



ISSN: 2395-1958
IJOS 2016; 2(3): 162-165
© 2016 IJOS
www.orthopaper.com
Received: 25-05-2016
Accepted: 26-06-2016

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Evaluation of the effectiveness and safety of intra-articular injection of sodium hyaluronate in the Treatment of patients with painful knee osteoarthritis

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Abstract

Background: Osteoarthritis, a disorder of the joints which is progressive is caused by gradual loss of cartilage and is characterised by the development of bony spurs and cysts at the margins of the joints. Hyaluronic acid, a mucinous glycoprotein secreted by synovial fibroblasts is a major component of joint synovial fluid (SF). Intra-articular hyaluronan (HA) therapy has been suggested as a symptom-modifying therapy. This study aims at assessing the functional efficacy and safety of two dose intra-articular Sodium Hyaluronate 500-730 kilodalton (kDa), using the WOMAC and VAS Scores in Indian patients with grade I and II osteoarthritis of the knee over a two-month period.

Material and method: Thirty patients with osteoarthritis of knee with grade I and grade II attending the OPD of the Department of Orthopaedics in Vydehi Institute of Medical Sciences and Research center during the study period were included in this study.

All patients were administered with 2 injections of intra-articular Sodium Hyaluronate 500-730 kilodalton (kDa) once a week for two weeks under strict aseptic precautions and followed up to assess the response.

Results: 24 of the 30, 80% of all subjects showed improvement of both the WOMAC and VAS scores during each follow up in the two month period following intra articular injection with hyaluronic acid.

Keywords: Osteoarthritis, hyaluronic acid, intra articular

Introduction

Osteoarthritis, a disorder of the joints which is progressive is caused by gradual loss of cartilage and is characterised by the development of bony spurs and cysts at the margins of the joints^[1]. It is the most common joint disease with prevalence of 22% to 39% in India^[2-3].

Hyaluronic acid, a mucinous glycoprotein secreted by synovial fibroblasts is a major component of joint synovial fluid (SF)^[4]. Its unique viscoelastic, shock absorbing and lubricating. It modulates cell proliferation, migration, and gene expression^[5].

Many authors have supported intra-articular hyaluronan (HA) therapy as a symptom-modifying therapy but despite recent progress, many unresolved issues require further study. They had concluded that intra-articular HA injections can lead to short-term improvement in pain and function in patients with knee OA^[6].

In most studies, HA is reported to have lessened pain and improved joint function yet there are discrepancies as to the precise type of treatment that should be used. The number of doses and follow up need standardization^[7].

Our study aims at reconfirming the effectiveness and safety of intra-articular use of hyaluronic acid in the treatment of knee osteoarthritis and establishing the same in our population with a two dose regimen.

Aim of the study

To assess the functional efficacy and safety of two dose intra-articular Sodium Hyaluronate 500-730 kilodalton (kDa), using the WOMAC and VAS Scores in Indian patients with grade I and II osteoarthritis of the knee over a two-month period.

Materials and methods

Source of data: Patients who complain of painful knee and diagnosed of osteoarthritis of knee with grade I and grade II attending the OPD of the Department of Orthopaedics in Vydehi

Institute of Medical Sciences and Research center during the study period were included in this study.

Sample size: A total of 30 patients were studied in the period of two months (01/02/16 to 03/04/16).

Inclusion criteria: All patients diagnosed of grade I and II degenerative osteoarthritis of knee.

Exclusion criteria: Grade III and IV osteoarthritis and pain in knee due to other reasons were not included.

Study design: It is prospective study.

Procedure: Patients complaining of painful knee were clinically and radiologically assessed for osteoarthritis and will be graded according to Kellgren-Lawrence grading system^[8]. All patients were administered with 2 injections of intra-articular Sodium Hyaluronate 500-730 kilodalton (kDa) once a week for two weeks. The injections were given under strict aseptic precautions in the medial joint / lateral joint line using a pre loaded sterile syringe. The joint is aspirated before injecting the hyaluronic acid. The patient was mobilised immediately after a small dressing. All patients were put on a 3day course I generation cephalosporin antibiotics.

The efficacy parameters are the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) for pain, stiffness and physical function and VAS. The efficacy was assessed prior to the injection at first visit after which the first injection was given. The scores were again assessed during successive visits on the fourth, sixth and eighth week.

Outcome measures:

Outcomes were assessed on the basis of the scores obtained on the WOMAC scoring which is a questionnaire based scoring method.



Fig 1: showing painting of the part.



Fig 2: showing the palpation of joint lines



Fig 3: showing injection of the intra articular hyaluronic acid.

Results

In the present study, the patients' ages were between 38 and 49 years with a mean value of 43.13 years. Majority of the patients were obese as seen in table 4. 24 of the 30 subjects showed improvement of both the WOMAC and VAS scores during each follow up in the two month period following intra articular injection with hyaluronic acid as seen in table 1. This accounts for 80% of all patients. After the injection of Sodium Hyaluronate, all WOMAC index revealed the significant improvement from baseline. Most patients and investigators found the treatment efficacy as moderate to effective at the end of the study. Paracetamol consumption decreased from baseline until the last follow-up. No systemic or serious adverse event was reported.

Table 1: Showing Gender distribution

	Number	Percentage
Males	18	60
Females	12	40

The number of males is greater than the number of females participating in the study.

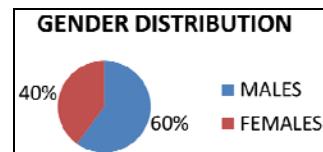


Fig 4: pie chart showing the gender distribution.

Table 2: Grade distribution

Grades	Number	Percentage
I	19	63
II	11	37

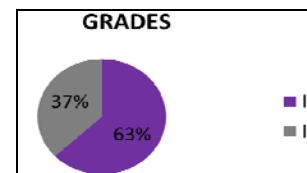


Fig 5: pie chart showing grade distribution.

Table 3: weight distribution

BMI	Number	Percentage
<18(underweight)	0	0
18-22.99(normal)	9	30
23-24.99(overweight)	8	27
>25(obese)	13	43

Majority of the participants were found to be obese according to the Asia pacific classification of BMI. The mean BMI was 24.86. Since the knee is a weight bearing joint, its wear and tear is dependent on the weight of a person. Obesity is a predisposing factor for osteoarthritis.

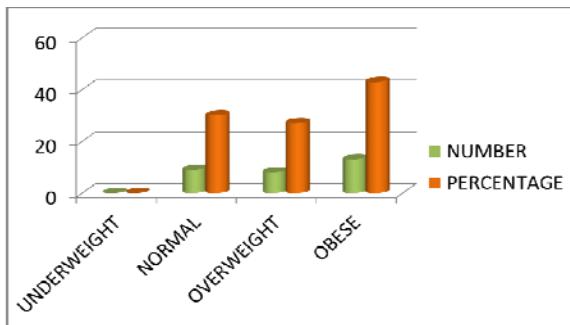


Fig 6: showing weight distribution

Table 4: Comparison Womac Scores

	Mean	SD	P- Value
Before Intervention	29.83	2.06	<0.001
8 th Week	26.63	2.34	
12 th Week	26.16	2.36	

*SD-standard deviation.

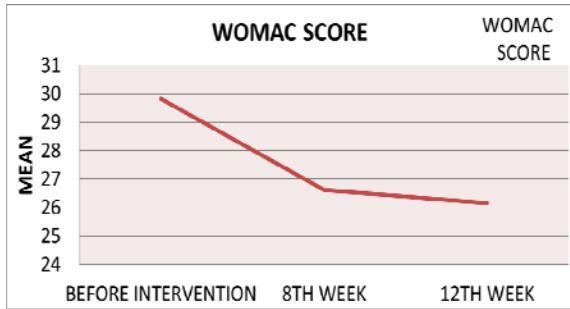


Fig 6: Showing improvement on WOMAC score.

Table 5: Comparison of Vas Score

	Mean	Sd	P- Value
Before Intervention	5.03	0.61	<0.001
8 th Week	3.4	0.93	
12 th Week	3.16	0.91	

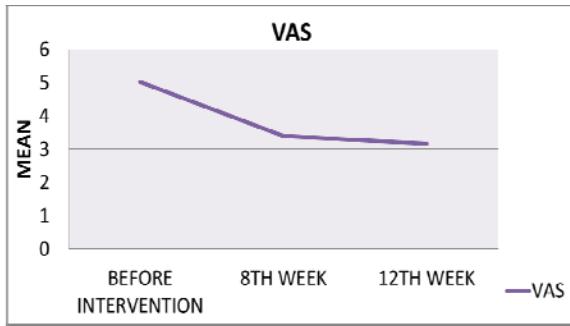


Fig 7: showing improvement of VAS

Discussion

So far many authors have supported intra-articular hyaluronan (HA) therapy is both a symptom-modifying therapy and a treatment which may significantly decrease the rate of deterioration of joint structure. There is data to support the benefit and safety of repeated treatment with Intra articular

hyaluronic acid. Many trials indicate that sodium hyaluronate is well tolerated and as effective after multiple courses of treatment as it is after a single course [9].

The analysis by Lo *et al* supports the use of HA for the treatment of OA knee [10].

At present no case of septic arthritis has been reported in any clinical trial. Most adverse events are minor and transient at the injection site. Painful post-injection reaction occurred in 1%-2% of patients, the pain did not last more than 72 hours. Systemic allergic reactions due to individual hypersensitivity were rarely recorded. Therefore viscosupplementation seems to be an efficacious and safe treatment.

The randomised, controlled, multicentre trial conducted by chevalier *et al* to compare efficacy and safety of a single injection of hyaluronic acid, versus a placebo found HA to be effective. The primary outcome measure was change from baseline over 26 weeks using the WOMAC® pain score [11].

In another RCT, Diracoglu *et al* determined the short-term effects of intra-articular HA on proprioception, isokinetic muscle force, pain and functional conditioning in patients with knee OA. The authors concluded that intra-articular HA injections can lead to short-term improvement in pain and function in patients with knee OA [12].

Study by Berg P¹, Olsson U. show that a single intra-articular injection of NASHA is a well tolerated and potentially effective therapy in the treatment of hip OA [13].

The present study had concurrent results. The probable reasons for the 20% non-improvement are:

- did not receive 2nd injection
- obese patients
- persistent squatting
- Did not follow instructions such as quadriceps strengthening exercises and adequate rest.

Conclusion

Viscosupplementation like HA is a reasonable treatment of choice for patients with early osteoarthritis of knee. The effect lasts longer with low-molecular weight preparations, and patients can experience improvement in clinical outcomes for up to 1 year. Intra-articular low molecular weight HA appears to have a slower onset of action than intra-articular steroids and high molecular weight HA but the effects seem to last longer. Disadvantages of low molecular weight HA is the need for multiple injections. No adverse outcomes were reported with the treatment. This method of injection is safe and convenient. Hence intra articular injection of low molecular weight HA is safe and cost effective treatment modality.

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