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Comparison of anterior cruciate ligament reconstruction with and without concomitant meniscal repair: A prospective comparative study

Ashish Arya[1], Dheepan Kumar S[2], Rajkumar V[3] and Ram Sudhan S[4,*]

[1]Department of Orthopaedics, Kalpana Chawla Government Medical College, Model town, Karnal, Haryana 132001, India
[2]Department of Orthopaedics, Velammal Medical College Hospital, Madurai, Tamil Nadu 625009, India
[3]Department of Orthopaedics Govt. Medical College and Hospital, Omandurar Government Estate, Chennai -600002, India
[4]Department of Orthopaedics, PK DAS Institute of Medical Sciences – Hospital and Medical College, Vaniamkulam, Ottapalam, Kerala 679522, India

Abstract

Background: The treatment of anterior cruciate ligament (ACL) injury includes ACL reconstruction (ACL-R) or ligament preservation, where the former is considered the gold standard. But in meniscal injury, though commonly followed is menisectomy, meniscal repair has gained popularity and success which necessitates the analysis of outcome between ACL-R + meniscal repair and ACL-R + menisectomy as clear consensus have not been established so far in deciding the better overall procedure with respect to function.

Methods: This is a prospective, comparative study done in 122 patients with ACL injury and medial/ lateral meniscus in south Indian population at a single center. Where meniscal repair (61) and menisectomy (partial/complete, n=61) with ACL-R were carried out and were evaluated pre-operatively, during the postoperative period at 6 weeks, 3 months, and 6 months of follow-up for function and compared. The primary outcome evaluated was pain and other symptoms like limping, giving way, swelling and locking were also noted and analysed using KOOS, IKDC and Lysholm scores.

Results: The mean difference in KOOS score in postoperative period, at 3 and 6months were significantly higher among the ACL-R + meniscal repair group than the ACL-R + meniscectomy group which is statistically significant. Moreover the median percentage change in IKDC and Lysholm scores from baseline to postoperative 3 and 6 months were significantly higher in ACL-R + meniscal repair group than the other.

Conclusion: The meniscal repair with ACL-R has a lower failure rate and shows better functional outcomes than the other group which underwent ACL-R and meniscectomy.

Keywords: anterior cruciate ligament reconstruction; ACL-R; meniscectomy; meniscal repair; meniscal tear

Introduction

Injuries around the knee joint are commonly encountered in the practice of orthopaedics. Of all the knee injuries, ligamentous injuries contribute around 34 to 48%, and anterior cruciate ligament (ACL) happens to be the most commonly injured among them [1]. The anterior cruciate ligament combined with others acts as the "primary stabilizer of the knee", thereby preventing anterior translation, and a certain degree of rotational stress and restricting the valgus [2]. Hence when an injury to the anterior cruciate ligament occurs, it opens a pathway of events resulting in certain changes in the

***Corresponding author:** Dr. Ram Sudhan S, D'Ortho, DNB (Ortho), MNAMS, MIMSA. Assistant Professor, Department of Orthopaedics, PK DAS Institute of Medical Sciences – Hospital and Medical College, Vaniamkulam, Ottapalam, Kerala 679522, India. Email: sudhansubramaniam@gmail.com

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knee like instability leading to pain and reduced knee function. Even though, conservative management like bracing, physiotherapy, and lifestyle modifications can be tried in young active individuals, in the majority of cases "Anterior cruciate ligament reconstruction (ACL-R)" is necessary [3]. The gold standard treatment for ACL rupture is the Arthroscopic reconstruction of ACL. Open reconstruction is not widely practiced nowadays because of the associated post-operative pain, stiffness, and prolonged rehabilitation phase [4]. Before deciding upon the management protocol, various characteristics of the injuries should be taken into account. Literature has shown that meniscal tears are the commonest injury among the other injuries associated with ACL tears. If the meniscal injury is not addressed properly, it can lead to early-onset knee osteoarthritis [5]. In a study done by Warren et al the prevalence of medial meniscus injury in chronic ACL injury was found to range between 90 and 98% [6]. It was also shown that radiographic signs of osteoarthritis of the knee are more common among those with ACL rupture along with meniscal tear than with ACL rupture alone without any correlation with symptoms. Medial meniscus deficiencies may result in ACL failure, resulting in OA and general weakness of the knee. Studies have probed the value of meniscectomy in isolated meniscal injury, as meniscal repair can lead to improved patient outcomes and enhanced laxity scores than meniscectomy [7]. Yet, there is strong evidence, which suggests that there are increased re-surgery rates after meniscal repair than meniscectomy (16.5 –20.7% versus 1.4–3.9% respectively) [8]. Spang et al have shown that medial meniscectomy can lead to knee instability, resulting in increased stress forces in ACL reconstruction, specifically when the anterior-posterior translation is considered [9]. Whether meniscal repair/meniscectomy has an altering effect on simultaneous ACL reconstruction is unclear. We aimed to compare the functional outcomes in patients undergoing ACL-R + meniscectomy with that of those undergoing ACL-R + meniscal repair and to compare the functional outcomes of meniscus preserving surgeries with that of partial meniscectomy.

Patients and methods

This was a prospective, comparative study conducted in the Department of Orthopaedics at Velammal Medical College and Hospital, Madurai, Tamil Nādu from June 2018 to Oct 2020. The study was approved by the Ethical committee and scientific committee of the Institutional Review Board of Velammal Medical College and Hospital. Patients with acute knee injuries involving the anterior cruciate ligament and medial/lateral meniscus were included in the study with informed and written consent from all the study participants and the study was carried out by relevant guidelines and regulations based on the Declaration of Helsinki.

Inclusion criteria: (1) Patients aged between 18 and 55 years whose symptoms interfered with their daily routine activities, (2) Patients who had knee instability clinically with MRI findings of ACL injury associated with meniscal injuries, (3) Patients with stable vital signs and without any organ dysfunction (in the heart, liver, or kidney) complicating the surgery, (4) Patients who were willing for surgery and participate in the study.

Exclusion criteria: (1) Patients who had ACL injuries with fracture avulsions or associated intra-articular or condylar fractures, (2) Patients with multi-ligamentous injuries on the knee, (3) Patients who are a known case of pre-existing, congenital, developmental, or collagen diseases, (4) Patients who had signs of infection.

Sample size

Based on the median and quartiles of fundamental outcome KOOS-sports/Rec in isolated ACL-R group, 40(20,65) and ACL-R with meniscal repair 35(15,35) in injuries of knee joint patients observed in an earlier publication and with 95% confidence and 80% power, minimum sample size comes to 61 per group and totaling to 122. Out of a total of n=122 cases, n=61 each was allotted to ACL-R + menisectomy (partial/complete) and ACL-R + meniscal repair as shown in Figure 1.

The outcome was evaluated by comparing pain (frequency, severity), presence of other symptoms (limp, giving way, swelling, locking), function in daily living, function in sport and recreational activities, and knee related quality of life using Knee injuries and Osteoarthritis Outcome Score (KOOS), International Knee Documentation Committee (IKDC) score and Lysholm scores pre-operatively and post-operatively at 6 weeks, 3 months and 6 months on follow up. The functional outcome of those cases with ACL-R with meniscectomy (partial & complete) was compared with those who underwent ACL-R with meniscal repair.

Anterior cruciate ligament reconstruction

The surgery was performed by standard methods under general or regional anesthesia with a tourniquet applied. The patient was positioned supine on the operating table with the knee flexed to less than 90 degrees. A linear incision was made, measuring about 4 cm, over the medial aspect of the proximal third of the leg 4cm distal from the joint line, and 3 cm medial to the tibial tuberosity. Soft-tissue dissection was done and pes anserinus was exposed. The sartorial fascia was incised

to expose the insertion of the tendons. The insertion of the semitendinosus tendon was released, and it was held with a right-angled thermostat. Tendon was harvested with the help of a stripper which was advanced into the thigh along the tendon with a gentle pull until it was detached from the muscle. The tendon was folded to attain the triple or quadruple configuration and the ends were sutured by Krakow stitches. The size of the

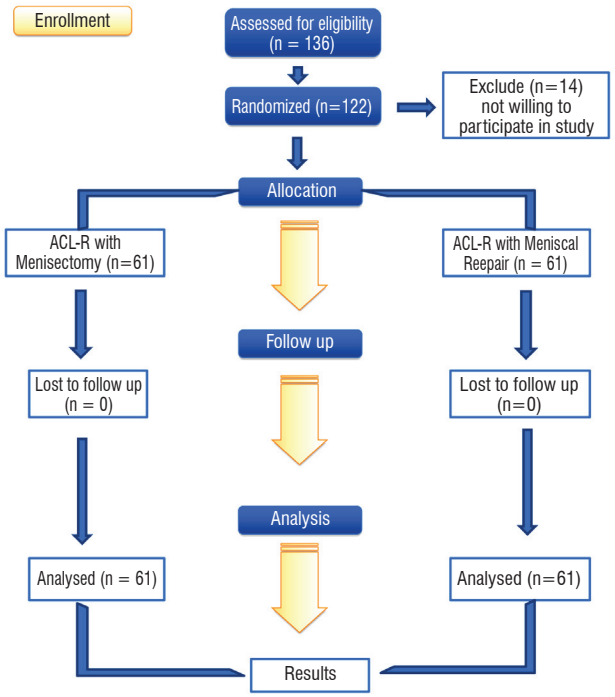

Figure 1: Consort flow diagram showing flow of patients through the study tendon was measured, and it was preserved in a wet mop containing a mixture of saline and vancomycin.

Standard anteromedial and anterolateral portals were made, and diagnostic arthroscopy was performed. Through the medial portal, the femoral tunnel was drilled first after passing the guide pin with a 5mm drill bit piercing the lateral cortex of the femur. A second drill was performed for 15mm only which was the length of the graft that should be present inside the femoral tunnel. The tibial tunnel was drilled in the center of the footprint of the native ACL. A drill of size equal to the width of the graft was used. The graft with the adjustable loop device was passed through the tibial tunnel into the joint and then into the femoral tunnel. The adjustable loop button was maneuvered and flipped such that it is flush against the lateral condyle of the femur. An "interference screw" was used for the tibial fixation of the graft.

Meniscectomy

In this group, meniscal excisions are categorized into 3 subgroups: Partial meniscectomy, subtotal meniscectomy and total meniscectomy. Partial meniscectomy is preferred over the other 2 techniques. The objective here is to remove the unstable, torn fragment alone and contour the stable and balanced peripheral rim of meniscal tissue. It is vital to carefully probe and classify the lesion before deciding on the procedure. The excision can be performed either as en-bloc resection or by morselization and removal of the unstable fragment of which the former method is preferred.

Meniscal repair

Arthroscopic meniscal repair is done on another group where the indications can be broadly divided into patient factors and characteristics of the tear itself. Active patients less than 40 years of age, BMI of less than 30, no significant co-morbidities, and willingness to comply with post-operative rehabilitation protocol are patient factors favoring this procedure. Simple tears, tears in the red-red zone, tears that are less than 3 months old, and those that are associated with ACL tears are scenarios where this technique is indicated.

Arthroscopic meniscal repairs can be divided into 4 categories: inside-out repairs, outside-in repairs, all-inside repairs, and hybrid repairs. In the inside-out technique, the sutures are introduced from inside the knee, and they are knotted onto the joint capsule. Tears involving the middle and posterior thirds of the meniscus are suitable for repair by this method. In the outside-inside technique, the suture is inserted from outside to inside the joint penetrating the meniscal rim and the torn fragment. A vertical mattress suture is used to repair the torn meniscus. The all-inside technique uses the same principles as the inside-out technique. Here, various suture-based fixators are used for repair.

Rehabilitation protocol

Anterior cruciate ligament reconstruction Stage 1: From the day of surgery to 2 weeks, the patient is allowed to weight bear as tolerated with a motion control brace applied to the knee and locked in full extension. Active knee flexion from 0 to 90 degrees is started. Isometric quadriceps exercises and straight leg raises are also initiated. Stage 2: Between 2 to 4 weeks period, the patient is allowed full weight-bearing ambulation with a motion control brace. A full range of movements of the knee joint is encouraged. The goal of physiotherapy during this period is to achieve 120 degrees of knee flexion by the end of 4 weeks. During the 4 to 6 weeks period, gradual progression to the full range of movements is completed by 6 weeks. The patient continues full weight-bearing ambulation. We begin Kin-Com isokinetic hamstring progression and Kin-Com dynamometer quadriceps work 90 to 40 degrees isotonic with an anti-shear pad. Slow-form running

with sports cord, and isokinetic quadriceps work at different speeds is commenced between 8 to 10 weeks post-surgery. Stage 3: 12 to 16 weeks full range isotonic exercises on Kin-Com dynamometer. Knee extension machine with low weight/ high repetitions. Lateral sport cord drills. Progress isokinetic quadriceps to full extension by 16 weeks. Stage 4: 16 to 18 weeks: Kin-Com dynamometer test for quadriceps, retest hamstrings if necessary. Begin plyometric program. Begin jogging program if quadriceps strength is 65%. Stage 5: 5 to 6 months of Agility training. Sport-specific drills. Retest quadriceps if necessary. Stage 6: 6 months Return to sporting activities if motion is more than 130 degrees, hamstring power more than 90 degrees, quadriceps power more than 85 degrees.

In the menisectomy group

For the first 48 hours, partial weight-bearing with crutches is allowed until the patient is comfortable. Range of motion exercises, straight leg raises, and ankle pumps are started in the recovery room itself. By 3 to 4 weeks, return to sporting activities is allowed.

In the meniscal repair

A knee immobilizer is applied for 7 to 10 days post-surgery. Range of motion exercises began from 20 to 80 degrees. Touchdown weight-bearing for the first 2 weeks, partial weight-bearing between 2 to 4 weeks, and full weight-bearing at 4 to 6 weeks. Return to sports allowed by 4 to 6 months.

Availability of data and materials: All data generated or analyzed during this study are included in this published article (and its supplementary information files) and any further requirements can be submitted on reasonable request by the corresponding author.

Statistical analysis

The collected data were checked for completeness before entering the Microsoft Excel spreadsheet. The validation of the data was checked at regular intervals. Data analysis was performed to treat the approach using Statistical Package for Social Sciences (SPSS IBM) 21. The quantitative data were expressed in frequency and percentage. To test the statistical significance of the difference in the mean of continuous functional outcome between 2 groups, the student's t-test/ Kruskal Wallis test was applied, and the statistical significance of the difference in the proportion of categorical factors between 2 groups, the Chi-square test was used.

Results

The majority of the study participants in both groups belonged between 21 to 40 years of age. There was statistically no significant difference in the age class between the two groups. Hence, the two groups are comparable as depicted in Table 1. Out of n=61 cases in ACL-R + Menisectomy, n=50(81.96%) were males and n=11(18.03%) were females. Similarly, in the ACL-R + meniscal repair group, n=49(80.32%) were males and n=12(19.67%) were females.

Table 1: Comparison of age among the study participants.

Age in years	*ACL-R +meniscectomy n=61*	*ACL-R + meniscal repair n=61*	*p value*
	Frequency (%)	*Frequency (%)*	
18 – 20	5(8.2%)	4(6.6%)	
21 – 40	40(65.6%)	43(70.5%)	0.675
41 – 50	16(26.2%)	14(22.9%)	

In our study, the pre-operative KOOS score in ACL-R + meniscal repair group was slightly lower than the ACL-R + menisectomy group. The Mean difference of KOOS score in the postoperative period and at 6 weeks, and 3 months were significantly higher among the ACL-R + meniscal repair group than the ACL-R + menisectomy group which is statistically significant (p value<0.001 and p value=0.004 respectively) as depicted in table 2. Yet there is no statistically significant difference in the KOOS score at 6 months postoperatively between the two groups (p value = 0.543).

Table 2: Comparison of KOOS score between groups.

KOOS score	*ACL-R + meniscectomy*		*ACL-R + meniscal repair*		*p value*
	Mean ± SD	*Median (IQR)*	*Mean ± SD*	*Median (IQR)*	
Pre-operative	37.23 ± 6.89	36(33-43.5)	29.33 ± 6.74	30(26-33)	<0.001*
6 weeks post-operative	42.22 ± 6.98	44(38-46)	32.84 ± 10.0	30(25-39)	<0.001*
3 months post-operative	68.72 ± 5.05	68(66-71)	65.52 ± 4.93	66.7(63-70)	0.004*
6 months post-operative	78.36 ± 5.22	78(74-81)	78.55 ± 3.68	78(76-81)	0.543

In comparison, the median percentage change of KOOS score at 3 and 6 months after the surgery between the two groups (Table 3) shows a significant statistical change with a p value <0.001(at both 3 and 6 months).

Table 3: Comparison of percentage change of KOOS score from the pre-operative to the different postoperative periods between the two groups.

KOOS score	*ACLR+ Repair*		*ACL-R + Meniscectomy*		*p value*
	Median	*IQR*	*Median*	*IQR*	
Pre-operative- 6 weeks post-operative	10	(23.3,6.7)	13.6	(33.3, 5.0)	0.184
Pre-operative-3 months post-operative	126.7	(159.3, 95.4)	88.2	(106, 62)	<0.001*
Pre-operative-6 months post-operative	161.3	(221.6, 136.4)	113	(138.2, 88.3)	<0.001*

* Significant

The mean and median IKDC score during the 6 weeks postoperative period was significantly higher among ACL-R + meniscectomy group than the other group (p = 0.004). However, the mean IKDC score during the 3 and 6 months postoperative period was significantly higher among ACL-R + meniscal repair group than the ACL-R + menisectomy group (p = <0.001) as shown in Table 4. The Median percentage change of IKDC score from baseline to 3 and 6 months after the surgery in the ACL-R+ menisectomy group was 140.7(200, 110) and in ACL-R + meniscal repair was 164.3(227.3, 137.5). The change was high in the ACL-R + meniscal repair, which is statistically significant (p value=0.005) as depicted in Table 5.

Table 4: Comparison of IKDC score at different time points between the groups.

IKDC score	*ACL-R + meniscectomy*		*ACL-R+meniscal repair*		*p value*
	Mean ± SD	*Median (IQR)*	*Mean ± SD*	*Median (IQR)*	
Pre-operative	26.37± 7.56	27(20,31)	25.08± 6.28	25.6(22,29)	0.389
6 weeks post-operative	33.92± 5.96	34(31,36.5)	31.74± 8.09	30(26,34)	0.004*
3 months post-operative	63.15± 6.36	64(58,67.5)	67.90± 5.22	68.4(65,72)	<0.001*
6 months post-operative	77.19± 6.62	78(71,82.2)	82.00± 3.56	81(79,84)	<0.001*

* Significant

Table 5: Comparison of percentage change of IKDC score from the pre-operative to the different postoperative period between groups.

IKDC score	*ACL-R+ meniscectomy*		*ACL-R + meniscal repair*		*p value*
	Median	*IQR*	*Median*	*IQR*	
Pre-operative- 6 weeks post-operative	33.3	(63.9, 11.1)	22.2	(51.9,0)	0.156
Pre-operative-3 months post-operative	140.7	(200, 110)	164.3	(227.3, 137.5)	0.005*
Pre-operative-6 months post-operative	140.7	(200, 110)	164.3	(227.3, 137.5)	0.005*

* Significant

The mean and median difference in Lysholm score was significantly higher in the ACL-R + meniscectomy group during the 6 weeks postoperative period, which is statistically significant (<0.001) as depicted in Table6. Meanwhile, there is no statistically significant change in (both mean and median), the Lysholm scores at postoperative 3 and 6 months between the two groups.

Table 6: Comparison of Lysholm score between the two groups.

Lysholm score	*ACL-R + meniscectomy*		*ACL-R + meniscal repair*		*p value*
	Mean ±SD	*Median/IQR*	*Mean ±SD*	*Median/IQR*	
Pre-operative	35.78±8.05	36(30,40)	28.54±6.48	28(25,89)	<0.001*
6 weeks post-operative	48.98±7.66	51(46,54)	41.11±12.5	36(30,51)	<0.001*
3 months post-operative	73.00±4.63	73(70,75)	73.41±4.29	73(70,77)	0.604
6 months post-operative	85.29±5.19	84(81,89)	85.90±3.95	86(83,89)	0.349

* Significant

The median percentage change of Lysholm scores from baseline to 3 and 6 months after the surgery was higher in ACL-R + meniscal repair group than the ACL-R + menisectomy group and is statistically significant (p value<0.001) as shown in Table 7.

Table 7: Comparison of percentage change of Lysholm score from the pre-operative to the different postoperative periods between groups.

Lysholm score	*ACL-R+ meniscectomy*		*ACL-R + meniscal repair*		*p value*
	Median	*IQR*	*Median*	*IQR*	
Pre-operative to 6 weeks post-operative	40	(63.5, 22.8)	28.6	(94.8, 1.7)	0.678
Pre-operative to 3 months post-operative	101.7	(138.7, 77.6)	153.6	(190.3, 136)	<0.001*
Pre-operative to 6 months post-operative	141.7	(178.3, 110)	210	(239.7, 164.7)	<0.001*

* Significant

Discussion

Active patients with anterior cruciate ligament tears are mostly disturbed by the frequent episodes of giving way and chronic instability leading to intra-articular injuries. The timing of the ACL reconstruction is important. It has an impact on the functional outcome of the surgery. If there is a delay in reconstruction and an increased level of activity along with the presence of symptomatic anterior cruciate ligament deficiency, the consequential chronic state may result in a varied clinical entity than existed with the acute deficiency of anterior cruciate ligament. Progressive instability and subsequent loss of secondary static restraints result due to a delay in surgery. The prevalence of concomitant meniscal injury with an ACL tear is different for the medial and lateral, because of the different mechanisms of injury in respective compartments. Tears of the menisci happen in around 16% - 40% of patients with an acute knee injury and the prevalence is higher among those with an associated rupture of the ACL [10]. The present study compared the functional outcome of ACL-R + meniscal repair with that of ACL-R + meniscectomy.

A clear majority of the participants involved in our study in both groups belonged between 21 to 40 years of age. Similarly, in a study done by Pathak et al [11] it was shown that the range of age was from 17 to 44 years and the mean age of the study population was 29.1 years. Our study also shows that the majority of the study participants were males (80.15%)., which is similar to a study done by Schurz et al [12] which showed 67.08% of males in the study participants. This might be due to their greater exposure to athletic tasks, while in athletes, females predominate ranging from 2:1 to 9:1and is considered due to the contribution of a variety of determinants including neuromuscular control, hormonal causes, biomechanical factors, and magnitude and timing of muscle activation [13].

The present study has shown that the mean KOOS score difference in the ACL-R + meniscectomy and ACL-R + meniscal repair in the postoperative period, 6 weeks, 3, and 6 months respectively was - 4.99 ± 7.55 vs -3.51 ± 7.03, -31.49 ± 6.02 vs -36.19 ± 7.5 and - 41.13 ± 5.78 vs -49.23 ± 6.67. Thus, the mean difference in the postoperative period, 6 weeks, 3 months, and 6 months were significantly higher among the ACL-R + meniscal repair group than the ACL-R +/- meniscectomy group. Svantesson et al stated that the KOOS symptom score was significantly higher among the isolated ACL reconstruction group than the meniscal resection or repair group [14]. However, the KOOS pain score was higher among the meniscus resection group than the isolated ACL reconstruction and meniscal repair group. This study was done with a follow-up period of 6 months. Samuelsson et al the follow-up for 2 years showed similar reports [15]. Besides, this has shown significant differences occur concerning the variation in the KOOS improvement in the first year. Terry et al [16] showed that at 5 years, the KOOS symptoms, pain, sports, QoL, activities daily living sub score, aggregate KOOS score, and Lysholm score were significantly lower in the ACL-PLC group. Similarly, a study done by Phillips et al [17] has shown that meniscus resection had a significantly poor outcome for KOOS Symptoms in both lateral and medial meniscus resection. KOOS QoL subscale had significantly poor results in meniscal resection. The results did not have any significant difference between the isolated ACL reconstruction and the combined meniscal repair group.

The present study has shown that the mean IKDC score difference in the ACL-R +/- meniscectomy and ACL-R + meniscal repair in the postoperative period, 3 and 6 months respectively was -7.55 ± 6.19 vs -6.6 ± 8.98, -36.79 ± 6.53 vs -42.82 ± 6.61 and -50.82 ± 6.23 vs -56.92 ± 6.17. The mean IKDC score during the immediate postoperative period was significantly higher among ACL-R +/- meniscectomy than the other group (<0.001).

However, the mean IKDC score during the 3- and 6-months postoperative period was significantly higher among ACL-R + meniscal repair group than the ACL-R +/- meniscectomy group. A study done by Pathak et al [11] showed that the mean IKDC score preoperatively was 38.46, which got a significant improvement to 80.3 at their final follow-up.

However, a study done by Lee et al has shown that both meniscectomy and meniscal repair groups had significant improvement in mean IKDC scores in the postoperative period when compared with that of the pre-operative scores [18]. The mean IKDC scores in the meniscectomy group increased from 46.6 to 81.7 and the mean IKDC score in the meniscal repair group increased from 45.9 to 84.40. Our study has shown that the mean Lysholm score difference in the ACL-R + meniscectomy and ACL-R + meniscal repair in the postoperative period, 3 and 6 months respectively was -13.19 ± 9.75 vs -12.58 ± 14.83, -37.22 ± 7.93 vs -44.88 ± 7.25 and -49.51 ± 9.05 vs -57.36 ± 7.51. The mean difference in Lysholm score was significantly higher in the ACL-R +/- meniscectomy group during the immediate postoperative period (<0.001). However, the mean difference in Lysholm score was significantly higher in ACL-R + meniscal repair group during the 3- and 6- months postoperative period. Similarly, a study by Basar et al [19] has shown that the Lysholm score was better among the meniscal repair group than the meniscectomy group. The partial meniscectomy group had a mean preoperative Lysholm score of 41.36 ± 11.99, while the mean postoperative mean Lysholm knee score was 90.56 ± 6.20. Meniscal repair patients had a mean preoperative Lysholm knee score of 47.29 ± 9.67, while the mean postoperative Lysholm knee score was 95.06 ± 5.70. However, a study done by Yang YP et al [20] showed no variation in Lysholm score improvement. The pre-operative Lysholm score was 61.50 and 50 in the meniscal repair and partial meniscectomy group and the postoperative score was 95 in both groups.

Limitations: Lack of blinding and short follow-up period are major limitations in our study especially on the outcome, yet the sample size and patient reported scores of the outcome, standardize the result and might decrease the magnitude of these biases as well. Studies with much larger sample size and a follow up of more than 5 years might prove the long term results along with complications.

Conclusion

The copious growth factors and blood, moderately limited physical activity, and reduced rehabilitation are the well-documented advantages of concomitant ACL-R with meniscal repair. However, literature reporting the functional outcomes following ACL-R with concomitant partial meniscectomy and meniscal repair is still relatively restricted. The available body of evidence has shown that meniscal repair with ACL reconstruction has a lower failure rate. Our study has shown that the functional outcomes are better in the group undergoing ACL-R + meniscal repair than the group which underwent ACL-R + meniscectomy and that meniscus-preserving surgeries have superior outcomes to those involving meniscectomy.

Conflicts of interest

Authors declare no conflicts of interest.

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