COMPARISON OF COLD-GEL PACK THERAPY WITH ORAL IBUPROFEN FOR THE PAIN RELIEF BEFORE INTRALESIONAL INJECTION OF TRIAMCINOLONE ACETONIDE IN THE TREATMENT OF KELOIDS

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ABSTRACT

Objective: To compare the efficacy of cold gel pack therapy with oral ibuprofen for the pain relief before intralesional injection of triamcinolone acetonide in the treatment of keloids.

Study Design: Randomized controlled trial.

Place and Duration of Study: Study was conducted at Combined Military Hospital Rawalpindi, from Apr 2017 to Sep 2017.

Material and Methods: Patients of both genders with keloids larger than 3 cm in greatest dimension were included in the study. They were divided into two equal groups by lottery method. In first group i.e. group A, cold gel pack was applied 20 minutes before intralesional steroid injection whereas group B received oral ibuprofen 400 mg single tablet 30 minutes before the intralesional steroid injection. Patients rated their pain on a 10 point numeric rating scale (NRS) with 0 as no pain and 10 as worst possible pain immediately after procedure. Mean pain score was recorded for both the groups.

Results: The mean NRS score for group A patients receiving the cold gel pack therapy was 3.22 ± 0.20 whereas mean NRS score in group B with oral ibuprofen was 5.92 ± 0.40 (p-value<0.001). The pain scores in the cold gel pack group were significantly lower than the ibuprofen group.

Conclusion: Cold gel pack therapy before administration of intralesional steroid injection into the keloids emerged as an effective tool to reduce the pain of the patients. It was found superior to the ibuprofen and its routine use before the intralesional injections can help the patients to cope well with the painful therapy.

Keywords: Cold-gel pack, Ibuprofen, Injection site pain.

INTRODUCTION

Keloid is a Greek word derived from "chele" meaning "crab's claws" pertaining to penetration into the surrounding skin[1]. This condition has a debilitating effect on the physical and psychological health of the patients because of its chronic nature[2]. There is approximately 5-15% chance of keloid formation in all the wounds with both genders equally predisposed to it[3]. The average age at onset is 10-30 years and people at extremes of age rarely develop them[3].

There are multiple treatment options available for the keloids. It is difficult to assess the efficacy of each modality because of diverse range of influencing factors such asage, race, gender and location of the lesion[3]. Intralesional injection treatments have shown good results over the years in improving both functional and aesthetic appearance of the keloids[4]. Although variety of agents are used for this purpose but evidence is lacking regarding their individual effectiveness[1]. Corticosteroids, most commonly triamcinolone acetonide has been a major intralesional injection option (alone or in combination) for keloids in our part of the world[5,6]. The corticosteroids need to be injected at correct depth in mid-dermis[5] and then repeated every 3-4 weeks for the optimal response[7,8].

Corticosteroid therapy is an effective treatment for the keloids but one of the main reasons for discontinuation of this therapy has been the severe pain encountered by the patient

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during injection administration[9]. Many studies have shown that this injection fear can cause a variety of deleterious effects including the discontinuation of therapy[10,11]. Therefore pain all eviation is important for reducingthe fear of patients and ensuring compliance towards the treatment[12].

Addition of lidocaine injection has traditionally been used to decrease the pain but its effectiveness is in question[13] as it is the injection site pain which is more distressing for the patient than the post procedural pain itself. Many methods have been in practice to reduce the intralesional injection site pain including cooling[14], oral pain killers and vibration anesthesia[15] but exact effectiveness of any of these options has not been established. Therefore we planned this study with therational to compare the effectiveness of cold-gel packs with oral ibuprofen for relief of pain due to intralesional injection of steroid therapy.

PATIENTS AND METHODS

After approval from hospital ethical committee this randomized control trial was conducted at Plastic Surgery Department Combined Military Hospital Rawalpindi from April 2017 to September 2017. Patients were selected using purposive sampling technique. Sample size was calculated by using the WHO calculator. Patients of both genders coming to outpatient department with keloids on any site for >1year, >3 cm in greatest dimension, and with or without any previous history of intralesional steroid therapy were included in the study. Patients less than 12 years and more than 80 years and with uncontrolled diabetesmellitus were excluded from the study. Patients having clinically active infection in keloid lesion marked by any discharge, warmth and erythema were also excluded from the study. Patients were randomly divided into two equal groups through lottery method. Group Areceivedcold gel packs which were kept at temperature <4^{o}C, applied directly on the keloid for 20 minutes[16]. Group B received oral ibuprofen 400 mg single tablet 30 minutes before the intralesional injection[17]. In both the groups,intralesional steroid injection 20mg/ml diluted triamcinolone acetonide with lignocaine plain injection 2% was administered with a 27 G 11 mm needle attached on a dental syringe. Administration of injection to all the patients by the same surgeon was ensured to reduce the chance of operator bias. Immediately after the procedure patients completed the self-rating pain questionnaire.

The numeric rating scale (NRS) for pain is a one-dimensional measure of pain intensity in adults[17]. Although various variations exist, the most commonly used is the 11-item NRS18 with '0' represents no pain and '10' represents worst pain possible. The NRS can be administered verbally or graphically for self-completion[19]. The patient indicates the numeric value on the segmented scale that best describes their pain intensity. Higher scores indicate greater pain intensity.

Data was analyzed by using SPSS 21.0. Descriptive statistics were used for the age, gender and site of the keloid. Mean NRS score was calculated for both the groups. Student t-test was applied to establish the difference in the efficacy of the treatments and NRS score of the two groups. A p-value <0.05 was considered significant.

RESULTS

A total of 90 patients were approached to participate in the study. Three refused participation and 04 were ineligible due to exclusion criteria (02 had uncontrolled DM and 02 had infected keloid). After being consented, an additional 03 did not provide complete data at baseline, leaving 80 patients. Mean age of the patients was 35.96 (± 5.975). Commonest site of keloid was the chest (65%) followed by shoulder (25%) and the back (3%). General characteristics of study participants are given in table-I. In group A (cold-gel pack therapy group) 24 patients weremale and 16 were females. Whereas in group B 25 patients were male and 15 were female. Overall out of 80 patients, 70 (87.5%) patients

received first injection therapy whereas only 10 (12.5%) had second or third session. Table-II shows that the mean NRS pain score for group A was 3.22 ± 0.20 and for group B it was 5.92 ± 0.40 (*p*-value<0.001).

DISCUSSION

Injection site pain can be a major concern for any patient undergoing repeated injections. It has always been under prioritized and under-treated[11,12]. Management of pain is a human right. Alleviation of pain has a direct link with the local as well as foreign literature[5,13]. Though local studies have been done on their treatment option[5,6] but no study is conducted in our setup to look for the pain and discomfort associated with this treatment.

Pain is a complex phenomenon with perceptual, affective, motivational, cognitive and personality components. This is the reason that many modalities not directly linked to neuro-chemical effects of pain may show efficacy in reducing the anxiety and thus increasing the

Table-I: Baseline characteristics of the study patients (n=80).

Age (years)					
Mean ± SD	35.96 (± 5.975)				
Range (min-max)	12-48 years				
Site of keloid					
Chest	52 (65%)				
Shoulder	20 (25%)				
Back	02 (2.5%)				
Forearm	01 (1.25)				
Others	05 (6.25)				
Average duration (years)					
Mean ± SD	7.5 ± 2.5				
Range (min-max)	0.6-13				
Gender	**Group A (n=40)**	**Percentage (%)**	**Group B (n=40)**	**Percentage (%)**	***p*-value**
Male	24	60	25	62.5	0.343
Female	16	40	15	37.5	

Table-II: Pain scores of the subjects in both the groups.

Characteristics	**Group A (Cold gel pack)**	**Group B (Ibuprofen)**	***p*-value**
Pain score after procedure, mean (SD)	3.22 ± 0.20	5.92 ± 0.40	<0.001

compliance and continuation of the therapy[12,20]. Intralesional steroid therapy for keloids is notorious for severe pain and discomfort[9,20]. Patients usually hesitate to complete these therapies due the fear of needle and pain associated with this procedure[20]. Most of our patients had NRS score >5 showing considerable pain despite administration of cold-gel pack or ibuprofen. Multiple factors are important for injection site pain including injection site, injection volume, viscosity and patient's pain threshold[11].

Most of our patients had keloids on chest and the shoulders, which is in accordance with threshold for pain. Reading of verses of Holy Quran before the procedure is one of them[21]. Reducing the inflammatory response by NSAIDs is along tested and well documented method[16]. Use of local anesthetics or ice packs is also under trial and shown positive results in various studies[13,14].

Direct comparison of an oral NSAID and local application of cold gel pack has never been done before. Ibuprofen has been studied to irreversibly inhibit the cyclooxygenase system thus causing reduction in the pain[16], while application of cold gel packs reduces the cellular metabolic rate and oxygen demand limiting the

production of tissue damaging free radicals via suppression of exotoxins. Additionally, it decreases free nerve ending sensitivity and increases nerve firing thresholds and slow down the synaptic activity. All these mechanisms increase the patient's pain threshold and he can tolerate the painful procedure with ease[14]. This multifactorial model of working of cold gel pack may be responsible for the superiority of this modality in our analysis. This is not only more efficacious but also cheaper in cost than ibuprofen which makes it more lucrative for a developing country like ours.

Our study had few limitations. As gel packs and tablets had to be administered in each group so blinding of patients and the staff was not possible. Moreover there was no placebo control group and self-rated scale was used which increases the chance of over or underrating of the symptoms by the patient. Outcome of this study cannot be generalized due to small sample size so we suggest further trials on a broader based and a more representative sample size using locally developed and standardized tools.

CONCLUSION

Cold gel pack therapy before administration of intralesional steroid injection into the keloids emerged as an effective tool to reduce the pain of the patients. It is superior to the ibuprofen and its routine use before the intralesional injections can help the patients to cope well with the painful therapy.

CONFLICT OF INTEREST

This study has no conflict of interest to declare by any author.

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