Evaluation of results of arthroscopic debridement and lavage with injection of hylan polymer in the management of osteoarthritis of knee

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Abstract

Objective: An evaluation of safety and efficacy of high molecular weight hyaluronic acid (HA) delivered at the time of arthroscopic debridement of the osteoarthritic knee.

Methods: Thirty-four consecutive patients who met inclusion and exclusion criteria underwent arthroscopic debridement by a single surgeon and concomitant delivery of 6 ml/90 mg HA. These patients were evaluated preoperatively, at 3 months, 6 months and 9 months postoperatively. Evaluations consisted of WOMAC pain score and complications.

Results: No complications occurred during this study. Pre-op average mean WOMAC pain score was 65.050 (n = 34) and 80.544 at 3 months (n = 34). Final average WOMAC pain score improved to 79.994 at six months (n = 34). No patients had deterioration of the WOMAC pain score.

Conclusion: The results show that concomitant delivery of high molecular weight hyaluronan is safe when given at the time of arthroscopic debridement of the osteoarthritic knee. By delivering HA at the time of the arthroscopic debridement, there may be a decreased risk of joint infection and/or injection site pain. Furthermore, the combination of both procedures show efficacy in change of WOMAC pain scores.

Keywords: High molecular weight hyaluronic acid (HA), arthroscopic debridement, osteoarthritic knee

Introduction

Knee joint is a complex hinge joint. It withstands a variety of forces during, walking, running or even at the time of rest. Knee joint is the most common joint to develop osteoarthritis. Osteoarthritis (OA) is a common disease of aged population and one of the leading causes of disability [1]. Incidence of knee OA is rising by increasing average age of general population [2]. Ages, weight, trauma to joint due to repetitive movements in particular squatting and kneeling are common risk factors of knee OA. The likelihood of developing osteoarthritis increases with age. Studies have shown that knee osteoarthritis in men aged 60 to 64 is more commonly found in the right knee (23%) than in the left knee (16.3%), while its distribution seems to be more evenly balanced in women (right knee, 24.2%; left knee, 24.7%). The prevalence of osteoarthritis of the knee is higher among 70 to 74 year olds, rising as high as 40% [3]. Several factors including cytokines, leptin, and mechanical forces are pathogenic factors of knee OA [4]. In patients with knee pain attribution of pain to knee OA should be considered with caution. The primary goal of treatment is the alleviation of pain, leading to an improvement in joint function and quality of life. Treatment options for knee OA include conservative therapies (education, weight loss, physical therapy, etc.). Pharmacological therapies (simple analgesics, NSAIDs (including COX-2s)), intra-articular injections (corticosteroids, visco supplements) and surgical intervention (e.g. arthroscopic debridement and lavage, meniscectomy, total knee replacement (TKR)). More than 90% of patients with symptomatic OA of the knee have evidence of meniscal tears on magnetic resonance imaging [6], and arthroscopic meniscectomy can be used to treat patients who are unresponsive to more conservative therapies, but are not yet TKR candidates. However, the clinical benefit of arthroscopic debridement is unclear. Visco-supplementation (intra-articular supplementation of hyaluronic acid) is a well established treatment option in knee OA [7] and is included in the professional guidelines for treatment of the disease in this joint. Several meta-analyses have been conducted on the
therapy class, which agree broadly that visco-supplementation is effective and safe. The use of visco-supplementation for the symptomatic relief of knee OA in patients after arthroscopic meniscectomy has not been widely studied. The purpose of the present study is to evaluate the effectiveness of arthroscopic debridement followed by intra-articular injection of hylan polymer in OA of knee [19-16].

Methodology
The aims of the study were to achieve satisfactory function and painless movement of knee by arthroscopic debridement and lavage with injection of hylan polymer inside knee joint in a case of osteoarthritis of knee and evaluation of efficacy, limitations and complications of such procedure. The objectives of the study were to determine the effectiveness and adverse effects of arthroscopic debridement, with or without lavage and injection of hylan polymer inside joint, in the treatment of symptomatic osteoarthritis (OA) of the knee, and to conduct an analysis if evidence for effectiveness can be established. The study was conducted in Department of Orthopaedics, Institute of Post Graduate Medical Education and Research and SSKM Hospital from December 2013 to Oct 2015. In this prospective study total 34 patients with pain not relieving by conservative methods in osteoarthritis of knee stage I, II and early stage III were taken into consideration. The exclusion criteria was patient with inflammatory OA, joint tuberculosis, septic joints, psoriatic joints (e.g., psoriatic knee joint synovitis), synovitis, chondroplasty of the knee and gonarthrosis, patients with associated comorbidities, patients with meniscal tears from an acute injury (e.g., sports injury), OA in children, patients with OA stage late III and IV. All patients underwent arthroscopic debridement and lavage followed by injection of hylan polymer. Proper history regarding symptoms, stiffness, pain and activity of daily living were taken. Patients were evaluated pre-op by WOMAC score. Radiological data though not included in study were noted and correlated. All patients’ undergone arthroscopic debridement and lavage of knee joint. Arthroscopic procedure was performed in a standard manner. From first post op day knee movement was allowed along with muscle strengthening exercise. Arthroscopic findings like meniscal injury, presence of loose bodies and status of articular cartilage were documented. Injections of hylan polymer were injected inside knee joint by superolateral approach. Patients were then re-evaluated 3, 6, 9 and 12 month post-op by WOMAC score.

Results and analysis
The study was conducted in the department of orthopedics, Institute of Post Graduate Medical Education& Research and S.S.K.M. Hospital,Kolkata-20, from January 2014 to June 2015.In this prospective study we have studied a total 34 patients with knee osteoarthritis who have undergone arthroscopic debridement and lavage with injection of hylan polymer inside knee joint. Out of 34 patients 14 were male and 20 were female.

Table 1: Distribution of study population as per age, group and gender

| Age (years) | Male | Female | Total |
|------------|------|--------|-------|
| 40-49      | 04   | 09     | 13    |
| 50-59      | 08   | 07     | 15    |
| 60-69      | 02   | 04     | 6     |
| Total      | 14   | 20     | 34    |

Fig 1: Bar diagram showing distribution of study population

Table 1 and Figure 1 shows age of the patients ranges from 42 to 67. Mean age of the study subjects was 53.15 years. Maximum number of patients was in the age group of 50-59 which was 44.12 percent of the total study population.

Table 2: General statistical description of continuous variables

| Parameters            | N  | Range | Minimum | Maximum | Mean  | SD    | Variance | Skewness | Kurtosis | Normality (Ks) |
|-----------------------|----|-------|---------|---------|-------|-------|----------|----------|----------|----------------|
| Age                   | 34 | 25    | 42      | 67      | 53.15 | 6.805 | 46.311   | 0.345    | -0.759   | 0.128          |
| Score Before Arthroscopy | 34 | 6.8   | 62.1    | 68.9    | 65.050| 9.074 | 3.638    | 0.206    | -0.665   | 0.104          |
| Score After 3 Months  | 34 | 18.2  | 68.9    | 87.1    | 80.544| 4.407 | 19.720   | -1.035   | 0.721    | 0.178          |
| Score After 6 Months  | 34 | 20.4  | 66.7    | 87.1    | 79.994| 4.704 | 22.135   | -1.108   | 1.534    | 0.165          |
| Score After 9 Months  | 34 | 18.9  | 66.7    | 85.6    | 79.047| 4.499 | 20.243   | -1.183   | 1.312    | 0.184          |
| Score After 12 months | 34 | 19.6  | 65.2    | 84.8    | 77.556| 4.2972| 18.466   | -1.155   | 1.747    | 0.218          |

Evaluation was done using WOMAC score. Table 2 shows mean pre-op WOMAC score was 65.05+/−1.9074,Mean 3, 6, 9 and 12 month post-op score was 80.544+/−4.44,79.994+/−4.70,79.047+/−4.50 and 77.556+/−4.30 respectively. Mean WOMAC score of each post op value was more than mean pre-op value. Significance of increase in p value was ascertained by sample T test.

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Figure 2 shows that total number of male patients was 14 which was 41% of the study population compared to 20 female patients which was 59% of the total population.

Table 3: One sample T test of continuous variables

| Parameters            | T     | df  | P     | Mean Difference | 95% Confidence Interval of the Difference |
|-----------------------|-------|-----|-------|-----------------|------------------------------------------|
|                       |       |     |       |                 | Lower                     | Upper                     |
| Age                   | 45.538| 33  | 0.000 | 53.147          | 50.77                     | 55.52                     |
| Score Before Arthroscopy | 198.855 | 33 | 0.000 | 65.0500         | 64.384                    | 65.716                    |
| ScoreAfter3Months     | 105.759 | 33 | 0.000 | 80.5441         | 78.995                    | 82.094                    |
| ScoreAfter6Month      | 99.143 | 33  | 0.000 | 79.9941         | 78.353                    | 81.636                    |
| ScoreAfter9Month      | 102.445 | 33 | 0.000 | 79.0471         | 77.477                    | 80.617                    |
| ScoreAfter12Month     | 105.236 | 33 | 0.000 | 77.5559         | 76.057                    | 79.055                    |

One Sample T test shows increase in mean WOMAC score in each post-op value was significant (p=0.000).

Figure 3: Scatter plot of WOMAC scores by age of study subjects
Mean WOMAC score after intervention was higher than before intervention. The change in scores after intervention was significant over the time. But the mean scores gradually decreased with time.

Table 3a: Mean of the arthroscopic scores at different time

| Parameters | Pre-op score | Score 3 m post-op | Score 6 m post-op | Score 9 m post-op | Score 1 year post-op |
|------------|--------------|--------------------|-------------------|-------------------|----------------------|
| N          | 34           | 34                 | 34                | 34                | 34                   |
| Mean       | 65.050       | 80.544             | 79.994            | 79.047            | 77.556               |
| SD         | 1.9074       | 4.4407             | 4.7047            | 4.4992            | 4.2972               |

Table 4: Weighted Average percentiles of WOMAC score

| Scores     | Parameters     | Percentiles |
|------------|----------------|-------------|
|            |                | 5           | 10          | 25           | 50           | 75           | 90           | 95           |
| Score pre- |                | 62.100      | 62.100      | 63.600       | 65.200       | 66.700       | 67.800       | 68.750       |
| Score 3m   |                | 70.100      | 73.100      | 78.000       | 82.200       | 83.300       | 85.900       | 86.575       |
| Score 6 m  |                | 68.350      | 72.000      | 78.600       | 80.300       | 82.775       | 85.600       | 87.100       |
| Score 9 m  |                | 68.350      | 71.200      | 77.100       | 79.900       | 82.000       | 84.100       | 85.000       |
| Score 1 yr |                | 66.850      | 70.450      | 76.325       | 78.000       | 79.500       | 82.950       | 83.675       |

For further evaluation pre-op WOMAC was taken as base line score and 50th percentile of baseline score was 65.200 as shown in table 4.50th percentile of post-op scores were 82.200, 80.300, 79.900 and 78.000 respectively.

Table 5: Weighted Average percentiles of WOMAC scores

| Group Statistics | Group | N   | Mean       | Std. Deviation | St Standard Error Mean |
|------------------|-------|-----|------------|----------------|------------------------|
| Score _1         | 1     | 20  | 79.275     | 4.7089         | 1.0529                 |
| Score _2         | 2     | 14  | 82.357     | 3.4108         | 0.9116                 |
| Score _3         | 1     | 20  | 78.520     | 4.9015         | 1.0960                 |
| Score _4         | 2     | 14  | 82.100     | 3.5994         | 0.9620                 |

Considering the baseline score as cut-off value whole study population was divided in two groups named Group1 (<65.2) & Group2 (>65.2). The group statistics of post-op scores is shown in table 5.

Table 6: Independent sample T test of Arthroscopic scores after grouping assuming equal variance

| Parameters | t    | df  | Sig. (2-tailed) | Mean Difference | Std. Error Difference | 95% Confidence Interval of the Difference |
|------------|------|-----|-----------------|-----------------|----------------------|------------------------------------------|
| Score _1   | 2.091| 52  | .045            | -3.0821         | 1.4740               | 6.0845                                  | -.0798                                  |
| Score _2   | 2.325| 52  | .027            | -3.5800         | 1.5399               | -6.7166                                 | -.4434                                  |
| Score _3   | 2.168| 52  | .038            | -3.2229         | 1.4867               | 6.2511                                  | -1.946                                  |
| Score _4   | 1.887| 52  | .068            | -2.7221         | 1.4425               | 5.6604                                  | 2.161                                   |

Intra group comparison of mean WOMAC scores at same point of time revealed an inverse relationship. It means higher was the score before operation there was less chance of improvement (denoted by a negative “t” value) in table 6.

Discussion

Osteoarthritis is a burning problem today. Osteoarthritis of knee is a very common problem in aged population and is a leading cause of disability. The incidence of osteoarthritis is increasing day by day in younger populations also. The primary goal of treatment is the alleviation of pain, leading to an improvement in joint function and quality of life. Treatment options for knee OA include conservative therapies (education, weight loss, physical therapy, etc.). Pharmacological therapies (simple analgesics, NSAIDs (including COX-2s)), intra-articular injections (corticosteroids, visco-supplements) and surgical intervention (e.g. arthroscopic debridement and lavage, meniscectomy, total knee replacement (TKR)). Most commonly used treatment modality is physiotherapy and pharmacological therapy. TKR is reserved for mainly late stage III and IV. Most of the patient with symptomatic osteoarthritis have evidence of meniscal tear, presence of loose body or chondral defects. Patients whose symptoms are not relieved by physiotherapy and pharmacological therapy arthroscopic debridement to get rid of meniscal tear, loose bodies and chondral defect along with lavage is done. Intra-articular injection of corticosteroids can relieve knee pain and inflammation temporarily. Intra-articular injection of hyaluronic acid is also used to improve symptoms and quality of life. In this study we evaluated the efficacy of arthroscopic debridement of knee following by injection of hylan polymer done 3 week post arthroscopy in improvement of symptoms in OA of knee. Sample size of this study was 34 with mean age being 53.15±6.805 years with range of 42 to 67 years. Higher percentage of patients were between 50-59 years. Out of 34 patients 14(41.18%) was male and 20(58.82%) was female. Many studies have evaluated the efficacy of...
arthroscopic debridement with injection of hyaluronic acid in OA of knee. Heybeli N et al. (2008) [18] studied on 67 patients dividing them into 2 groups, one group with only arthroscopic debridement and the other with post arthroscopy injection of hyaluronic acid(HA). Improvement in pain scores at 6 weeks did not differ between the two groups (HA 21%, control 16%; p=0.478), whereas improvement in function scores was significantly higher in the HA group (23% vs 9.2%; p=0.018). The rates of improvement in pain and function scores increased in subsequent evaluations, but these did not differ significantly between the two groups. In our study also there is in increase in mean WOMAC score from 65.05 pre-op to 80.544, 79.994, 79.047 and 77.666 three, six, nine month and one year post-op respectively. Harald Hempfling (2006) [17] evaluated 80 patients and assessed that three month after arthroscopy the outcome to be considerably more favourable in the group with hyaluronic acid injection post arthroscopy (A+HA) compared to the group with arthroscopy alone (A)(82.5% compared to 65%).75% of A+HA group had good to very good global impression of treatment compared to 50% in A group. In our study 94.12% of the patients had good to very good outcome and 5.88% of the patients had fair outcome. Xinning li et al (2008) [19] studied 30 patients who underwent arthroscopic debridement by a single surgeon and concomitant delivery of 6 ml/90 mg HA. Pre-op average WOMAC pain score was 6.8 +/-. 3.5 (n = 30) with a reduction to 3.4 +/- 3.1 at 6 weeks (n = 27). Final average WOMAC pain score improved to 3.2 +/- 3.8 at six months (n = 23). No patients had deterioration of the WOMAC pain score. In our study also WOMAC score increased in all the patients but there was gradual decrease in WOMAC score from 3 month post-op to one year post-op. In our study there was significant increase in mean WOMAC score from pre-op to up to 1 year post-op. pre-operative mean WOMAC score was 65.040+/-1.907. Mean post-operative WOMAC score was 80.544+/-4.4407 at 3 month,79.994+/-4.7047 at 6 month,79.047+/-4.4992 at 9 month and 77.556+/-4.2972 at 1 year. Difference of mean WOMAC score according to Pre-op to Post-op up to 1 year was statistically significant (p=0.000). There was improvement of both symptoms (pain, terminal stiffness) and activity of daily living in all patients. There was inverse relationship between magnitude of pre-op WOMAC score and post-op improvement. Higher the score before operation there was less chance of improvement. In patients with high pre-op WOMAC score had less symptoms pre-operatively in contrast to radiological deformity. Subjective improvement of symptoms thus was less evident in patients with higher pre-op WOMAC score. It also shows that magnitude of symptoms does not correlate always with the magnitude of radiological deformity. Post-op rehabilitation was not properly followed by older patients as compared to younger patients. Thus WOMAC score increased in all the patients though increase in mean WOMAC score decreased with advancement of age of the patients. Increase in WOMAC score was slightly more for male patients but it was not significant. In two patients WOMAC score was not increased significantly. The cause of that was inadequate rehabilitation in these patients. One patient developed swelling of knee 3 month after operation for which aspiration of knee was done. This is a minimally invasive technique with less morbidity and cost effective in compared to TKR. There is less chance of infection and DVT. It is also a cost effective treatment compared to TKR. It can be repeated if required. In younger patient this procedure can buy some time before doing TKR. The limitation of our study is that we don’t have a large patient number in this study. So some results may differ from other studies. Another limitation of this study is there was no control group in this study. This study followed the patients for one year and the results of the above mentioned factors after one year of the surgery built up the postoperative values, which makes it a limitation for the study since long- term results might be different. Effectiveness of either arthroscopic debridement or injection of hylan polymer cannot be ascertained separately from this study.

Conclusion
In conclusion it can be said that arthroscopic debridement and lavage with intra-articular injection of hylan polymer is effective in symptomatic relief in osteoarthritis of knee and also improving quality of daily living in adjunct with post-op rehabilitation.

Conflict of Interest
The authors have no conflict of interest.

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