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Evaluation of efficacy of ACL reconstruction with use of bone patellar tendon auto grafts and hamstring auto grafts: A Meta-analysis

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Abstract
Objectives: The objective of this research work was to assess the efficacy of ACL reconstruction with the utilization of either BPTB (Bone Patellar Tendon) or HT (Hamstring) auto grafts.
Methodology: We searched for the already published research works in Medline & Embase. All these research works were about the comparison of the HT and BPTB autografts for the ACL reconstruction. We utilized the Cochrane Collaboration Rev-Man 5 for the analysis of the collected information.
Results: 9 RCT (Random Controlled Trials) (with 300 patients) fulfilled the criteria of inclusion. Collaborate findings of the analysis showed that there was a significant low rate of negative pivot test Relative Risk 0.870, 95.0% CI (Confidence Intervals) 0.790-0.960, P=0.0040], pain at anterior knee (Relative Risk 0.660, 95.0% CI 0.450-0.960, P= 0.030) and pain during kneeling (Relative Risk 0.490, 95.0% CI 0.270-0.910, P= 0.020) in the group of HT as compared to the group BPTB.
Conclusions: There are same after-surgical impacts of the ACL reconstruction with the utilization of BPTB and HT autografts especially in terms of restoration of the knee joint function. There was inferiority of HT autografts to BPTB autografts for the restoration of the stability of knee joint, but it was associated with few complications after surgical interventions.

Keywords: Reconstruction, Intervention, Bone Patellar Tendon, Hamstring, Confidence Intervals, Auto grafts, Analysis, Random Controlled Trials.

Introduction
There are many controversies about the most suitable graft for ACL reconstruction [1, 2]. There are reports about allografts to have significant low rate in the achievement of the normal stability as compared to the autografts [3-5] and it is highly suitable for the multiple injured ligaments of knees needing extra tissue. So, autografts, including BPTB & HT autografts, are the grafts of choice for routine ACL reconstruction [6]. There is provision of better stability after the ACL reconstruction by BPTB as compared to the HT autografts [7], there is association of former with the morbidity from donor-site [8, 9], an incident which is present much less commonly with the HT autografts [7, 10]. One systematic research work [11] and different other analyses [7, 12-14] have provided the comparison of these two choices of graft, with findings displaying no difference in the ACL reconstruction outcomes between both types of autografts [23]. But these research works have identified the differences in the stability of joints [7, 11, 13, 14], complications after surgical intervention [7, 13] &kneeling pain [11, 15].
This research work is totally depending upon the findings of RCTs. Polling of these trials may introduce the bias, permitting the results with misinterpretations. The purpose of this research work was to perform analysis of different RCTs for the comparison of the efficacy of ACL reconstruction with the utilization of either HT or BPTB autografts. We also took into account some current published works that were not present at the time of previous research works [7, 11, 14]. We conjectured in current research work that ACL reconstruction with the utilization of either BPTB or HT autografts would provide the functional as well as stability outcomes with similarity, whereas utilization of BPTB autografts would be present with association to more complications after surgical intervention.

Material and Methods

In this current research work, we included the RCTs related to ACL reconstruction providing the comparison of HT and BPTB autografts and we did not include the quasi-RCTs. We included the patients present with the unilateral injury of ACL in need of reconstruction, whereas patients present with the revision of ACL or with anomalous radiograph or having injury of the opposite knee joint were not included in this current research work. Outcome evaluations included scores of IKDC, Lachman test, pain at anterior knee, pivot test, loss of extension, kneeling pain, loss of flexion, failure of graft, rate of infection, and reoperation. Search features included the ACL, methods of surgical interventions for reconstruction, autologous, transplants, hamstrings, patellar ligament, gracilis and HS. We combined the results with Cochrane highly sensitive strategies of search for the identification of the RCTs, as elaborated previously [16]. We screened the research works with the analysis of their titles as well as their abstracts. We obtained the full text when it was easily possible; we compared the articles to ensure the non-repetition of the information. After gathering the data, we entered in review manager software.

We assessed the methodological quality of screened research works with the utilization of the specific tool for evaluating the bias as described by Higgins [17]. This was a 6-point scale. One point was obtained when the criteria of quality was met. We utilized the Rev-Man 5 software for the analysis of the collected information. Our two authors examined the information during entry to avoid any type of error. We used the RR (Relative Risk) for statistical analysis of various dichotomous variables and with 95.0% CI. We used the v2 test to evaluate the heterogeneity between various research works and we considered the P value of less than 0.10 as significant. We adopted a fixed effect model when we found no statistically significant heterogeneity significantly. We adopted a random effect model if there was presence of significant heterogeneity statistically. We performed the descriptive analysis of the data for the data which was not able to be merged because of the inconsistent type of data. We performed the sensitivity analysis with the omission of one research work one by one to check the impact of that single research work on the overall estimation of this analysis research work. We performed the PP (per-protocol) analysis first for outcome measures and then we performed its verification by the ITT (intention-to-treat) analysis.

Results

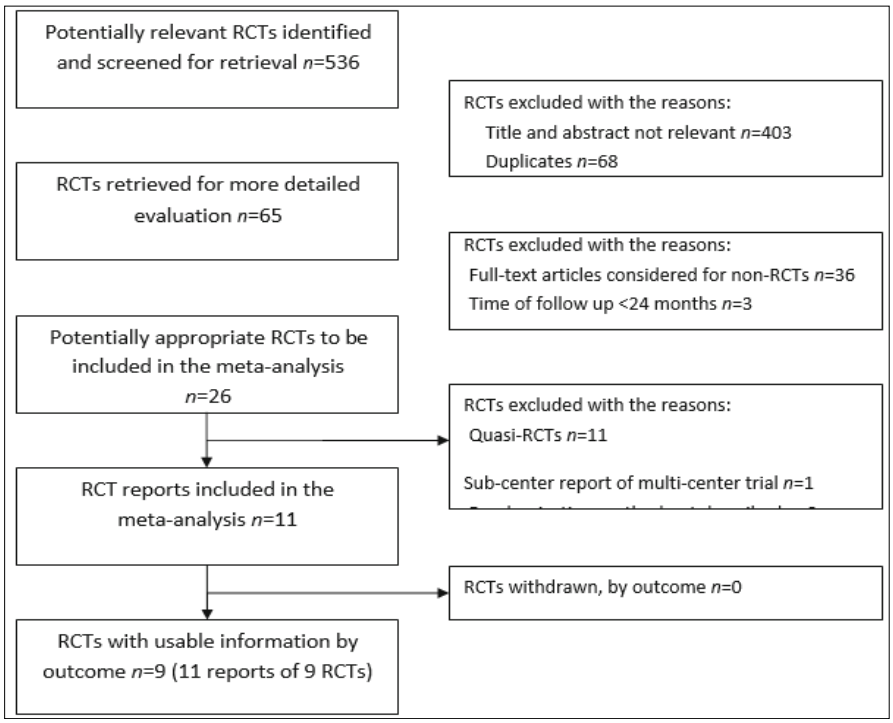

Fig 1: 65 of more than 400 research reports screened were retrieved for elaborate review initially

As summarized in. We considered 26 in those RCTs as appropriate for this current analysis. Among these, 11 reports [18-28] describing 9 different RCTs were included ultimately. A sum of 300 patients got inclusion in 9 trials with 180 in group of treatment (HT) and 120 in the control group (BPTB). We divided the subjects of one trial [18] into 3 groups BPTB autografts and HT autografts with an extra articular intensification method and HT autografts with no extra articular intensification method. All the 9 included RCTs stated the loss of flexion. 3 research works reported the patella femoral crepitation [18, 25, 28]; 4 stated the anterior knee pain [19-24], 5 trials stated the Lachman tests [19-23, 27, 28] and reoperation associated with the meniscus [18, 20-23, 26, 27], 6 trials stated the Pivot tests [18, 19, 28, 27, 25, 23] and rate of infection [18, 20-26]. 8 trials reported the failure of graft [18, 20-28] and IKDC score [18-26, 28], of which 7 trials [18-25, 28] utilized the IKDC criteria of 1995 [29, 30] and one trial [26] utilized the IKDC criteria of 2000 [31].

The range of the patients in all trials was from 12 to 64 years. Detail information of the involved trials is present in Table-1 and quality estimations of all the methodologies used in the trials are available in Table-2. The range of the ratio of male to female was from 1.20 to 4.80, and the range of the follow-up was from 24-105 months. The results of this analysis showing the comparison of the HT autografts and BPTB autografts are present in Table-3.

Table 1: Details of included RCTs

Included Studies	Patients Enrolled (H/B)	Sex (M/F)	Age (Years)	Follow-up (Months)	Depletion Number (H/B)	Patients Followed-up (H/B)	HT strands	Hta		BPTB[a]		Outcome measures
								Fem	Tib	Fem	Tib	
Anderson [16]	33/33	1.5	12–45	33	2/0	31/33	2	St	Su	ISc	St	IKDC, PT, EL, FL, GF, IR, RM, PC
Beynnon [17]	26/26	1.2	16–50	34	08-Jun	20/20	2	ISc	ISc	St	St	IKDC, LT, PT, AKP, FL
Ejerhed [18]; Lide´n [19]	35/32	2.3	12–57	84	05-Feb	32/30	3 or 4	ISc	ISc	ISc	ISc	IKDC, LT, AKP, KP, EL, FL, GF, IR, RM
Webster [20];	32/29	2.6	16–38	34	05-May	29/24	4	EB	P	EB	ISc	IKDC, LT, PT, AKP, KP,
Feller [21]												EL, FL, GF, IR, RM
Laxdal [22]	88/42	2	10–50	22	14-Apr	76/38	3 or 4	ISc	ISc	ISc	ISc	IKDC, AKP, KP, EL, FL, GF, IR, RM
Maletis [23]	51/44	3.3	12–46	22	3/0	48/44	4	Sc	2 Sc	Sc	ISc	IKDC, PT, KP, FL, GF, IR, PC
Taylor [24]	30/30	2.6	15–43	34	07-Mar	25/27	4	EB? ISc	Isc? Sc? W	EB? ISc	Isc? Sc? W	IKDC, KP, EL, FL, GF, IR, RM
Drogset [25]	55/56	1.5	16–43	22	12-Aug	45/48	4	Sc	Sc	ISc	ISc	LT, PT, KP, EL, FL, GF, RM
Wipfler [26]	29/29	1.3	23–62	103	11-May	20/24	4	K	Su	BP	BP? Su	IKDC, LT, PT, KP, EL,

M male, F female, Fem femoral, Tib tibial, ISc interference screw, EB endo button, P post, Sc screw, St staple, W washer, Su sutures, K knot, BP bone plug, LT Lachman test, PT Pivot test, AKP anterior keen pain, KP kneeling pain, EL extension loss, FL flexion loss, GF graft failure, IR infection rate, RM reoperations related to the meniscus, PC patellofemoral crepitation a Fixation type; H/B: hamstring (HT)/bone-patellar tendon-bone (BPTB)

Table 2: Quality (risk of bias) Assessment of Included RCTs

Included studies	Was the allocation sequence adequately generated?	Was the allocation adequately concealed?	Was knowledge of the allocated interventions adequately prevented during the study?	Were incomplete outcome data adequately addressed?	Are reports of the study free of suggestion of selective outcome reporting?	Was the study apparently free of other problems that could put it at a risk of bias?	Quality Score	Level of evidence
Anderson [18]	Yes	Unclear	Unclear	Yes	Yes	Yes	4	I
Beynnon [19]	Yes	Unclear	Unclear	No	Yes	Yes	3	I
Ejerhed [20]; Lide´n [21]	Yes	Unclear	Yes	Yes	Yes	Yes	5	I
Webster [22];	Yes	Unclear	Yes	No	Yes	Yes	4	I
Feller [23]								
Laxdal [24]	Yes	Unclear	Yes	No	Yes	Yes	4	I
Maletis [25]	Yes	Yes	Yes	Yes	Yes	Yes	6	I
Taylor [26]	Yes	Yes	Yes	No	Yes	Yes	5	I
Drogset [27]	Yes	Yes	Yes	Yes	Yes	Yes	6	I
Wipfler [28]	Yes	Unclear	Yes	Unclear	Yes	Yes	4	I

Table 3: Meta-Analysis Outcomes Comparing ACL Reconstructions with HT Autografts versus BPTB Autografts

Outcome	No. of studies	HT	BPTB	*P* value for Heterogeneity	Analysis model	RR (95% CI)	*P* value
IKDC	5	120/156	89/155	0.05	R	1.05 (0.93–1.19)	0.41
Lachman test	3	38/83	42/76	0.00001	R	0.65 (0.18–2.34)	0.51
Pivot test	5	139/181	156/177	0.11	F	0.87 (0.79–0.96)	0.004
Anterior knee pain	4	33/159	39/116	0.88	F	0.66 (0.45–0.96)	0.03
Kneeling pain	6	46/147	76/196	0.002	R	0.49 (0.27–0.91)	0.02
Extension loss	5	24/117	27/176	0.5	F	0.63 (0.39–1.01)	0.05
Flexion loss	3	60/139	35/103	0.8	F	1.03 (0.78–1.35)	0.85
Graft failure	8	15/138	9/191	0.98	F	1.37 (0.67–2.81)	0.38
Infection rate	6	8/177	6/120	0.23	F	1.04 (0.46–2.35)	0.93
Reoperations related to the meniscal	5	11/177	5/173	0.16	F	1.78(0.75–4.22)	0.19

F fixed-effect model, *R* random-effect model

IKDC scores of 8 trials were treated as the dichotomous variables; abnormal and severely with the normal and nearly normal but only seven trials [18-25, 28] which utilized the IKDC criteria of 1995 were pooled. There were normal and nearly normal IKDC scores 120 out of 156 patients in the group of HT and 89 out of 155 patients in group of BPTB, correspondingly.

Fig 2: Comparison of IKDC scores [29, 30] between HTs and BPTBs after ACL reconstruction

Study or Subgroup	HT Events	Total	BPTB Events	Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
Anderson 2011	20	13	14	25	18.0%	0.81 [0.67, 0.98]	
Beynnon 2012	09	12	08	12	13.2%	1.06 [0.82, 1.37]	
Ejerhed 2013; Lidén 2015	07	24	05	22	5.2%	1.07 [0.65, 1.76]	
Laxdal 2014	28	44	09	28	8.7%	1.30 [0.91, 1.86]	
Maletis 2015	26	30	32	36	23.3%	1.01 [0.89, 1.14]	
Webster 2011; Feller 2013	19	21	09	16	13.6%	1.28 [1.00, 1.65]	
Wipfler 2016	11	12	12	16	17.9%	1.13 [0.94, 1.36]	
Total (95% CI) Total events	120	156	89	155	100.0%	1.05 [0.93, 1.19]	

Total 5 trials [19-23, 27, 28] stated the post-surgical Lachman test data, but pooling of only three analyses [19-23] was carried out. Postsurgical Lachman test was present as negative in 40 out of 85 patients in HT group and 44 patients out of 78 patients in the group of BPTB. This particular analysis explained no significant disparity in the results of Lachman test after the ACL reconstruction with the both type of autografts (RR= 0.650, CI= 95.0% 0.180-2.340, P = 0.510). Total 6 trials [18, 22, 19, 23, 25, 27, 28] compared the postsurgical Pivot tests, but 5 trials [18, 19, 22, 23, 27] were underwent pool. Heterogeneity test displayed that there were steady results across all trials (P= 0.110). Figure-3 showed the results of analysis. We found significant difference in the postsurgical Pivot tests between both groups (RR= 0.870, CI= 95.0%, 0.790-0.960, P= 0.0040), showing that, after ACL reconstruction, BPTB is superior to HT. Morbidity

Fig 3: Comparison of Pivot tests between HTs and BPTBs outcomes after ACL reconstruction

Study or Subgroup	HT Events	Total	BPT Events	B Total	Weight	Risk Ratio M-H, Fixed, 95% CI	Risk Ratio M-H, Fixed, 95% CI
Anderson 2011	10	23	16	25	15.7%	0.82 [0.58, 1.14]	
Beynnon 2012	13	12	09	12	11.8%	0.68 [0.47, 1.01]	
Drogset 2013	33	37	35	40	27.2%	1.02 [0.90, 1.15]	
Maletis 2015	29	40	32	36	27.3%	0.85 [0.72, 1.01]	
Webster r2011; Feller 2003	16	21	16	16	17.9%	0.84 [0.71, 1.00]	
Total (95% CI) Total events	100	133	108	128	100.0%	0.87 [0.79, 0.96]	

Total 4 trials [19-24] stated that postsurgical anterior knee pain, occurring in 35 out of 161 HT patients and 41out of 118 BPTB patients. Total 7 research works [20-28] compared the postsurgical occurrence of kneeling pain, but only 6 trials [20-27] underwent pool (Figure-4).

Postsurgical anterior knee pain as well as kneeling pain after the reconstruction of the ACL was much lower in the patients of HT group as compared to the patients of BPTB group. Total 7 trials stated the loss of extension [18, 20-24, 26-28]. Heterogeneity tests results showed that these findings are consistent across the trials (P= 0.5) (Figure-5). Three research trials [18, 25, 28] stated that postsurgical patella femoral crepitation. But there was variation in the definitions of patellofemoral crepitation in these research trials.

Fig 4: Comparison of kneeling pain after ACL reconstruction between HTs and BPTBs after ACL reconstruction

Study or Subgroup	HT Events	Total	BPT Events	B Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
Drogset 2015	0	37	2	40	3.6%	0.21 [0.01, 4.31]	
Ejerhed 2013; Lidén 2015	4	24	15	22	21.3%	0.88 [0.51, 1.52]	
Laxdal 2014	4	54	17	28	15.1%	0.12 [0.04, 0.33]	
Maletis2015	10	29	19	21	21.0%	0.46 [0.26, 0.82]	
Taylor 2016	10	14	8	11	19.3%	1.20 [0.60, 2.42]	
Webster 2011; Feller 2013	6	21	17	16	19.8%	0.39 [0.20, 0.76]	
Total (95% CI) Total events	34	179	78	138	100.0%	0.49 [0.27, 0.91]	

Fig 5: Comparison of extension loss between HTs and BPTBs after ACL reconstruction

Study or Subgroup	HT Events	Total	BPTB Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI		Risk Ratio M-H, Fixed, 95% CI
Anderson 2011	0	23	0	25		Not estimable		
Drogset 2012	0	37	5	40	14.3%	0.85 [0.24, 2.98]		
Ejerhed 2013; Lidén 2015	7	24	5	22	21.3%	0.94 [0.37, 2.38]		
Laxdal 2014	4	54	3	28	50.8%	0.55 [0.29, 1.05]		
Webster 2011; Feller 2013	1	21	4	13	13.6%	0.19 [0.02, 1.55]		
Total (95% CI) Total events	12	159	17	128	100.0%	0.63 [0.39, 1.01]		
Heterogeneity: Chi² = 2.37, df = 3 (P = 0.50); I² = 0% Test for overall effect: Z = 1.93 (P = 0.05)				0.01			0.1	1 HT BPTB 10 100

Discussion

There is one limitation of RCTs: they are suppressed with much small sizes of samples [32] and RCTs with low-quality may accountable for biased estimations of the effectiveness of treatment [33]. Systematic examinations with permits us to study the multiple RCTs of similar nature quantitatively to rise the size of sample and it has the ability for the improvement of the statistical power. The systematic analyses may not include the research works available with low-quality analysis [33] and it can offer very good evidences for the support of the medical decision with the provision of timely updates created after the research results of the advanced trials. Systematic reviews of different RCTs of same nature gave us one single authentic information source about the efficacy of the interventions in the field of health-care [35, 36]. The variations in the quantity in RCTs can have impact on the meta-analyses [37]. Anterior stability & rotational stability are the indices of stability of knee [38]. Moreover, postsurgical instability of knee was less frequent with BPTB autografts as compared to the HT autograft after the ACL reconstruction. This finding may be because of ligament biodynamic as well as histological features of the graft-tissue interface [39-41].

There is more rapid healing of the BPTB autografts due to their interfaces of boneto-bone [42], while the soft interface of tissue-to-bone with HT autografts covers from 9 to 12 weeks for complete healing [43]. There is creation of the patellar bone abnormality by the harvesting of the central 3rd patellar tendon with autograft of BPTB and closure of anomaly can lead to patella baja, there can increase in the sensitivity of pain when there is direct pressing of anterior knee during walking or kneeling [44, 45]. Findings of 9 different research trials stated the very high scores of kneeling pains with application of autografts of BPTB [11]. One other research work stated the median incision required for central 3rd patellar tendon's harvesting which may harm the infra-patellar portion present in the saphenous nerve [46].

Conclusions

In the findings of this study analysis showed a significant difference between the BPTB and HT autografts regarding negative findings of pivot tests, kneeling pain & anterior knee pain. The findings of 9 different trials concluded that ACL reconstruction with the use of HT autografts obtained same after surgical impacts in terms of restoration of function of knee joint to the BPTB autografts.

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