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FUNCTIONAL OUTCOMES IN THE MANAGEMENT OF EARLY OSTEOARTHRITIS OF THE KNEE JOINT TREATED BY ARTHROSCOPIC DEBRIDEMENT ALONE VERSUS COMBINATION OF ARTHROSCOPIC DEBRIDEMENT ALONG WITH INTRA-ARTICULAR HYALURONIC ACID OR INTRA-ARTICULAR HYALURONIC ACID ALONE



Orthopaedics

Dr. Devashis Barick

Department of Orthopedics, NKP Salve Institute of Medical Sciences, Digidoh Hills, Hingna Road, Nagpur 440019, Maharashtra, INDIA.

Dr. Utsav Agrawal*

Department of Orthopedics, NKP Salve Institute of Medical Sciences, Digidoh Hills, Hingna Road, Nagpur 440019, Maharashtra, INDIA. *Corresponding Author

ABSTRACT

To compare the outcomes of arthroscopic lavage with debridement and visco- supplementation of intraarticular hyaluronic acid versus arthroscopic debridement alone in early symptomatic osteoarthritis of the knee. Sample for the study include 60 patients (40 Male and 20 Female) aged >40 years. Referred to Orthopedics department, NKPSIMS and Lata Mangeshkar Hospital from central India Nagpur. The present study shows statistically significant differences in all areas of treatment of <0.05. This study concludes that combination of arthroscopic lavage with debridement and intra-articular hyaluronic acid visco-supplementation is a worthwhile procedure for providing symptomatic relief, with less operative risk and morbidity, providing significant improvement in function and quality of life over a long term, reducing the need for daily analgesics, and with a major difference with respect to expenses incurred in other procedures like arthroplasty, in management of patients with early osteoarthritis of knee joint. The above procedure is thus advisable in patients with early arthritis desiring a functional improvement of arthritic symptoms.

KEYWORDS

Visco-supplementation, Osteoarthritis Knee, Arthroscopic Debridement, Hyaluronic Acid

INTRODUCTION

Osteoarthritis of knee joint is one of the most prevalent chronic disabling diseases affecting the aging population.

Osteoarthritis is considered a spectrum of cartilage failure ranging from symptomatic focal chondral defects to established arthrosis.¹

Radiographically, osteoarthritis has long been graded according to the Kellgren-Lawrence (KL) radiographic grading scale, as follows.^{2,3,4}

Table No.1- radio-graphic Grading System For Osteoarthritis

GRADE	Classification	Description
0	Normal	No features of osteoarthritis.
1	Doubtful	Minute osteophyte, doubtful joint space narrowing.
2	Minimal	Definite osteophyte, definite joint space narrowing.
3	Moderate	Moderate osteophytes, moderate joint space narrowing.
4	Severe	Marked joint space reduction with subchondral sclerosis and cysts with large osteophytes.

The primary goal of treatment in osteoarthritis is the alleviation of pain, leading to an improvement in joint function and quality of life.

Patients with osteoarthritis are faced with significant morbidity, which leads to over-consumption of NSAIDs for symptomatic relief, which leads to several side effects while offering no regression in the progress of the disease.⁵

Treatment options for knee osteoarthritis include conservative therapies including education, weight loss, physical therapy, pharmacological therapies (analgesics, NSAIDs), intra-articular injections of corticosteroids, visco-supplements and surgical intervention e.g. arthroscopic lavage and debridement, meniscectomy, autologous chondrocyte implantation, OATS, and total or uni-compartmental knee arthroplasty.

AIMS & OBJECTIVES

The study consists of a systematic review of the available literature and a prospective randomized trial evaluating the functional outcome in the management of early osteoarthritis of the knee joint treated by five weekly doses of intra-articular hyaluronic acid visco-supplementation alone, OR arthroscopic debridement alone, OR combination of arthroscopic debridement along with five weekly doses of intra-articular hyaluronic.

MATERIALS AND METHODS

This institutional based randomized prospective comparative study was conducted after approval of the Institutional Ethics Committee.

During this period a total of sixty patients attending the out-patient department with complaint of pain in knee joint with radiologically proven osteoarthritis of the knee joints, for at least past 6 months and requiring consumption of analgesics regularly for relief of pain, with activity limitation, were enrolled into the study.

INCLUSION CRITERIA:

1. Age >40 years
2. either sex
3. Early osteoarthritis of knee joint – grade II and III Kellgren-Lawrence
4. No relief from routine analgesics and NSAIDs

EXCLUSION CRITERIA:

- Secondary arthritis
- Acute injury
- Varus or valgus >15° or instability
- Any other procedure or injections in the study knee
- Unfit for required anaesthesia
- Prior hyaluronic acid injections and/or hypersensitivity
- Not willing for required follow-up

All patients were evaluated clinically and radiographically.

GROUP SELECTION CRITERIA -

Randomization was done through simple random sampling using random chit method into three groups.

- **Group 1** – AL (Arthroscopic lavage) and VS (Visco-supplementation) - underwent arthroscopic lavage and debridement and were administered 5 weekly intra-articular injections of sodium hyaluronate.
- **Group 2** – VS - received 5 weekly intra-articular injections of sodium hyaluronate.
- **Group 3** – AL - underwent only arthroscopic lavage and debridement.

Pre-operative consent and anaesthesia fitness:

Routine pre-operative blood investigations and anesthetic assessment were obtained for all patients. All the patients were asked to not consume any kind of analgesics and non-steroidal anti-inflammatory drugs during the period of study.

OUTCOMES CONSIDERED

Only patient oriented outcomes were considered and analyzed.

Surrogate or intermediate outcomes were not considered.

Subjective scoring system was used to assess severity of osteoarthritis using Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).^{6,7,8} Base-line WOMAC score was recorded before intervention. WOMAC score in this study was expressed as a percentage with a score of 100 corresponding to the best function of knee and lowest possible score being 0.

The functional outcome for each patient was assessed at 3rd and 5th week and at end of 3rd and 6th month from the initiation of the treatment as per WOMAC score. Dropouts were excluded from the study.

Surgical Procedure – Arthroscopic Lavage And Debridement

40 patients enrolled under the study underwent arthroscopic debridement (group 1 and 3). Knee joint was thoroughly washed with at least 3 litres of normal saline and all loose bodies, debris was cleared. Fraying cartilage, meniscal fragments, synovial plicae and excess synovial tissue were debrided.

Arthroscopic grading of articular cartilage lesion was done according to Outerbridge Score.

Technique of Intra-articular Injection

Under all aseptic precautions, Intra-articular hyaluronic acid was administered at weekly intervals for 5 weeks in all 40 patients (20 after arthroscopic lavage and debridement and in 20 without arthroscopic lavage) through supero-lateral pole of patella with knee in 30° flexion.

Hyaluronic acid was administered using 2mL pre-filled sterile syringe, containing 5,00,000 to 7,30,000 Dalton (High Molecular Weight) hyaluronan.

POST-OPERATIVE PROTOCOL -

All patients under the study went through a similar post-intervention rehabilitation program.

STATISTICAL ANALYSIS

The obtained data was statistically analyzed by applying descriptive (Mean, Standard Deviation, Paired t-test, ANOVA) of significance of mean differences in term of various variables. We have entered all data and further Statistical Analysis was done with the help of IBM- SPSS-25 software.

OBSERVATION AND RESULTS

Represented in the following section are the results of the current study.

Table 2- Demographic Data (age Distribution)

Age range (years)	No. of patients (%)
40-50	17 (28.33)
51-60	34 (56.66)
61-70	7 (11.66)
>70	2 (3.33)
Total	60
Range	42-75
Mean±SD	54.96±7.23

Table 3- Demographic Data (sex Distribution) (n=60)

Sex	No. of patients (%)
Male	40 (66.66%)
Female	20 (33.33%)

Table 4- Demographic Data (side Affected) (n=60)

Side	No. of patients (%)
Left	25 (41.66%)
Right	35 (58.33%)

Table 5- Demographic Data (mean Kellgren Lawrence Grade) (n=60)

Kellgren Lawrence grade	No. of patients (%)
2	32 (53.33%)
3	28 (46.66%)
Mean±SD	2.46±0.503

Table 5a- Demographic Data (mean Kellgren Lawrence Grade In Three Groups) (n=20)

Groups	Mean±SD
Group I	2.50±0.51
Group II	2.45±0.51
Group III	2.45±0.51

It was found to be statistically NOT significant when compared with each other (p>0.05).

Statistical comparison of WOMAC score from baseline to final follow up of each group

Table 6 - (n=20) Statistical Significance Of Mean Womac Score From Baseline To Final Follow Up In Group I (ALVS)

Time intervals	Mean±SD	Statistical significance
Pre-intervention	56.79±10.70	
3 rd week	65.73±7.00	<0.001 Highly Significant
5 th week	68.83±7.19	<0.001 Highly Significant
3 rd month	71.06±5.28	<0.001 Highly Significant
6 th month	72.33±7.65	<0.001 Highly Significant

Table 6 shows that WOMAC score increased as the duration of follow-up increased.

Table 7- (n=20) Mean±sd Of Womac Score At Various Time Intervals In Group Ii (vs)

Time intervals	Mean±SD	Statistical significance
Pre-intervention	53.11±8.84	
3 rd week	58.08±6.56	<0.001 Highly Significant
5 th week	63.19±6.63	<0.001 Highly Significant
3 rd month	66.16±8.96	<0.001 Highly Significant
6 th month	64.40±7.76	<0.001 Highly Significant

Similarly Table 7 also shows that WOMAC score increased as the duration of follow up increased.

Table 8- (n=20) Mean±sd Of Womac Score At Various Time Intervals In Group Iii (al)

Time intervals	Mean±SD	Statistical significance
Pre-intervention	57.22±7.05	
3 rd week	67.31±6.28	<0.001 Highly Significant
5 th week	64.24±6.61	<0.001 Highly Significant
3 rd month	60.81±7.16	<0.05 Significant
6 th month	59.76±5.77	<0.05 Significant

In group III, there was an increase in WOMAC score till the 5th week which then showed a decline, with the score at 6th month being just over the baseline.

INTERGROUP COMPARISON

Table 9 - (n=20) Mean Comparison Of Womac Score Of Group I (alvs) Vs. Group Ii (vs)

Time intervals	Group I	Group II	Statistical significance
Pre-intervention	56.79±10.70	53.11±8.84	>0.05 Not significant
3 rd week	65.73±7.00	58.08±6.56	<0.001 Significant
5 th week	68.83±7.19	63.19±6.63	<0.01 Significant
3 rd month	71.06±5.28	66.16±8.96	<0.01 Significant
6 th month	72.33±7.65	64.40±7.76	<0.001 Significant

We found a significant difference at all the time intervals between two groups, with higher scores for patients in group 1, except only baseline period, where it was found to be non-significant (p>0.05).

Table 10 - (n=20) Mean Comparison Of Womac Score Of Group I (alvs) Vs. Group Iii (al)

Time intervals	Group I	Group III	Statistical significance
Pre-intervention	56.79±10.70	57.22±7.05	>0.05 Not significant
3 rd week	65.73±7.00	67.31±6.28	>0.05 Not significant
5 th week	68.83±7.19	64.24±6.61	<0.05 Significant
3 rd month	71.06±5.28	60.81±7.16	<0.001 Significant
6 th month	72.33±7.65	59.76±5.77	<0.001 Significant

We found no significant difference at baseline and 3rd week but from 5th week onwards we found significant difference with better score for group 1. At 3rd month and 6th month, we found highly significant

difference.

Table 11- (n=20) Mean Comparison Of Womac Score Of Group II (vs) Vs. Group Iii (al)

Time intervals	Group II	Group III	Statistical significance
Pre-intervention	53.11±8.84	57.22±7.05	>0.05 Not significant
3 rd week	58.08±6.56	67.31±6.28	<0.001 Significant
5 th week	63.19±6.63	64.24±6.61	>0.05 Not significant
3 rd month	66.16±8.96	60.81±7.16	<0.05 Significant
6 th month	64.40±7.76	59.76±5.77	<0.05 Significant

We found no significant difference at baseline & 5th week, but on 3rd week, 3rd and 6th month we found significant difference between Group II and Group III.

Table 12- Mean Outerbridge Score

Outerbridge score	Group I	Group II	Group III
Mean±SD	2.6±0.59	=	2.55±0.82

One-way ANOVA						
		Sum of Squares	df	Mean Square	F	Significance
Pre-intervention	Between Groups	203.913	2	101.956	1.261	.291
	Within Groups	4609.961	57	80.877		
	Total	4813.874	59			
3rd week	Between Groups	974.025	2	487.013	11.090	.000
	Within Groups	2503.149	57	43.915		
	Total	3477.174	59			
5th week	Between Groups	359.186	2	179.593	3.863	.027
	Within Groups	2649.661	57	46.485		
	Total	3008.847	59			
3rd month	Between Groups	1051.330	2	525.665	9.883	.000
	Within Groups	3031.811	57	53.190		
	Total	4083.142	59			
6th month	Between Groups	1617.277	2	808.639	15.934	.000
	Within Groups	2892.623	57	50.748		
	Total	4509.900	59			

By using Analysis of Variance (One-way ANOVA) above tables shows that only baseline WOMAC score of all the three groups did not show any significant difference. Rest all the time intervals clearly shows significant difference in all the three groups.

DISCUSSION

In the current study, the average age of the 60 patients was 54.96 years with 66.66% patients being males and 33.33% being females, with no specific side predilection.

Kellgren-Lawrence grading scale was used to assess the degree of osteoarthritis. Of the 60 patients under study, 32 had grade II Kellgren-Lawrence changes, 28 had grade III changes.

With exception of three patients, all patients had significant reduction of consumption of NSAID's and analgesics on long term.

Over all, the results of the current study indicate a superiority of arthroscopic lavage and debridement with visco-supplementation over arthroscopic debridement or visco-supplementation alone.

Also it was found that patients with lower radiographic Kellgren-Lawrence grades had better outcome at 6 months follow-up.

Arthroscopic Lavage And Debridement Group

In the arthroscopic lavage and debridement group, the mean pre-intervention score was 57.22. This improved to 67.31 at 3rd week and then showed a gradual decline to 64.24 at 5th week, 60.81 at 3rd month

and 59.76 at 6th month. Mean improvement over 6th month was 2.54. Of 20 patients who received arthroscopic lavage, 13 patients reported an improvement at 6th month while 7 had a decline in the WOMAC score.

Importantly all patients had significant symptomatic improvement at 3rd and 5th week.

The above results are in accordance with those of Jackson and Rouse⁹ who experienced early improvement in 88% and maintenance of improvement in 68%.

In our study 100% patients had early improvement while 65% retained this improvement over 6 months.

This view was also shared by Wai and co-workers¹⁰, and Hawker and colleagues¹¹ who reported a transient improvement of symptoms in patients of osteoarthritis knee and a delay in time to total knee arthroplasty.

A study by Steadman¹² reported a success rate of 71% at 2 years follow-up. Improvement in the WOMAC score at 3rd and 5th week was statistically significant.

Table No. 13. Average Improvement In Womac Score In Grade Two And Three Kellgren-lawrence :

Grade	3 rd week	6 th month
Grade II	10.59	4.63
Grade III	9.32	-0.61

The overall improvement was much more significant in grade II Kellgren-Lawrence which was 4.63 as compared to reduction in score by an average of 0.61 in grade III at 6th month, which was also reported by Ike et al¹³, & Aaron and colleagues¹⁴.

Spahn and colleagues¹⁵ in 2013, concluded that in middle stages of osteoarthritis, arthroscopic joint debridement can effectively reduce subjective complaints. They also concluded that because this treatment does not stop the process of osteoarthritis, the improvements decrease over time.

Finally, Experienced arthroscopic surgeons all over Europe believe arthroscopy in osteoarthritis is appropriate, under certain conditions. The major task for surgeons is to select the right patients who are likely to benefit from this intervention.¹⁶

Figuroa et al¹⁷ concluded that most patients with knee osteoarthritis associated with unstable cartilage reported good-to-excellent symptomatic results at the short- and mid-term follow-ups.

Intra-articular Visco-supplementation Group

Visco-supplementation came into vogue with the onset of use of orthobiologics in the treatment of orthopaedic diseases. Hyaluronic acid is considered as a first generation orthobiologic.

In the visco-supplementation group, the mean pre-intervention score was 53.11, which showed a gradual improvement over the study period of 6 months. Score improved to 58.08 at 3rd week, 63.19 at 5th week, 66.16 at 3rd month, which was sustained to 64.40 at 6th month.

These findings indicate a significant improvement at 5th week, which is sustained till at least 6 months. Maximum improvement in the score was observed at the 3rd month.

Over all average improvement at third week was 4.97 and at 6th month was 11.29. Of 20 patients, only one patient showed deterioration at third week and one at 6th month as compared to pre-intervention score.

These results were similar to results of Altman and Moskowitz¹⁸, who reported that 47.6 % patients were pain free at 26 weeks following 5 weekly doses of hyaluronic acid injection. Kotz and Lolarz¹⁹ reported 68% symptomatic relief at 4 weeks and 55% at 1 year.

In a recently concluded multicentre, double-blind, placebo-controlled AMELIA trial²⁰, which tested the efficacy of HA injections with a follow-up period of 40 months, it was found that patients receiving HA had significantly more relief and there was a carry over effect of these injection to 1 year post therapy.

Kusayama et al²¹ administered a course of 5 weekly HA injections in patients with symptomatic osteoarthritis and concluded that there was an improvement in pain score and range of motion in patients with osteoarthritis knee managed with visco-supplementation. They further noted a reduction in IL-6, chondroitin sulfates and improvement in quality of synovial fluid in patients who received HA injections.

The improvement was less significant initially and the relief improved over time with maximal improvement at 3rd month, which was also reported by Petrella et al.²²

Average improvement in patients with grade II osteoarthritis was 4.97 which was similar to improvement in grade III at third week. The improvement at 6th month was of an average of 11.82 in grade II and 10.64 in patients with grade III changes. See table no.14.

Table No. 14- Average Improvement In Patients With Grade II And Grade III.

GRADE	3 RD WEEK	6 TH MONTH
Grade II	4.97	11.82
Grade III	4.97	10.64

This difference was significant and goes on to shows that patients with grade II had more improvement as compared to grade III in the current study.

Also Evanich²³ reported a worse outcome, less relief, and increased number of procedures in patients with more severe osteoarthritis following intra-articular visco-supplementation.

In our study, 2 patients had acute exacerbation of symptoms following intra-articular injections, which resolved with appropriate treatment. Most patients were pain free from 5th week onwards, and rarely required rescue drugs for relief of symptoms.

This view was shared by Adams et al²⁴, who reported a superiority of Hyaluronic acid injections over NSAIDS in pain relief at 26 weeks follow-up.

The results of visco-supplementation in this group indicate that hyaluronic acid provides a significant relief of pain and improvement of symptoms in patients having early osteoarthritis of the knee joint. The relief offered has a gradual progression with time and is sustained for a period of at least 6 months. Hyaluronic acid supplementation can thus be used as a stand-alone therapy in the management of early osteoarthritis of the knee joint.

Arthroscopic Lavage And Debridement With Intra-articular Visco-supplementation

Finally in the patients receiving arthroscopic debridement and visco-supplementation, the mean score before debridement was 56.79 which showed a significant improvement to 65.73 at 3rd week, 68.83 at 5th week which was maintained at 71.06 at 3rd month and 72.33 at 6th months. The mean improvement in WOMAC score at 6th month was 15.54.

Hempfling²⁵, in his study which was published in 2007, compared functional outcomes in 80 arthritic knees, 40 of which received arthroscopic debridement and other 40 received visco-supplementation following debridement. The results demonstrated that post-arthroscopic instillation of visco-supplementation was a suitable was of achieving stabilization of treatment, which was similar to the findings of this study.

At the third week patients with grade II changes showed an average improvement of 17.48 and grade patients with grade III changes had an improvement of 11.03.

At 6th month, the improvement in patients with grade II changes was 20.54 and in patients with grade III changes was 10.49.

Table No. 15- Average Improvement In Patients With Grade II And Grade III On 3rd Week And 6th Months.

GRADE	3 rd week	6 th month
Grade II	17.48	20.54
Grade III	11.03	10.49

Both these differences were significant and indicate a significantly better functional outcome in patients with grade II changes as compared to grade III changes.

Li et in²⁶ 2008 studied 30 patients who underwent arthroscopic debridement and concomitant delivery of high molecular weight hyaluronic acid and concluded that combination of both procedures show efficacy in reducing WOMAC pain scores and improving SF-36 PCS scores over a six month period.

Zietz and Selesnick²⁷ concluded that Arthroscopy and visco-supplementation was more beneficial for those patients who desire to increase their activity levels than those who wish relief of pain.

INTERGROUP COMPARISON

As a prospective randomized comparative study, we sought to compare the outcomes of management of osteoarthritis by either of the three methods.

Comparison of group III with group II showed more improvement in group III group at 3rd week, no significant difference at 5th week, and significant improvement in group II group as compared to group III group at 6th month. These statistics indicate that though debridement has an early benefit as compared to visco-supplementation, this improvement is not sustained. The symptomatic relief offered by intra-articular visco-supplementation gradually improves over a course of time and are sustained for a longer duration.

Comparison of group I and group II showed statistically significant difference in both the groups at all follow-ups with more improvement and higher scores in group I.

This was also found in the study of 81 patients by Vad et al²⁸, who reported the success rate of visco-supplementation alone was 54 %, at 1.1 years after treatment while it was 79.5% when combined with lavage.

Comparison of group I with group III showed significant differences at 5th week, 3rd month and 6th month, with difference at 3rd and 6th month follow-up being highly statistically significant in favor of group I.

In a randomized controlled study by Westrich et al²⁹, they concluded that in patients with osteo-arthritis knee with meniscal tear, patients receiving arthroscopic surgery and visco-supplementation had better pain relief and functional benefit as compared to those who received arthroscopy alone. In a similar study by Westrich et al³⁰, who studied 46 patients, found similar results. Scores at 3rd week were not statistically significant.

The above results go on to prove that the early improvement achieved in group I is probably more due to the effects of arthroscopic debridement than the effect of intra-articular administration of hyaluronic acid.

From the fifth week the effects of arthroscopic debridement seem to fade off but there is sustained improvement in group I and II was is due to hyaluronic acid administration. As the exogenously administered hyaluronic acid is washed out of the knees in a few weeks, it is believed that the long-term relief may be due to stimulation of endogenous synthesis of hyaluronic acid as reported in a study by Smith and Ghosh³¹, where it was found that in cultures of arthritic human synoviocytes, exogenous hyaluronic acid stimulated the synthesis of endogenous hyaluronic acid.

CONCLUSION

The current study concludes that the results of arthroscopic debridement combined with five weekly doses of intra-articular hyaluronic acid visco-supplementation provides a better functional relief and improvement of symptoms in arthritic knees as compared to debridement or visco-supplementation alone. The symptomatic relief obtained following a combination of both the procedures was higher and for a longer duration as compared to debridement or visco-supplementation alone.

Arthroscopy alone provides a transient, short-lived improvement in symptoms, and can be used to examine the status of articular cartilage, to plan further procedures like micro-fracture, abrasion chondroplasty, autologous chondrocyte implantation etc., or radical surgeries

including uni-condylar or total knee arthroplasty, and patient wishing to delay a more radical procedure. Also arthroscopy can be aide in debridement of torn meniscal fragments, fibrillating cartilage and in removal of loose bodies providing some relief from symptoms.

In this study, we found that following visco-supplementation with hyaluronic acid, the improvement in symptoms was delayed in onset but the relief was sustained over a longer duration. Visco-supplementation can be carried out as an outpatient procedure. If carried under strict aseptic precautions, the procedure is not associated with significant adverse reactions or side effects, and is a cost-effective procedure. Visco-supplementation can thus be used as a worthwhile procedure in patients with early osteoarthritis of the knee joint, alone as well as in combination with arthroscopic debridement.

It was also noted that all the patients undergoing arthroscopic debridement and/or visco-supplementation had a significant reduction in consumption of analgesics for pain relief.

Two patients had acute exacerbation of symptoms following hyaluronic acid injections, which subsided with appropriate treatment. Apart form this there were no complications following either arthroscopic procedure or intra-articular injection.

The study also concludes that the improvement following arthroscopic debridement and/or Hyaluronic acid visco-supplementation is dependent on the stage of osteoarthritis, with higher grades showing less improvement in WOMAC score.

This study concludes that combination of arthroscopic debridement and intra-articular hyaluronic acid visco-supplementation is a worthwhile procedure for providing symptomatic relief, with less operative risk and morbidity, providing significant improvement in function and quality of life over a long term, reducing the need for daily analgesics, and with a major difference with respect to expenses incurred in other procedures like arthroplasty, in management of patients with early osteoarthritis of knee joint. The above procedure is thus advisable in patients with early arthritis desiring a functional improvement of arthritic symptoms without undergoing the morbidity of an arthroplasty.

LIMITATION -

Further studies involving a larger population under study and longer follow-up period are needed to evaluate the outcomes of arthroscopic debridement combined with intra-articular hyaluronic acid visco-supplementation in early osteoarthritis of the knee joint.

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Conflict Of Interest- The authors declare that they have no conflict of interest.

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