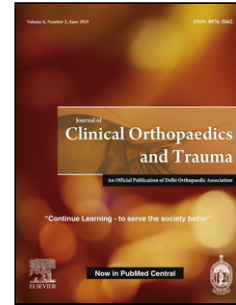


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Title of the article: Comparison of Patellar Tendon versus Hamstrings autografts for anterior cruciate ligament reconstruction in Indian population: A Randomised control Trial study.

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Introduction:

The Anterior Cruciate Ligament (ACL) is critical to the normal functioning of the knee.¹ Reconstruction of the ACL allows the patient to resume sporting activities and prevents damage in meniscus and articular cartilage in turn reducing chances of arthritis.^{2,3,4} Currently, ACL reconstruction is most often performed using an arthroscopic assisted technique⁵. For the past three decades, the gold standard in ACL reconstruction has been the patellar tendon graft from the middle third of the patella tendon⁶, but increasingly the combined semitendinosus and gracilis tendons (QHT) graft is being used. This shift in popularity has occurred for several reasons: concerns in BPTB about damaging the knee extensor apparatus, the potential for subsequent patellofemoral joint pain, patella fracture,

patella tendon rupture, and infra patella tendon contraction⁷. Also there are some potential but minor possible issues in QHT group like paresthesia over anterolateral aspect of upper leg, premature amputation of graft while harvesting. Although several studies have published long-term results of ACL reconstructions, the outcomes reported have not consistently demonstrated the superiority of one technique over the other. This prospective, randomized clinical trial aimed to compare bone-patellar tendon-bone (BPTB) graft and four-strand semitendinosus-gracilis tendons (QHT) graft for ACL reconstruction in Indian population with complete tear of ACL. Comparisons were made over a one-year period and consisted of return to pre-injury level of sporting activity, pain, knee stability, range of motion, Lysholm score, Cincinnati score and complications.

The appropriate consent was taken from all the patients in the study stating their wilful participation and no objection in using/publishing their clinical and scientific data for publication in scientific journal without revealing their identity.

Material and Methods:

This is a prospective study where patients were selected from the sports medicine OPD with inclusion criteria: age group 17 to 45 years, symptomatic with clinical instability of the knee following ACL injury with or without associated meniscal injury and/or medial collateral ligament injury (grade 1 and 2). Exclusion Criteria: Age <17 years and > 45 years, ACL injuries associated with femoral or tibial fractures, or injury to other ligaments like posterior cruciate ligament, lateral collateral ligament or medial collateral ligament (grade 3), bilateral knee involvement, patients with other pathologies in the involved knee like osteoarthritis, rheumatoid arthritis and osteochondral defects and those not willing to participate. There were 56 patients who qualified according to the inclusion criteria but only 42 patients consented to be included in this study. These patients were randomized into two groups by pick and draw method. BPTB autograft was used in 21 patients and in rest 21 patients, four

strand QHT autograft was used. One patient from the BPTB group had an accident 2 months post surgery resulting in a traumatic rupture of the graft and 3 months later he had a second procedure for reconstruction. One patient from the QHT group was lost after second follow-up. These patients were excluded from the study. Hence, the study is based on observation of 40 patients who were followed upto a period of one year.

Surgical Procedure

BPTB graft : A 10 mm wide bone-patellar tendon bone graft was harvested from the central third of the tendon of the ipsilateral knee with 20 to 25 mm of bone plug from the patella and tibial tuberosity using saw and preventing overshoots (fig1). The femoral tunnel was drilled over femoral guide (smith and nephew, USA) through AM portal to give 2 mm posterior cortical rim to the femoral tunnel according to the size of bone plug. Similarly, tibial tunnel was drilled placing pin in-line with posterior margin of anterior horn of lateral meniscus in the foot print of old ACL. The graft was seated such that the bone plug are fully accommodated in the respective tunnel. The femoral end was secured by a interference screw via anteromedial portal followed by tensioning of graft and fixing the tibial end by interference screw under tension in 30° of flexion.

QHT graft: Oblique incision on anteromedial aspect of upper tibia 2 cm distal to tibial tuberosity was used to expose the pes attachment. The Semi T and Gracilis tendons were identified and lifted from the bed and secured with whipstitch using No 2 Ethibond (fig 2) Closed end tendon stripper was used to harvest the graft which was quadrupled over an endobutton. The endobutton was secured in femoral tunnel such that at least 20 mm of graft was inside the tunnel. Rest of the procedure i.e. cycling, tensioning, fixing of tibial side with RCI interference screw remained the same.

Follow up

Regular follow up of each patient was done at 14 days, 6 weeks, 3 months, 6 months and 1 year. Post-operative complete instability assessment of the patients was performed with Lachman, Anterior drawer and Pivot shift test while functional progress was evaluated by Lysholm and Cincinnati score.

Statistical methods

Statistical testing was conducted with the statistical package for the social science system version SPSS 17.0. Continuous variables are presented as mean \pm SD, and categorical variables as absolute numbers and percentage. The comparison of normally distributed continuous variables between the groups was performed using Student's t test. Nominal categorical data between the groups were compared using Chi square test or Fisher's exact test as appropriate. $P < 0.05$ was considered statistically significant.

Results

The mean age of participants in both the groups was similar, 25.90 ± 6.198 yrs in the BPTB group and 25.80 ± 7.544 yrs in the QHT group ($P = 0.964$). The patient complaints were also similar with instability in 100% patients of BPTB and 95% of the QHT group. Pivot shift test was positive in all the patients. Lachman and Anterior drawer tests were grade 2 in 35% and grade 3 in 65% patients in QHT group which is same as in BPTB group also. One patient in the QHT group had grade 1 opening on varus strain, while 1 patient in each group was grade 1 on valgus strain test. Mc Murray test was positive in 11 patients (55%) of BPTB group and 9 patients (45%) of QHT group ($P = 0.527$). The pre-op mean Cincinnati scores were 46.90 ± 17.429 in the BPTB and 42.50 ± 14.017 in the QHT group ($P = 0.385$), while the Lysholm score was 56.25 ± 14.520 and 57 ± 13.075 in the two groups respectively ($P = 0.865$) [Tables

1 and 2], showing no significant difference in preoperative finding among the two groups. On arthroscopy, in the BPTB group, medial meniscus was found to be torn in 9 patients (45%) and lateral meniscus in 11 patients (55%), of which 4 patients had tear in both the menisci. In the QHT group 8 patients (40%) patient had medial meniscus tear and lateral meniscus was found torn in other 8 patients (40%), out of which 2 patients had bilateral meniscus involvement.

The 14 days, 6 weeks and 3 months, follow-up assessment scores were similar, with no statistically significant difference between the two groups [Table 1 and 2].

At 6 months, the overall Cincinnati score 83.35 ± 2.796 in BPTB group and 85.45 ± 4.383 in QHT group [Table 1] showed no significant difference ($P = 0.079$). However, breakup of Cincinnati scoring revealed that the running activity sub-group score in BPTB group was 3.05 ± 0.510 while it was

3.75±0.444 in QHT group, which is statistically significant ($P<0.001$). While in pain sub-group the mean score in BPTB group is 17.20±1.881 and QHT group 16.20±0.894 ($P=0.038$) and overall activity sub-group in BPTB score is 12.80±1.642 and QHT group 14±2.052 ($p=0.048$). Further looking at overall performance 3 patients (15%) out of 20 in BPTB group had mild difficulty in running while 15 patients (75%) moderate and 2 patients (10%) severe, while in QHT group 15 patients (75%) out of 20 patients had mild difficulty and only 5 patients (25%) moderate with no patient with severe difficulty. This suggests that at 6 months QHT group performed better than BPTB group.

Lysholm score at 6 months showed no statistically significant difference as the score in BPTB group was 90.55±2.395 and QHT group 90.90±1.619 ($P=0.591$), [Table 2]. None of the patients complained of instability or locking, though one patient in the BPTB group had catching sensation occasionally. There was no statistically significant difference in the mean Lysholm score regarding pain and squatting (Table 3). At that point in time, none of the patients had extension lag, while one patient in the BPTB group had 10° loss of flexion. Two patients, one in each group had grade 1 positive Lachman test. Pivot shift test was negative in all the patients.

At one year follow-up, there was no significant difference with respect to pain, overall activity level and running as Cincinnati score of BPTB 91±4.117 and QHT group 89.29±5.371 [Table 1], this showing that the BPTB group patients were able to catch up with QHT group by the end of 1 year. None of the patients had any difficulty in running in either group. Similarly, at 1 year, the Lysholm score was 92.84±2.630 in BPTB group and 93.00±1.862 in QHT group ($P=0.842$), [Table 2]. There were no episodes of locking or instability and there was no significant difference in the mean Lysholm scores with respect to pain and squatting. The loss of flexion in the single patient of BPTB group persisted at 1 year review. The pivot shift test continued to be negative in all the patients, and the Lachman test was grade 1 positive in the same one patient from each group, as it was at 6 months follow-up. Altered sensation over the anterolateral aspect of the proximal leg was present in 9 patients (45%) in the BPTB group and 5 patients (25%) in the QHT group ($P=0.320$) [Table 4].

Anterior knee pain especially on kneeling was complained by 3 patients (15%) in the BPTB group and 1 patient (5%) in the QHT group ($p=0.605$) [Table 5]. No intraoperative or postoperative complications occurred in this study group. One patient, as mentioned earlier had traumatic graft rupture and later had second procedure for reconstruction, therefore had to be excluded from the study.

Discussion

The two most commonly used grafts for anterior cruciate ligament reconstruction are the Bone-Patellar Tendon-Bone and QHT consisting of the Semitendinosus and Gracilis tendons. The

superiority of one over the other is a matter of debate as each graft has its own pros and cons. BPTB graft has been shown to be associated with harvest site morbidities like anterior knee pain and loss of range of motion but the graft provides good initial fixation and permits early return to play. On the other hand, the QHT graft is thought to have less prevalence of anterior knee pain but there are concerns with the development of laxity in the graft in the long term. A number of studies⁸⁻²² using varying fixation constructs have been conducted to evaluate the differences between BPTB and QHT grafts but no clear advantage of one over the other could be proved. Our study is an effort to compare the BPTB and QHT autografts in patients operated at our hospital to draw the definitive conclusion on this issue in Indian scenario as no study to this effect was found in literature. The strength of this study is that it is prospective and randomized, thereby minimizing selection bias. A single surgical team with experience in using both the techniques performed all the surgeries. Rehabilitation was consistent for all the patients. There was a high rate of follow-up. Looking at the patient profile, presenting complaints and preoperative findings in our study, there was no significant difference between the two groups. Therefore, there was no preoperative advantage of one group over the other. Anterior knee pain especially in relation to kneeling is a common donor site morbidity of the BPTB graft.²³ Shaieb et al¹¹ in a prospective two years follow-up study of 70 patients reported that at the last follow-up, significantly higher number of patients in the BPTB group had anterior knee pain (42%) than the patients in the QHT group (20%). Significantly higher kneeling pain in the patellar tendon patients has been reported in other studies also^{9,10,14,15} but in our study kneeling pain was much less. This could be attributable to filling the patellar bone defect after graft harvesting with bone graft in our centre resulting in early and proper healing of bone defect.

Loss of range of motion of the knee is another concern which has been reported to be more in case of the patellar tendon than the hamstring graft.^{8,11,13,22} Ibrahim et al⁸ observed that Loss of extension of $\leq 5^\circ$ was greater in the BPTB group (12 patients, 30%) than in the QHT group (8 patients, 17%). There was loss of flexion of $\leq 15^\circ$ in 5 patients (12%) in the BPTB group and 1 patient (2.2%) in the QHT group. Shaieb et al¹¹ also reported a loss of motion at an average of 3.4% in 52% of BPTB patients and 0.97% in 27% of QHT group ($p=0.01$). We noted that in our study except one patient in the BPTB group who had 10% loss of active flexion, there was no clinically significant loss of motion in either group. This can be attributed to the emphasis on preoperative and early aggressive postoperative rehabilitation on each visit, as maintaining full range of motion is important for maximal functional recovery. Sajovic M¹⁸ found at the end of 5-year follow-up, no statistically significant differences with respect to the Lysholm score, clinical and KT- 2000 arthrometer laxity testing, anterior knee pain, single-legged hop test, or International Knee Documentation Committee classification results and 23 patients (82%) in the QHT group along with 23 patients (88%) in the BPTB group returned to their pre-injury activity levels. Both QHT and BPTB grafts provided good subjective outcomes and objective stability at 5 years. No significant differences in the rate of graft

failure were identified. Maletis GB et al¹⁹ in a study of 99 patients reported a preoperative Lysholm score of 64 in the BPTB group and 67 in the QHT group and on one year follow-up the scores were 95 and 96 respectively, which improved to 97 and 98 after two years. In our study, mean preoperative Lysholm score was 56.25 in the BPTB group which improved to 90.55 at six months follow-up and 92.84 at one year follow-up and in QHT group the score was 57 improving to 90.90 and 93 at six months and one year follow-up respectively. Though, both the groups in our study showed significant improvement on follow-up at six months and one year as compared to the preoperative scores, we found no significant difference between the two groups, which is similar Maletis study.

There are studies that have also used the Cincinnati score for assessment in comparing the two autografts. One of them is by Aune et al¹⁰, who reported that the mean Cincinnati score at six months was 79 in the BPTB group and 81.4 in the QHT group and at one year these scores were 82.4 and 87.1 respectively. They found no significant difference between the scores of the two groups. Similarly, Feller et al¹³ also concluded the same. Our assessment showed that the mean preoperative Cincinnati scores were 46.90 in the BPTB group and 42.50 in the QHT group. These scores showed significant improvement on follow-up and increased to 83.35 in BPTB and 85.45 in QHT group on six months follow-up and 91 and 89.29 respectively at one year follow-up. Even though the overall Cincinnati scores at 6 month were marginally better in the QHT group, they did not differ significantly from the BPTB scores at the end of one year. Also on comparing the functional assessment for pain, overall activity and running activity in the Cincinnati score at six months follow-up, we found that patients in QHT group were significantly better than the patients in the BPTB group but, this difference was no longer significant at one year follow-up.

Conclusion

Patients with BPTB and QHT autograft at 1 year functional assessment showed no significant difference. Looking at 6 months scores the patients in QHT group performed better than BPTB group when assessed for pain, running and overall activity. Hence early return to sports is possible with QHT autograft.

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Fig .1

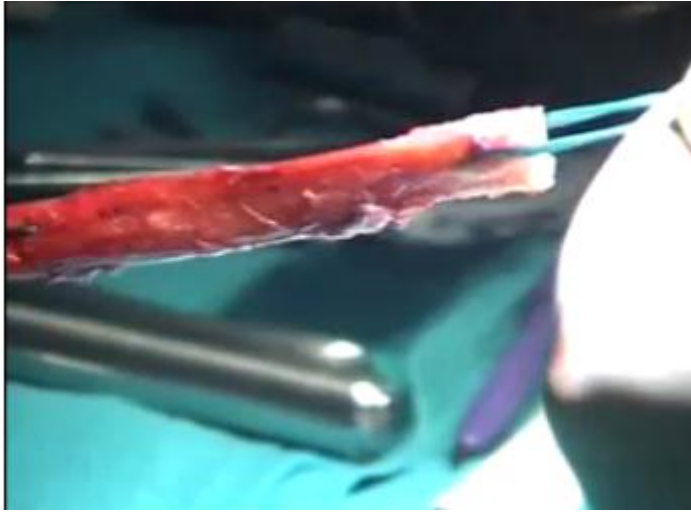


Fig. 2

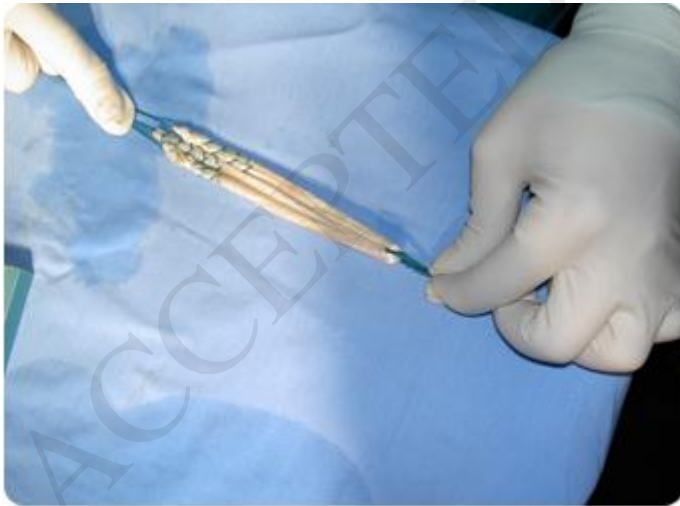


Table:- 1 Cincinnati score

Cincinnati score	BPTB Graft	QHT Graft	P Value
	Mean \pm SD	Mean \pm SD	
Preop	46.90 \pm 17.429	42.50 \pm 14.017	0.385
10 days	14.20 \pm 2.331	14.60 \pm 1.951	0.560
6 weeks	51.90 \pm 9.341	52.35 \pm 7.006	0.864
3 months	71.15 \pm 3.048	69.25 \pm 11.026	0.462
6 months	83.35 \pm 2.796	85.45 \pm 4.383	0.079
1 year	91 \pm 4.117	89.29 \pm 5.371	0.282

Table:- 2 Lysholm score

Lysholm score	BPTB Graft	QHT Graft	P Value
	Mean \pm SD	Mean \pm SD	
Preop	56.25 \pm 14.520	57 \pm 13.075	0.865
14 days	49.50 \pm 1.606	49.10 \pm 3.508	0.646
6 weeks	68.05 \pm 4.454	68.90 \pm 3.740	0.517
3 months	81.50 \pm 3.900	82.30 \pm 4.169	0.535
6 months	90.55 \pm 2.395	90.90 \pm 1.619	0.591
1 year	92.84 \pm 2.630	93.00 \pm 1.862	0.842

Table:- 3 Sub groups of Cincinnati and Lysholm score at six month follow-up.

Six month followup	BPTB Graft	QHT Graft	P Value
	Mean \pm SD	Mean \pm SD	
Cincinnati score			
Pain	17.20 \pm 1.881	16.20 \pm 0.894	0.038
Giving way	20.0 \pm 0.0	20.0 \pm 0.0	-
Overall activity level	12.80 \pm 1.642	14 \pm 2.052	0.048
Running activity	3.05 \pm 0.510	3.75 \pm 0.444	0.000
Lysholm score			
Locking	14.67 \pm 1.29	15.00 \pm 0.0	0.334
Instability	25.00 \pm 0.00	25.00 \pm 0.00	-
Pain	19.67 \pm 1.29	20.00 \pm 0.00	0.334

Squatting	3.87 ± 0.516	3.93 ± 0.594	0.745
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Table:- 4 Altered sensation over anterolateral aspect proximal leg

Altered Sensation	BPTB Graft		QHT Graft		P Value
	frequency	%	frequency	%	
No	11	55%	15	75%	0.320
Yes	9	45%	5	25%	
Total	20	100%	20	100%	

Table:- 5 Anterior knee pain

Anterior Knee Pain	BPTB Graft		QHT Graft		P Value
	frequency	%	frequency	%	
No	17	85%	19	95%	0.605
Yes	3	15%	1	5%	
Total	20	100%	20	100%	