.07 ± 0.54	2.94 to 3.20	03	04-02
VAS (3rd Visit)	2.18 ± 0.54	2.05 to 2.31	02	3.5-1

Table II: Comparison of Pain Relief with Diclofenac and Capsicum

Relief of pain	Diclofenac sodium Gel Group (n=36)	Capsicum Ointment Group (n=36)	Total
Yes	25 (69.44%)	16 (44.4%)	41 (57%)
No	11 (30.5%)	20 (55.5%)	31 (43%)
Total	36 (50%)	36 (50%)	72 (100%)

p- value< 0.001

self reporting to breast clinics complaint of breast pain so severe to hinder the daily chore.[9] The chronic pain disorder may even lead to an increased level of anxiety and depression. The challenge in managing mastalgia is to strike a safe balance between appropriate investigations, simple reassurance and treatment. A large number of studies have been conducted using systemic and topical agents for the pain relief however the outcome varied. Oral intake of medications can result in more adverse effects. Local agents are preferred to decrease the pain. In this context the drugs used in this study were capsicum and diclofenac gel. Both of these were found effective, cheap and acceptable.

The application of diclofenac sodium gel is a preferred choice in treatment of mastalgia.[10] The topical mode of administration was easy and acceptable along with the cheaper cost of this drug. The exact mechanism of action is not known. It is proposed that its action is due to the inhibition of prostaglandin synthesis by inhibition of cyclooxygenase. It also appeared to exhibit bacteriostatic activity by inhibiting bacterial DNA synthesis.[11] Its use in this study indicated that there was significant reduction in the overall mean pain score by the end of first month. A study also found topical non-steroidal anti-inflammatory drugs to be safe, effective, rapid and acceptable mode of treatment for mastalgia in addition to being superior to evening primrose oil in all aspects.[12]

Capsicum ointment is used to treat post herpetic neuralgia, diabetic neuropathy etc.[13] As an ingredient in topical agents, capsicum depletes substance P (SP), a substance that mediates pain transmission from the peripheral nerves to the spinal cord. It has been observed that adverse events from capsicum are mainly at the application site (burning, stinging, erythema), and systemic events are rare. These effects can be decreased with the use of a topical anesthetic spray and routine hand washing after contact.[14] Dosed on a regular schedule, every 6 hours, it generally takes 2 to 4 weeks to achieve a clinical effect.[15] In this study the common side effects experienced by most of the patients were burning and / or tingling sensation at the site of application which usually subsided after continued use of drug for five days to a week. It was also noted that the effect with this drug appeared after a delay of 3 or 4 days. Thus despite the growing use of capsicum, especially the cream presentation, its use is limited and compliance is also poor.[16] Thus due to the necessity for repeat applications, delayed therapeutic effect and application site pain, it is recommended that it should be reserved as a 2nd -line or adjuvant agent.

About 2/3rd of the women in the younger age group with breast pain have a problem called cyclic mastalgia. This pain typically is worse before menstrual cycle and gets relieved at the time period begins.[17] The pain may also happen in varying degrees throughout the cycle and is believed to be caused by hormonal changes. Non cyclic mastalgia occurs less often than the cyclic form. It typically occurs in women older than 40 years and is not related to the menstrual cycle. It was noticed that pain relief to local application of drugs used in this study was better in cyclic than non- cyclic mastalgia. This could be because cyclical mastalgia is also linked to hormonal changes.

CONCLUSION:

Both local application of diclofenac gel and capsicum ointment can be safely used in the treatment of mastalgia but diclofenace gel was found superior to capsicum ointment.

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