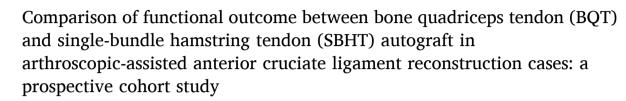
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# Andri MT Lubis, MD, PhD<sup>\*</sup>, Demy Faheem Dasril, MD

Department of Orthopaedic & Traumatology, Faculty of Medicine Universitas Indonesia - Ciptomangunkusumo Hospital, Indonesia

ARTICLE INFO	A B S T R A C T
Keywords: ACL reconstruction Arthroscopic-assisted BQT and SBHT graft	<i>Background:</i> ACL rupture has a high morbidity in productive-age population. The increasing incidence and proper management has become a point of interest in the musculoskeletal sport injury. Choosing the best graft has become the main focus in searching for a better outcome regarding ACL reconstruction in these patient popu- lation. Currently, single bundle hamstring tendon (SBHT) autograft was preferred in Asian population compared to bone quadriceps tendon (BQT) autograft. However, there are some problems such as short and small in diameter of SBHT. This study is focused on evaluation of the clinical outcome between BQT and SBHT in arthroscopic-assisted ACL reconstruction patients. <i>Materials and methods</i> : In this prospective cohort study, 30 subjects were divided into 2 groups (BQT and SBHT). Sampling was taken between February 2017–2018 (1 year) in one orthopaedic center. The instruments used for evaluation are rolimeter and patient-reported outcome (PRO) questionnaires (IKDC, Tegner-Lysholm, and KOOS) with data mining between 3 months, 6 months, and 1 year post operation. This study has been reported in line with the STROCSS criteria.
	Results: Mean difference of quadriceps $(3.12 \pm 0.94)$ and hamstring $(3.87 \pm 0.61)$ in rolimeter measurement 1 year post operation is statistically significant (p = 0.015). Side-to-side difference shows better result in quad- riceps $(0.34 \pm 0.70)$ compared to hamstring $(0.84 \pm 0.60)$ with p value 0.04. IKDC scores in one month (p = 0.002; CI95% [8.81–31.79]) and three months (p = 0.004; CI95% [4.85–20.39]) post operative is better in quadriceps group. <i>Tegner-Lysholm</i> assessment 1 month post operative showed consistent results between numeric (p = 0.004) and categoric data (p = 0.050) in quadriceps group. There was an improvement during six months and one year post operative KOOS sub-item scales; pain (p = 0.034) and symptoms (p = 0.001). <i>Conclusion:</i> Functional outcome of patient undergoing arthroscopic-assisted ACL reconstruction is better in BQT group compared to SBHT group, both in subjective and objective parameters given.

# 1. Background

Anterior Cruciate Ligament (ACL) rupture is one of the most frequent injury, compared to other ligamentous injury, that causes significant disturbance on physical activity, especially in young and active person. The incidence of this injury was 200,000 cases per year with 100,000 ACL reconstruction procedures in US only [1]. Unstable knee joint is the main problem along with symptoms such as pain, "giving way" sensation, and locking knee. Knee proprioceptive disturbance, deterioration of muscle strength, and downgrading of knee performance will cause secondary osteoarthritis of the knee if not treated adequately [2].

ACL reconstruction nowadays are performed using arthroscopy guidance [3]. In terms of biomechanics of graft choices, selection of the best graft source is still a major controversy in the scope of sports injury. The graft properties that were considered are: size/diameter, durability, healing capacity, tissue reaction, donor-site morbidity, post-operative infection rate, and patient-related factors [1,3,4]. Bone-patellar tendon-bone (BPTB) is still the gold standard in ACL reconstruction due to its biomechanical properties. In Asian population, BPTB is not popular for graft selection because most patients undergoing this procedure

\* Corresponding author. *E-mail addresses:* andri\_lubis@yahoo.com (A.M. Lubis), demyfaheem86@gmail.com (D.F. Dasril).

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complained about the pain during kneeling (when they were performing their prayer). The preferred graft for Asian patients are single-bundle hamstring tendon (SBHT) grafts. There are some studies that stated about unfavourable outcome of SBHT technique because of their short length and smaller diameter of tendon and post operative knee flexion problem [5]. Due to the existing data and the potential for other graft choices with better biomechanical properties than SBHT, authors are conducting this study of BQT autograft for one of the plausible choice of graft for ACL deficient patients in productive-age group.

The research question we formulated is: does BQT provides better functional outcome compared to SBHT ACL reconstruction? Based on the question, our hypothesis would be: BQT would provide better functional outcome compared to SBHT ACL reconstruction. We conducted this study to evaluate the functional outcome between BQT and SBHT graft in arthroscopic-assisted ACL reconstruction cases.

# 2. Material and method

The clinical data obtained was a multisite-based study from two sports center (single center). Study design is prospective cohort. All patients have met the inclusion and exclusion criteria regarded as follows: (1) patients 15–40 years old, (2) unilateral ACL reconstruction cases ranging from 2017 to 2018, (3) no multiple knee ligament injury, (4) no ligamentous laxity (confirmed with Beighton Hypermobility Score), (5) no history of previous knee ligament surgery, and (6) patient without recurrent rupture during a year of observation period. Ethical clearance was obtained prior to the data collection. This study has been registered in clinicaltrials.gov under the UIN NCT04536246 (Fig. 1).

Patient selection was based on the two sites which the study was carried out. Group I is BQT (intervention), whilst group II is SBHT (control); both groups has the same sample size. All of the patients had been examined through physical examination and additional tests for diagnostic confirmation (knee radiography and MRI). All the patients in this study had knowledge of the nature of the study and agreed upon the research requirements for the procedure and post operative follow up care. Patients then underwent arthroscopic-assisted ACL reconstruction by the same orthopaedic surgeons in both center to avoid interobserver liability. After the surgery, patients were having repeated-time measurements using patient-reported outcome (PRO) questionnaires in 3 months, 6 months, and 1 year post reconstruction.

In this study, we used two methods (subjective and objective) to verify and calculate the data results in order to draw a conclusion. Subjective measurement was obtained from 3 patient reported outcome (PRO) questionnaires. There is no standard PRO questionnaires for specific ACL cases. We used KOOS, Tegner-Lysholm, and IKDC to evaluate the results, based on several studies conducted for BQT grafts [6].

Objective measurement was conducted using rolimeter device, eventhough the gold standard for anterior translation measurement is

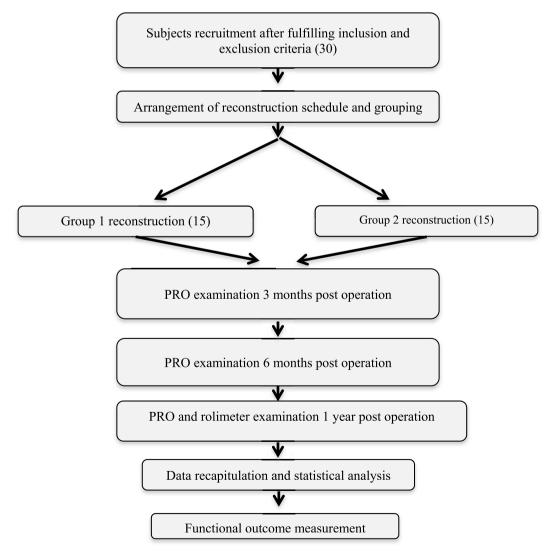


Fig. 1. Research Protocol using Patient-Reported Outcome (PRO) and Rolimeter Examinations to Assess Functional Outcome.

KT-1000/2000. Rolimeter can provide adequate data for statistical input without any remarkable difference compared to KT-1000/2000.

In this study, the intervention was BQT technique with hybrid fixation on both tunnel ends. We used endobutton fixation on femoral tunnel as well as bioscrew fixation on tibial tunnel, respectively. The company which provides these implants were from Tawada Health Care (THC). Vendor of the implants does not provide financial support of this study, henceforth no conflict of interests were experienced during and after the study was completed.

Patients were followed up coherently after the ACL reconstruction in the outpatient setting. We employ a repeated time measurements during 3 months, 6 months, and 1 year post operative for the PRO questionnaires.

The rolimeter measurement was assessed during 1 month and 1 year post operative. To avoid any milimeter mistakes, we measured the rolimeter for each individual knee 3 times and taking the mean value. In the statistical analysis, we checked the difference by side-to-side and time-to-time difference and comparing results between the two groups of this study.

For statistical analysis, we used the SPSS 24 software. Data normality was calculated using Shapiro-Wilk test. Baseline characteristic data was provided in mean and median data. Subgroup analysis was presented in tables and percentages. In hypothesis testing, we used *Pearson chi square* and *Fischer exact test* for categoric and numeric data. For the numeric non paired data, we used t Student/Mann-Whitney U. Time-to-time functional outcome were analysed using general linear model (GLM). The type I error ( $\alpha$ ) and type II error/power ( $\beta$ ) were designated 5% and 80%. Statistical results were correlated with clinical findings and analysed to reach the conclusion of the study. We used the sample size formula for two independent means. Based on the formula, the sample size for each group was 15 for a total of 30 subjects. This study has been reported in line with the STROCSS criteria.

For the sample recruitment, we deploy the stratified/clustered consecutive recruitment based on the site of surgery performed; BQT from National Teaching Hospital, SBHT from National Army Hospital over a period of 1 year.

# 3. Results

In this study, we enrolled 31 patients with ACL rupture whom had met the inclusion criteria; 15 patients from Army Hospital and 16 patients from University Hospital. From those 16 patients in University Hospital, one patient experienced re-rupture post ACL reconstruction due to self-inflicted trauma in his house. Therefore, this patient was excluded during final data calculation.

For the baseline characteristics data, male subjects is more (93,3%) than female (6,7%). The median age of subjects in this study is 27.5 years old (15–43 yeard old of interquartil range). The p value of data distribution is 0.503 (normal). The major cause for ACL rupture in the study is soccer (55% and 41%) in BQT and SBHT groups respectively. The tardiness of medical attention is 8.5 months post initial trauma. History of strenuous activity before onset of injury was found in some patient. There is no infection that occurred in all of the subjects that was followed up in this study. Characteristics comparison between the groups are shown in Table 1.

Subjective results from IKDC questionnaire on 3 and 6 months post operation, as seen on Fig. 2, showed significantly better result on BQT group (p = 0.002 and p = 0.004). Scoring on 1 year revealed insignificant statistical results despite mean difference from this study was still above clinical difference standard in IKDC scoring system (8 points). According to the results, BQT group has better functional outcome based on IKDC score. Tegner-Lysholm scoring results in 3 months post operation was statistically significant (p = 0.004) despite statistical indifference between 6 months and 1 year post operation follow up. Scoring results were also displayed in Fig. 3. There was an improvement during 6 months and 1 year post operative KOOS sub-item scales; pain (p = Table 1

Baseline data of the sub	jects in this study	between BQT and SBHT	groups.

	$\begin{array}{l} BQT \ group \\ N_1 = 15 \end{array}$	SBHT group $N_2 = 15$
Age (years old) Gender	28.00 (21.0–43.0).	27.00 (15.0–36.0).
Men	15 (100%)	13 (86.7%)
Women	0 (0%)	2 (13.3%)
Injury site		
Right	9 (60%)	9 (60%)
Left	6 (40%)	6 (40%)
Collateral injury		
Lateral meniscus	8 (72.7%)	1 (16.7%)
Medial meniscus	3 (27.3%)	5 (83.3%)

0.034) and symptoms (p = 0.001) which can be observed in Fig. 4.

Objective measurement using rolimeter on 1 year post operation also has a significantly better results in BQT group (see Fig. 5 and 6). The mean difference of injured knee rolimeter score was better in BQT group (3.12 mm;  $\Delta$  7.47) compared to SBHT group (3.87 mm;  $\Delta$  6.58) with significant p value of 0.015. Side-to-side difference was 0.34 mm for BQT group and 0.84 mm for SBHT group in 1 year post operation; statistical significance was profound (p = **0.04**) (see Table 2 and 3).

#### 4. Discussion

Demographic data in this study have similar characteristics with subjects in a study concerning 4355 ACL rupture patients in China (*Mei et al*). Both of our studies had the same cause of ACL injury, which is non-contact pivotal sports injury [7,8]. For the gender predominance, there is a striking difference between the baseline data in this study compared to the literature statement, which implies that women tends to sustain ACL injury due to several biomechanic and hormonal factors [5]. The likelihood of ACL injury in women is 5.3 times greater than men because of larger valgus force on knee joint, especially during strenuous and sports activity [10,11]. In this study, the gender predominance was male, not female patients.

In this study, right knee injury is higher than left knee. As many as 19 patients suffered ACL rupture on the right knee (63.33%). Some studies mentioned/postulated that the dominant knee will have higher probability to sustain ACL injury. Other study disagree with this notion and stated that the relation between dominant knee and ACL injury remains unclear [12,13].

The delay of medical treatment is an important prognostic factor in ACL injury cases [13]. If the treatment is delayed, the chance of secondary meniscal tear and subsequent cartilage defect will be higher compared to early treatment [14,15,16]. Mean treatment delay in this study is 8.5 months. Other studies stated that average of delayed treatment up to 11.6 months still gives favourable clinical outcome in ACL deficient patients. A meta-analysis by **Ramski et al** [26] found that children or adolescents undergoing nonoperative or delayed ACL reconstruction were 33.7 times more likely to be clinically unstable and 12 times more likely to subsequently have medial meniscus injury than those who had surgery earlier. During arthroscopic examination in this study, there was no lesion or defect in the articular cartilage for all subjects. The average delay of treatment in this study does not cause any problems in the surrounding knee structures.

Concomitant injury in the form of meniscus tear was found in 15% of subjects, mostly on lateral side. Study by *Mei et al* also reveals some subjects with lateral meniscus injury [9]. In other studies, they also found >50% of their subjects had concomitant meniscal injury. Since the rehabilitation protocol differs in these patients, we found that PRO questionnaire scores were slightly lower than the isolated ACL injury patients [7].

The results in this study is slightly better than the results of *Tow et al* (2000) in which 22% of their post operative patients still had side-to-

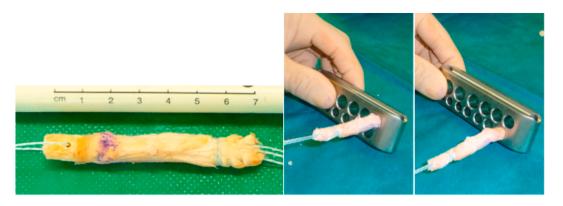


Fig. 2. BQT autograft model used in this study; bone plug is utilized in the femoral tunnel to enhance graft incorporation and healing.



Fig. 3. SBHT autograft model used in this study; graft incorporation and healing depends on soft tissue properties of the graft.

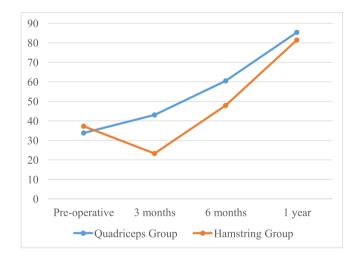


Fig. 4. Graphic of IKDC scoring comparison between groups in pre-operative and post-operative follow up.

side difference > 5 mm. Similar results can be seen in *Deehan et al* (2005) where > 80% of the subjects had anterior translation < 5 mm [17,18]. According to *Cavaignac et al* (2017), whose study involves 95 patients undergoing arthroscopic-assisted ACL reconstruction, functional outcome is superior in BQT compared to SBHT [1,18,27].

Mean rollimeter score in quadriceps group is 3.12 compared to 3.87 in hamstring group (p = 0.015). Favourable score with less than 3 mm mean difference indicates normal condition and successful operation rate [19].

Subjective evaluation were taken using 3 PRO's IKDC, Tegner-Lysholm, and KOOS scoring system where all three resulted in

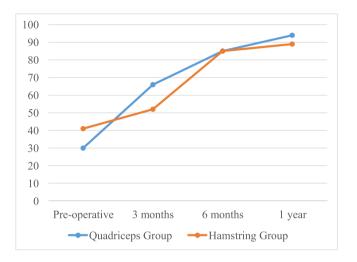


Fig. 5. Graphic of Tegner-Lysholm scoring comparison between groups in preoperative and post-operative follow up.

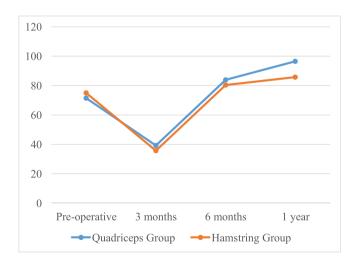


Fig. 6. Graphic of KOOS scoring comparison between groups in pre-operative and post-operative follow up.

favourable outcomes on BQT compared to SBHT group. Statistical value on these PRO's are enlisted as follows:

- 1. IKDC: p = 0.002 (3 months) and p = 0.004 (1 year)
- 2. KOOS: p = 0.034 (pain subscale) and p = 0.001 (symptoms subscale)

#### Table 2

Comparison of rolimeter results in BQT and SBHT groups during pre operative and 1 Year post operative.

Rolimeter (mm)	$\begin{array}{l} BQT\\ Group\\ N_1=15 \end{array}$	$\begin{array}{l} \text{SBHT} \\ \text{Group} \\ \text{N}_2 = 15 \end{array}$	Mean (CI95%)	p value <sup>a</sup>
Pre				
Operative				
Injured	10.59	10.45	0.14 (-0.96-1.13)	0.797
knee	(1.54)	(1.36)		
Normal	2.89	3.22	-0.34 (-0.71-0.03)	0.087
knee	(0.68)	(0.28)		
1 Year Post O	peratve			
Injured	3.12	3.87	-0.75 [-1.30-	0.015
knee	(0.94)	(0.61)	(-0.19)]	
Normal	2.78	3.03	-0.25 (-0.50-0.02)	0.078
knee	(0.46)	(0.25)		

Data was provided in mean value (standard deviation).

<sup>a</sup> p value was calculated using Student's *t*-test for two independent means.

# Table 3

Objective functional outcome between injured knee and normal knee in pre operative and 1 Year post operative.

Rolimeter (mm)	BQT Group N <sub>1</sub> = 15	SBHT Group N <sub>2</sub> = 15	Mean Difference (CI95%)	p value*
Mean difference of pre operative and 1 year post operative measurement on injured knee (time-to-time difference)	7.47 (1.31)	6.58 (1.36)	0.89 (0.01–1.88)	0.080
Mean difference of pre operative and 1 year post operative measurement on injured knee compared to their normal counterpart (side-to-side difference)	0.34 (0.70)	0.84 (0.60)	-0.50 [-0.97- (-0.02)]	0.044
Results were provided in mean v data. P value were calculated t				

3. Tegner-Lysholm: p = 0.004 (numeric) and p = 0.050 (categoric)

This subjective evaluation results were slightly better compared to *Lee et al* [8,18,22–24]. *Cavaignac et al* (2017) also reported similar satisfactory outcomes in PRO questionnaires. In his report, it is stated that subjects in BQT group had lower donor-site morbidity and also had faster recovery rate to their initial activity levels [1]. The possibility of intraobserver and interobserver liability can be ruled out due to consistent data and narrow standard deviation. The threshold of clinical significance in IKDC is 8 points; Tegner-Lysholm and KOOS were 10 points [6,21,25,28]. In this research, BQT group had better value than SBHT group.

Postoperative rehabilitation protocols were matched between two groups to avoid bias [20,22]. Based on the follow up, BQT group recovers faster to their strenuous activities than SBHT group. These findings are similar with various studies, basically due to the presence of bone plug in the femoral tunnel, which in turn, speed up the graft incorporation process and provides early stability compared to non bone block base. This theory is proven and could be seen in this study's results in 3 months, 6 months, and 1 year post operative evaluation.

# 5. Conclusion

There is a difference of functional outcome between BQT autograft and SBHT autograft in arthroscopic-assisted ACL reconstruction for isolated ACL injury patients.

In this study, BQT autograft had superior outcome in both subjective

and objective measurements (biomechanic, biomaterial, and return to strenuous/sport activity) compared to SBHT autograft.

#### Strengths and limitations

This is the first study conducted in our country regarding autograft BQT reconstruction which will serve as a basis for other future studies regarding this section. The results shows promising future for the usage of BQT graft, but still need more data and clinical practice as well as experience of the orthopaedic surgeons. Limitation of this study is no randomization during subject grouping.

Future studies are needed to overcome the aforementioned limitations and to draw a solid statement of BQT graft usage in daily orthopaedic clinical practice.

# **Ethical Approval**

Approval for this study has been given, by the medical research unit, ethical committee faculty of medicine Universitas Indonesia

#### **Author Contribution**

Andri Marulitua Lubis, MD main author, concept of study, evaluation and analysis of research data, publication

Demy Faheem Dasril, MD co-author, data collection, analysis and interpretation, writing papers, editorial duty, paper publication

#### Consent

Informed consent on all the subject of this study has been achieved

# **Registration of research studies**

- 1. Name of the registry: **ClinicalTrials.gov**
- 2 Unique Identifying number or registration ID: NCT04536246
- 3 Hyperlink to the registration (must be publicly accessible): https://clinicaltrials.gov/ct2/show/NCT04536246

# Guarantor

Andri Maruli Tua Lubis, MD

# Funding

There are no third-party sponsors that funded this study

#### Provenance and peer review

Not commissioned, externally peer-reviewed.

# Declaration of competing interest

There are no such conflicts of interest in this study

#### Acknowledgements

There is no conflict of interest regarding this study, since this is the first study ever conducted regarding quadriceps tendon autograft in ACL reconstruction cases in our country. The authors and all the team for data gathering and calculations are not sponsored by pharmaceutical or implant company whatsoever. Funding and research packaging were carried out by authors own monetary budget.

#### Appendix A. Supplementary data

Supplementary data related to this article can be found at https://do

#### i.org/10.1016/j.amsu.2020.11.023.

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