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Original Article

A prospective randomized controlled trial to evaluate clinico-radiological outcome of arthroscopic single bundle versus double bundle anterior cruciate ligament reconstruction

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Abstract: Purpose: The purpose of current research was to compare theclinico-radiological outcome of arthroscopic single-bundle versus double-bundle anterior cruciate ligament (ACL) reconstruction. Methods: Sixty patients with an isolated ACL injury were randomized into single bundle (SB, n=30) reconstruction group and double bundle (DB, n=30) reconstruction group. Patients were evaluated using GeNouRoB (GNRB) arthrometer, functional knee scores (International Knee Documentation Committee [IKDC]) and Lysholm scale. Magnetic resonance imaging (MRI) was performed to compare the graft orientation of the reconstructed ACL. Rotational stability was determined by lateral pivot-shift test. Results: The follow up in SB group and DB group was 34.8 months and 36.2 months respectively. At final follow up, there was no statistically different between Lysholm score, differential anterior tibial translation in SB group and DB group (P>0.05). All cases had a negative pivot shift test in DB group while 2 patients had positive pivot shift in SB group at final follow up. MRI scans of operated knees showed that the values of mean sagittal ACL graft-tibial angle and mean coronal ACL graft-tibial angle were comparable in both the groups (P>0.05). Conclusions: There was no difference between knee stability, knee scores, subjective evaluations & MRI evaluation of graft inclination angles between single-and double-bundle ACL reconstruction.

Keywords: Anterior cruciate ligament, double-bundle, single-bundle

Introduction

Anterior cruciate ligament (ACL) reconstruction is one of the most frequently reconstructive surgeries for knee. Single-bundle ACL reconstruction (SBACLR) have provided excellent success rates of over 80%, however, some studies have noted residual instability and patient dissatisfaction after surgery [1-3]. Recently the double bundle ACL reconstruction (DBACLR) has gained in popularity based on the theory that it support with better residual stability [4]. The proposed benefits of DBACLR followed from biomechanical studies that suggest that each bundle-anteromedial (AM) and posterolateral (PL)-makes a unique kinematic contribution to knee function. Two bundles function together, but the AM bundle provides the major anterior restraint, whereas the PL bundle functions at extension and contributes more to rotational stability.

Shen et al [5] performed an in-vivo study and found that SBACLR can most closely imitates AM bundle reconstruction, however, it does not sufficiently restore rotational stability. In addition, biomechanical study in a cadaveric body has found that DBACLR can better restore knee kinematics than SBACLR [6]. Recently, many anatomical studies have focused on the femoral and tibial insertion of the bundles of the ACL to determine correct tunnel placement when performing DBACLR [7, 8]. Exact anatomical positioning of the graft tunnels resulting into anatomic inclination angles of the grafts is essential for optimal clinical outcome in both single and double bundle ACLR. What's more, early graft failure are always associated with the inappropriate position of the graft [9]. Several clinical trials as well as biomechanics trials suggest that DBACLR has superiority in anterior knee stability and rotational stability compared with SBACLR [10-12]. However, there

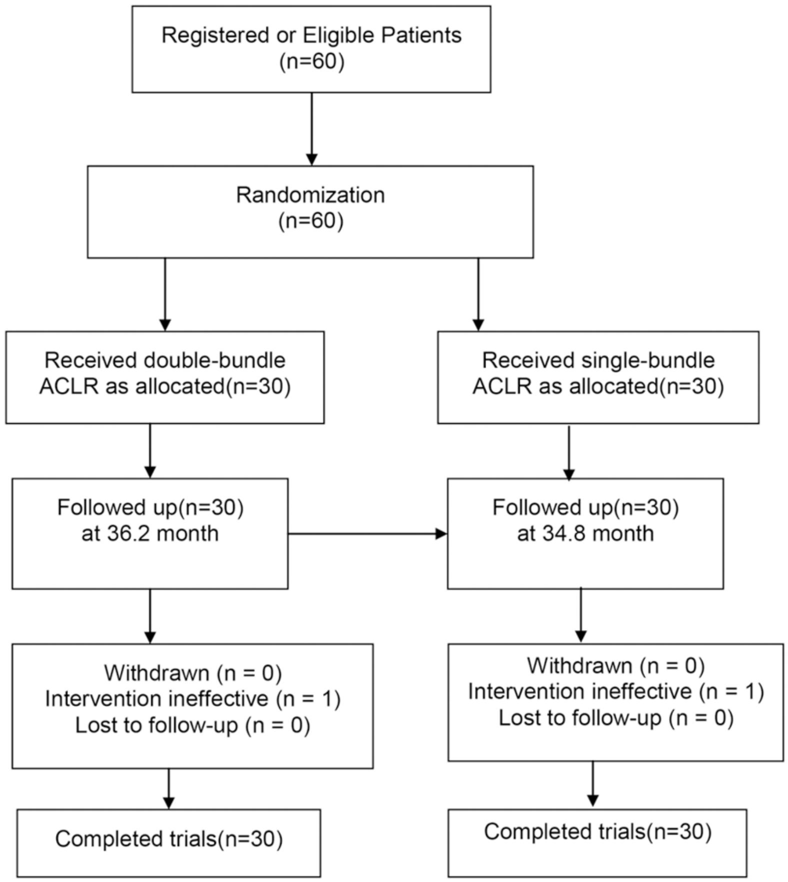

Figure 1. CONSORT flow diagram.

is no consensus about the clinical outcomes of DBACLR and SBACLR. The purpose of the present prospective trial was to evaluate the clinical and radiological outcome of arthroscopic DBACLR compared with that of SBACLR.

Materials and methods

From January 2009 to January 2015, 60 consecutive ACL injury patients for reconstruction surgeries were selected. Inclusion criteria: primary ACL reconstruction younger than 40 years old, chondral lesions less than Outerbridge grade III, no subtotal or total menisc-ectomy; no malalignment; and a normal contralateral knee. Exclusion criteria: combined posterior cruciate ligament injury, lateral collateral ligament injury, posterolateral rotatory instability, fracture around knee. The consort flow diagram can be seen in **Figure 1**.

Sixty patients were sequentially selected to undergo either single-bundle or double-bundle reconstruction based on random number table in Shanghai Eighth People Hospital. The general characteristics, clinical examination, knee examination (Lachman test, Pivot shift), Lysholm score, International Knee Documentation Committee (IKDC) scale (subjective as well as objective), standard radiograph (AP and lateral view) and Magnetic Resonance Imaging (MRI) were obtained and recorded. Written consent were signed and approved by the participants.

Operative technique

DBACLR: the semitendinosus tendon and the gracilis tendon were prepared and looped separately over closed loop Endobutton. The thickness of the graft construct was measured using a tendon thickness measuring gauge to the nearest of 0.5 cm. While viewing at 90° of knee flexion, "late ral bifurcate ridge" is often-seen on the femoral insertion between the AM and PL bundles, whereas a "lateral intercondylar ridge" is often seen on the upper limit of both the AM and PL bundles. These are useful surgical landmarks in addition to the native insertion fibers. Drilling of the AM femoral tunnel was done through the AM portal with the knee bent 90° to place the AM portal guide.

The femoral PL tunnel was drilled with the knee flexed to 120° and anatomic anterior cruciate ligament reconstruction (ACLR) PL femoral aimer (Smith and Nephew, Andover, USA) was inserted with an appropriate sized post into the already made AM tunnel. In a single-bundle arthroscopic reconstruction of the ACL, traditional AM bundle reconstruction was done with quadrupled semitendinosus tendon and gracilis tendon graft. The femoral footprint was identified and minimally debrided and was used as a landmark to make the femoral tunnel. In both SB and DBACLR, appropriate-sized endoscopic reamer was selected according to the graft

Figure 2. The medical imaging examination for SBACLR and DBACLR. A, B: Preoperative adem position and lateral x-ray for SBACLR, C: Preoperative MRI check for SBACLR. D, E: Postoperative adem position and lateral x-ray for SBA-CLR; F, G: Preoperative adem position and lateral x-ray for DBACLR, H: Is the preoperative MRI check for SBACLR. I and J: Postoperative adem position and lateral x-ray for DBACLR.

diameter and the femoral sockets were made. Depth was regulated according to the desired insertion length and was 9-10 mm greater than the desired graft insertion to allow for the Endobutton flip. Closed loop Endobutton was used for graft fixation on femoral side in both SB and DBACLR.

In DBACLR, for tibial tunnel, an ACL tip aimer (Smith and Nephew, Andover, USA) was set at 55° for the placement of the anteromedial guide wire. Once AM tunnel was drilled an appropriate sized post on Smith and Nephew anatomic ACLR PL tibial aimer was used. Once the post was secured, it was inserted into the AM tibial tunnel until the distal end was flush with the tibial surface. This slot was oriented to align with the anticipated center of the PL bundle. The PL tunnel had a more medial and distal entry point on the tibial cortex than a standard ACL tibial tunnel.

SBACLR: the center of tibial tunnel was the center of tibial footprint in line with the posterior border of anterior horn of the lateral meniscus. The fixation method used on the tibial side was titanium/biodegradable interference screw (**Figure 2**). In double bundle group AM bundle was fixed in 60° flexion and the PL bundle was fixed in full extension. Immediate quadriceps and hamstring exercises were started and partial weight bearing was allowed with crutches/walker in first postoperative week. After first week; range of motion in arc of 0-90° (closed kinetic chain) was started. Full weight bearing was allowed by 3-4 weeks and running and cycling after one month. The patients were followed up at 2 weeks for suture removal thereafter fortnightly for 2 months, monthly for next 3 months and then once in 6 months for clinical evaluation and complications if any.

Statistical analysis

Data were analyzed using the software of SPSS, version 20.0 (IBM, New York, United states). Preoperative values and values at the final follow up were compared using paired t-test. Discontinuous data were compared by chi-square test. $P<0.05$ was considered to be statistically significant.

Results

The detailed general characteristic of the patients in the two groups were shown in **Table**

Table 1. The general characteristic of the patients included for analysis

Parameter	Single bundle group (n=30)	Double bundle group (n=30)	Statistic value	*P* value
Age (years)	34.9±4.3	34.8±4.2	t=0.092	0.927
Female/male	18/12	16/14	χ^2=0.271	0.602
Height (cm)	171.2±5.6	168.9±2.9	t=1.987	0.052
Body weight (kg)	67.8±7.1	65.7±9.1	t=1.026	0.309
Follow up (month)	34.8±2.6	36.2±3.7		0.076
Preoperative Lysholm score	50.18±5.37	48.63±5.80	t=1.072	0.288
Preoperative subjective IKDC	45.60±4.51	45.33±5.66	t=0.207	0.837
Left/Right	8/22	6/24	χ^2=0.373	0.542

1. And results indicated that there is no statistically significant difference between the age, sex and other characteristic (**Table 1**).

The original data can be seen in Supplementary Table. At the time of final follow up, the mean Lysholm score was 95.13±2.67 in SB group and 93.13±3.31 in DB group (P>0.05). Postoperative subjective IKDC score at final follow up was 94.93±2.78 in SB group and 92.87±2.87 in DB group (P>0.05) All patients in both groups were in grade A or B as per the objective IKDC score at final follow up. The mean differential anterior tibial translation by GNRB, arthrometer was 1.47±0.6 mm in SB group and 1.07±0.8 mm in DB group (P>0.05) (**Table 2**).

Though most of the patients regained very good range of motion (0-120° or above), 5 cases in SB group and 4 cases in DB group had mean 15° loss of terminal flexion. No patient in the both groups had terminal extension loss.

All the patients showed a negative pivot shift test in DB group and 2 cases in SB group showed positive pivot shift at final follow up. Two patients in each group had Endobutton flipped (>2 mm) in soft tissue outside the femoral cortex. Magnetic resonance imaging scans of operated knees at 2 years follow up showed the mean postoperative sagittal tibial-ACL angle as 59.4±4.8 degrees in the single bundle group and 56.1±5.06 degrees in patients with double bundle reconstruction. Normal value for patients with closed physes is (58.8°±4.9°). Post-op mean coronal tibial-ACL angle in single bundle group was about 73.7±5.1 degrees and in the group reconstructed with double bundle it was observed to be 74.86±5.69 degrees (**Figure 2**). Normal value for patients with closed physes is 69.1°±7.4°. There was no statistically significant difference between the two groups with respect to all the discussed criterion (P>0.05).

Discussion

The fact that SBACLR does not completely correct the rotational instability and it may result in antero-posterior instability in knee position of terminal extension is well accepted now [2, 13]. Recently the DBACLR has gained in popularity, in which each bundle of the ACL was reconstructed separately with correct tensioning pattern of each bundle. The function of AM bundle and PL bundle is different. The AM bundle taut throughout the knee range of motion, whereas the PL bundle is only tight primarily in extension [13]. Therefore, the AM and PL bundles are fixated separately to restore the ACL function to an extent. An in-vivo study has shown that SBACLR can successfully restore anterior knee stability but does not sufficiently keep rotational stability [5]. In addition, cadaveric biomechanical studies have shown that double-bundle ACL reconstructions better restore knee kinematics than single-bundle ACL reconstructions [8]. Present study revealed that 6.6% patients in SBACLR group and none in DBACLR group. However there is no statistically significant between the two groups. Meredick et al [14] conducted a meta-analysis of randomized controlled trials and found that double-bundle reconstruction did not result in clinically significant differences in KT-1000 measurements for anterior stability or in pivot shift testing for rotational stability. Mascarenhas et al [15] conducted an overlapping meta-analyses and found that DBACLR provides better postoperative knee stability than SBACLR and no significant difference between graft failure.

Yasuda et al [16] proposed a new concept of anatomic reconstruction of anteromedial and posterolateral bundles. In the study, they analyzed 10 prospective randomized studies and 1 meta-analysis comparing SBACLR and DBACLR. 8 (80%) of the 10 studies, the anterior and/or rotational stability of the knee was significantly

Table 2. The comparison results of subjective assessments for the single bundle group and double bundle group

Parameter	Single bundle group (n=30)	Double bundle group (n=30)	Statistic value	*P* value
Clinical Outcomes				
Postoperative Lysholm score	95.24±2.59	93.06±3.29	t=2.838	0.108
Postoperative subjective IKDC score	94.72±2.90	93.06±3.17	t=2.110	0.309
Postoperative pivot shift	2 (6.67%)	0 (0.00%)	χ^2=2.069	0.150
Radiological outcomes				
Differential anterior tibial translation (mm)	1.51±0.33	1.37±0.26	t=1.862	0.068
Postoperative mean sagittal tibial ACL angle	60.1±3.1	59.0±1.58	t=1.751	0.085
Postoperative mean coronal tibial ACL angle	73.2±3.2	74.4±3.6	t=1.300	0.199

better with the anatomic DBACLR than with conventional single-bundle reconstruction. A meta-analysis of random controlled trials revealed that DBACLR resulted in significantly better anterior and rotational stability and higher IKDC objective scores compared with single-bundle reconstruction [17]. However, the meta-analysis did not detect any significant differences in subjective outcome measures between double-bundle and single-bundle reconstruction, as evidenced by the Lysholm score, Tegner activity scale, and IKDC subjective score. Similarly to our study, we also did not observe statistically significant difference between the two groups with respect to Lysholm score, subjective and objective IKDC, differential anterior tibial translation, as well as in postoperative mean sagittal and coronal tibial ACL angles on MRI scan.

Our study was conducted with a primary aim of comparing the post-operative clinic-radiological results of SBACLR versus DBACLR. To our knowledge, this is the first clinical prospective trial to compare the clinical outcomes in clinic-radiological perspective. MRI results indicated that the placement of graft of knees showed satisfactory results in both the groups. As mentioned above, exact positioning of the grafts is essential for optimal clinical outcome [18]. Final radiology results suggest that both groups can reach satisfactory position. Another assessment parameter, GNRB arthrometer showed marginally better results in DBACLR, however statistically significance has not be reached finally. The mean translation in group reconstructed with single bundle was 1.47 mm whereas the mean translation in DB group was found to be 1.07 mm. More collagen in ACL footprints and differential tensioning of the two bundles in DBACLR could be the reason for a better antero-posterior stability. The mean differential anterior tibial translation in both groups of patients in our study corresponded to the value observed in various studies over time.

Our study also showed that functional (Lysholm and IKDC scores) and objective results (arthrometerantero-posterior translation measurement) were similar in the two groups. DBACLR also has some disadvantages such as technical difficulty and the surgery time will be increased. DBACLR are usually need more tunnels to be created and thus more grafts to be fixed correspondingly, the DB technique can be associated with more technical difficulties than the traditional single bundle technique. And this technique will increase patients' costs due to more fixation material. In this study, the costs for each patients is not compared between the two groups since the economic costs may influenced by many uncontrolled factors.

This study has several limitations: (1) Many subjective tests was used to assess the clinical outcomes for SBACLR and DBACLR and thus patient's cooperation is important. (2) In DBACLR group, though significant improvement of rotational stability, which might be related to the additional PL bundle reconstruction. (3) One could also speculate that the high number of negative pivot shift tests might also be related to the four tunnel technique, which increases the size of the footprint of the reconstruction. (4) We failed to evaluate the characteristic proprioceptive function thought to be one of the merits of double-bundle reconstruction. In addition, there is the lack of a power analysis because of the small number of cases.

Conclusion

In our study, both SBACLR and DBACLR were found to yield similar/comparable clinical and radiological results. However, 6.6% patients in SBACLR group had rotatory instability in comparison to none in DBACLR. There is significant difference between SBACLR and DBACLR in other subjective and objective parameters. Thus, high quality RCTs with long follow up are still need to substantiate the long term advantages of DBACLR over traditional SBACLR.

Disclosure of conflict of interest

None.

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