Single-Bundle versus Double-Bundle Anterior Cruciate Ligament Reconstruction: A Meta-Analysis

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Objective: This meta-analysis study compares the treatment outcomes between single bundle (SB) and double bundle (DB) anterior cruciate ligament reconstructions (ACLR) including manual laxity tests, KT-1000 measurements and functional knee scores including International Knee Documentation Committee (IKDC) and Lysholm scores.

Data sources: Medline, Scopus, Web of Science and Cochrane Central Register of Controlled Trials (January 1985 to March 2008).

Material and Method: All randomized controlled trials reporting one or more outcomes related to single bundle versus double bundle ACLR were recruited in the present study. Random effect models were used to pool the data. Heterogeneity in the effect of treatment was tested on the basis of study quality, randomization status and type of ACLR.

Results: There were 2,119 studies initially identified, 7 studies met our inclusion criteria. Four hundred and eighty two patients (238 in SB group and 244 in DB group) were included in the present study. The results of KT 1,000 arthrometry in 7 studies favor DB-ACLR with statistical significance (p < 0.05). Pivot shift test were available for 374 patients from 6 studies, 183 and 191 patients in SB group and DB group respectively. The results favor DB-ACLR with statistical significance (p < 0.001). IKDC scores were available for 257 patients from 4 studies. The results trend to favor DB-ACLR but not statistically significant (p = 0.17). Lysholm scores were available for 174 patients from 3 studies. The results trend to favor DB-ACLR without statistical significance (p = 0.10).

Conclusion: The present study shows that DB-ACLR provides better AP and rotational stability than SB-ACLR. There is no difference in the results of functional scores. DB-ACLR should be considered in patients who particularly require rotational stability of the knee. In the future, the interesting issue is to develop the functional knee score that is more specific to rotational stability evaluation.

Keywords: Anterior cruciate ligament, Single bundle, Double bundle, Meta-analysis, Randomized controlled trials

J Med Assoc Thai 2012; 95 (Suppl. 9): S114-S121 Full text. e-Journal: http://jmat.mat.or.th

Anterior cruciate ligament (ACL) injury occurs 0.38 per 1,000 each year and surgical treatments for this ligament are more than 100,000 annually in the United States^(1,2). Expectations for these kinds of operations are focused on preventing further meniscal and chondral damage and allow the patients to return to their level of activities before the injury⁽³⁾. The most common operative treatment for ACL insufficiency is reconstruction which aims to restore anteroposterior

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Phone: 0-2419-7530 E-mail: sicls@mahidol.ac.th and rotational stabilities of the knee.

The single bundle ACL reconstruction (SB-ACLR) technique has been the gold standard procedure performed with one tibial and one femoral tunnel with reported clinical success ranging from 70% to 95% (4). However, recent biomechanic studies have shown that single-bundle technique cannot provide adequate rotational stability (5-9). The double bundle ACL reconstruction (DB-ACLR) technique, first reported in 1985, has been introduced to restore both anteroposterior and rotational stabilities. The principle of this technique is to restore both anteromedial and posterolateral bundles of native ACL. There are several studies showing better stability and more rotational control with DB-ACLR⁽¹⁰⁾. Nevertheless, there are few

randomized controlled trials with small samples to demonstrate the difference outcomes and the controversial issues about operative technique of ACL reconstruction.

The objective of this meta-analysis is to compare the outcome of DB-ACLR with that of SB-ACLR. Our hypothesis is that DB-ACLR is superior to the SB-ACLR technique in term of stability including manual laxity tests, KT-1000 measurements and functional knee scores (IKDC and Lysholm), as well as the results based on subjective evaluation.

Material and Method Search strategy

The authors searched the published literature using Medline, Scopus (January 1985 to March 2008), Cochrane Central Register of Controlled Trials and Web of Science databases (January 1993 to March 2008), not restricted to English-language articles. The authors used the following subject headings and key words in separated searches: anterior cruciate ligament, surgery, reconstruction, single bundle, double bundle, hamstring graft, bone patellar tendon bone graft. All potentially pertinent articles were retrieved and reviewed in detail by two reviewers (KK and CL) independently. Additionally, the authors performed manual search of the references listed in all relevant papers reviewed.

Trials selection and study characteristics

For the inclusion criteria, the studies were required to be:

- $\begin{tabular}{ll} \end{tabular} \begin{tabular}{ll} \end{tabular} Arthroscopic SB-ACLR compared with DB-ACLR \end{tabular}$
 - (2) Randomized controlled trial study
 - (3) A minimum 12 month follow-up

The authors excluded studies of revision ante-

rior cruciate ligament reconstruction, extra-articular augmentation procedure, bilateral anterior cruciate ligament injuries and allograft anterior cruciate ligament reconstruction.

Data abstraction and assessment of validity

Two of the authors (KK and CL) independently extracted data on study design, setting, population, condition of interest, interventions and cointerventions, outcomes and the quality of the studies by using standardized forms. Disagreements were resolved by discussion. Study information and details are shown in Table 1 and Table 2.

Data extraction

Each study was carefully analyzed by two reviewers (KK and CL). Any minor inconsistencies between reviewers were re-examined and resolved. From the selected publications, subjective and objective measures including Lysholm score, KT-1000 or KT-2000 arthrometry measurement, International Knee Documentation Committee (IKDC) scores, pivot shift scores were collected.

The odd ratios (OR) for a given outcome were calculated for individual studies, as well as combined for an overall summary odds ratio. Odd ratios were calculated for the odds of a bad outcome for single bundle versus double bundle anterior cruciate ligament reconstruction so a value greater than one indicates an outcome favoring single bundle anterior cruciate ligament reconstruction (SB group), whereas a value less than one would indicate an outcome favoring double bundle anterior cruciate ligament reconstruction (DB group). Shifting of the dots to the right favors the single bundle anterior cruciate ligament reconstruction outcomes.

Table 1. Study information

Study	Randomization concealment	Patient blinding	Outcome assessor blinding	Loss to follow-up	Intention to treat analysis
Adachi, 2004	improper	NA	blinded	0/108	improper
Yasuda, 2006	improper	not blinded	blinded	0/72	proper
Muneta, 2007	NA	NA	blinded	0/68	improper
Jarvela, 2007	improper	NA	blinded	0/55	improper
Yagi M, 2007	improper	NA	NA	0/60	proper
Nikolaus, 2008	improper	not blinded	blinded	0/49	proper
Siebold, 2008	block randomize	not blinded	blinded	0/70	proper

NA= Not available

Quantitative data synthesis

The authors entered eligible trials into Review Manager Software 4.2.10 version from Cochrane Collaboration. The results of comparable groups were pooled using random effect model.

The heterogeneity of comparable trials was tested by using Chi-square test and p-value < 0.1 was considered significant.

Results

Literature review

Of 2,119 studies initially identified, 7 studies fulfilled our inclusion criteria (Fig. 1) including 482 patients (238 in SB group and 244 in DB group)^(4,7,10-14). No additional articles were identified by the manual review of the bibliographies of relevant articles.

Eligible studies

Seven studies were relevant according to the title, abstract and complete retrieval of the article. The authors cannot contact the authors of Jarvela T et al⁽¹³⁾

to retrieve additional data and clarify number of sex difference in their study. Table 3 demonstrates availability of the study information.

Study characteristics

All of the eligible studies were published between January 1985 to March 2008 and entirely analyzed 482 patients (238 in the SB-ACLR group and 244 in the DB-ACLR group). All patients in the control group received SB-ACLR and treatment group were DB-ACLR. Patients had mean age of 27.5 years (27.3 years in the single bundle group and 27.66 years in the double bundle group). The male to female ratio cannot be evaluated due to lack of the data in one study. Follow-up period ranged from 12 to 33 months.

Quantitative data synthesis

International Knee Documentation Committee (IKDC) scores

There was great variability in the use of scoring systems. Some studies used more than one

Table 2. Details of studies

Study	Number of patients		Mean age (yrs.)		Follow-up period (mo.)		Operative technique	
	SB	DB	SB	DB	SB	DB	SB	DB
Adachi, 2004	55	53	29.5	29.2	33	30	НТ	НТ
Yasuda, 2006	24	48	25.7	26.1	24	24	HT	HT
Muneta, 2007	34	34	23.4	24.0	25.4	25.2	HT	HT
Jarvela, 2007	25	30	33.0	33.0	14	14	HT	HT
Yagi, 2007	40	20	22.5	22.3	12	12	HT	HT
Nikolaus, 2008	25	24	29.2	30.0	24.1	23.8	HT	HT
Siebold, 2008	35	35	29.0	28.0	19	19	HT	HT

HT = Hamstring tendon (Graft type)

Table 3. Availability of study information

Study	IKDC	KT-1000	or 2000	Lysholm score	Pivot shift test
		20° knee flexion	60° knee flexion		
Adachi, 2004	_	+	+(70° knee flexion)	_	_
Yasuda, 2006	+	+	+	-	+
Muneta, 2007	-	+	+	-	+
Jarvela, 2007	+	+	+	+	+
Yagi, 2007	+	+	+	-	+
Nikolaus, 2008	-	+	+	+	+
Siebold, 2008	+	+	+	+	+

[&]quot;+" = Information is available, "-" = Information is not available

score (IKDC, Tegner scores or Lysholm scores) to evaluate the outcomes of surgery. Data on IKDC scores were available for 257 patients in four studies $^{(4,7,12,13)}$. Three studies did not list IKDC scores in their articles $^{(10,11,14)}$. The test was positive (C and D, C = abnormal D = severely abnormal) in 4 of 133 patients (3%) in the treatment group (DB) and 10 of 124 (8.06%) in the control group (SB). The result of IKDC scores trend to favor DB-ACLR without statistical significance (odd ratios = 0.41 [95% confidence interval = 0.11 to 1.46, p = 0.17). The test for heterogeneity was not significant (p = 0.94) (Fig. 2).

Arthrometry testing KT-1000 or KT-2000 arthrometry measure-

ment

All seven studies have postoperative arthrometry measurements. Five studies used KT-1000^(4,7,10,13,14) and two studies used KT-2000^(11,12). Both KT-1000 and KT-2000 were tested in two different knee flexion angle, 20 and 60 degrees of knee flexion position (70 degrees in the present study of Adachi N et al). In

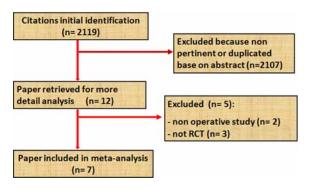


Fig. 1 Flow diagram representing the study identification process

20 degrees knee flexion, weighted mean difference (WMD) was -0.60 (95% confidence interval = -1.014 to -0.06), p = 0.0009). In 60 degrees knee flexion weighted mean difference (WMD) was -0.54 (95% confidence interval = -0.83 to -0.25), p = 0.0002). The tests for heterogeneity of both 20 and 60 degrees knee flexion angle were not significant (p = 0.29 and p = 0.36 respectively). Both degrees of knee flexion position show similar results of favors to treatment group (DB-ACLR) with statistical significance (Fig. 3 and Fig. 4).

Lysholm score

The data of Lysholm scores were available for 174 patients in three studies $^{(7,13,14)}$. Four studies did not list the Lysholm scores in their articles $^{(4,10,12)}$. The result indicated an outcome of trend to favoring DB-ACLR without statistical significance (p = 0.10). Weighted mean difference (WMD) was -1.88 (95% confidence interval = -4.11 to 0.36). The test for heterogeneity was not significant (p = 0.39) (Fig. 5).

Pivot shift test

Data of the pivot shift test were available for 374 patients in 6 studies. There were 183 patients in SB group and 191 patients in DB group. One study did not list the pivot shift test in the article (Adachi et al). The test was positive in 22 of 191 patients (11.5%) in DB group and 60 of 183 patients (32.78%) in SB group. The result indicated an outcome favoring DB-ACLR with statistical significance (odd ratios = 0.24 [95% confidence interval = 0.13 to 0.46] and p < 0.001). The test for heterogeneity was not significant (p = 0.35) (Fig. 6).

Rate of reoperation and graft failure

None of studies reported data of re-operation

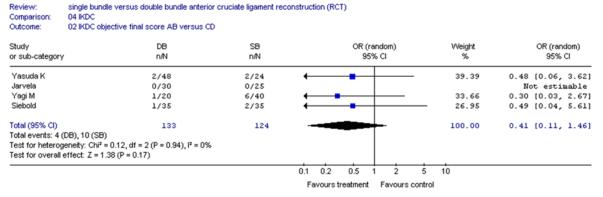
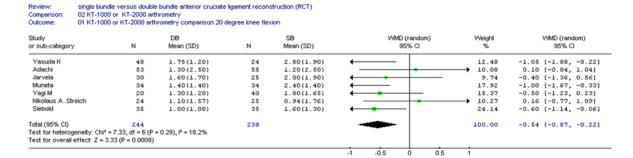


Fig. 2 IKDC scores (AB versus CD)
A = normal, B = nearly normal, C = abnormal, D = severely abnormal



Favours treatment Favours control

Fig. 3 KT-1000 or KT-2000 arthrometry with 20 degrees knee flexion

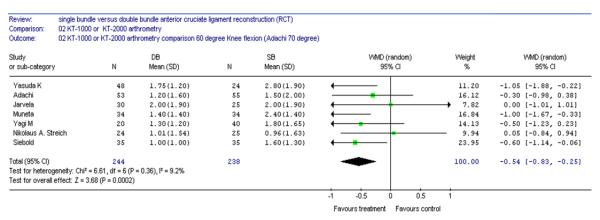


Fig. 4 KT-1000 or KT-2000 arthrometry with 60 degrees knee flexion

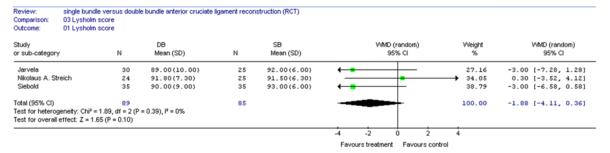


Fig. 5 Lysholm score

or graft failure. There was no heterogeneity and no significant difference in graft ruptures or complications between the two groups.

Discussion

Nowadays the single bundle anterior cruciate ligament reconstruction is gold standard for primary ACL reconstruction. However several studies have shown that double bundle technique was better than single-bundle reconstruction based on rotational stability and function knee scores. Our hypothesis in this study is that DB-ACLR is superior to the SB-ACLR

method in term of stability based on manual laxity tests, KT-1000 measurements and functional knee scores (IKDC and Lysholm), as well as subjective evaluation. The authors performed a meta-analysis of prospective randomized controlled trials comparing SB-ACLR versus DB-ACLR. The present study revealed that when concerning to anteroposterior stability, the result of KT-1000 arthrometry demonstrated that DB-ACLR provide more AP stability than SB-ACLR with statistical significance but without clinical significance because the difference is less than 3 mm. When concerning about rotational stability, the result of pivot shift test

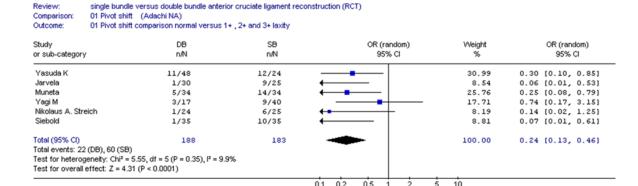


Fig. 6 Pivot shift test

demonstrated that DB-ACLR provides more rotational stability than SB-ACLR. The results of both functional scores trend to favor DB-ACLR than SB-ACLR without statistical significance. The authors found that there were no parameters for the evaluation of rotational stability in the IKDC and Lysholm score. In the future, the interesting issue might be the development of the functional knee scores that are more specific to rotational stability evaluation.

The authors recognize several limitations of the present study. First, a meta-analysis is only as good as the studies it examines. Some studies did not list data in articles, for example, sex difference, operative time, sports specific or a period for returning to sports activities. In addition, the authors need some important data such as details of associated injuries including severity of cartilage injury, meniscus injury or osteoarthritic change at the time of arthroscopic treatment for further evaluation of functional outcome and prediction of tendency to osteoarthritis in future. The authors tried to contact the authors about these information in their articles but no data was clarified.

Conclusion

The double bundle anterior cruciate ligament reconstruction provides better anteroposterior and rotational stability than single bundle technique. There is no significant difference in the results of functional scores. Double bundle technique might be considered in patients who particularly require rotational stability of the knee. In the future, the interesting issue is to develop the functional knee score that more specific to rotational stability evaluation.

Potential conflicts of interest

None.

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Favours DB

Favours SB

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การสังเคราะห์งานวิจัยเชิงทดลองแบบสุ่มและมีกลุ่มควบคุมที่เกี่ยวกับการผ่าตัดสร้างเอ็นไขว้ หน้าข้อเข่า ด้วยวิธี single bundle และ double bundle โดยวิธีการวิเคราะห์อภิมาน

ชนินทร์ ล่ำซ้ำ, กมลพร แก้วพรสวรรค์, จรัญ เหลืองสะอาด, กุลธร เทพมงคล, บวรรัฐ วนดุรงค*์*วรรณ, กราบแก้ว โสภาราษฎร์

วัตถุประสงค์: ใช้การวิเคราะห์อภิมานเพื่อเปรียบเทียบผลการรักษาระหว่างการผ่าตัดสร้างเอ็นไขว้หน้าข้อเข่าด้วยวิธี single bundle และ double bundle โดยเปรียบเทียบในแง่ความมั่นคงของข้อเข่า โดยการตรวจร่างกายและ การใช้เครื่องมือ KT 1000 และเปรียบเทียบในแง่ Functional Knee Scores (IKDC และ Lysholm scores) แหล่งข้อมูลที่นำมาศึกษา: การศึกษานี้ใช้ฐานข้อมูลจาก MEDLINE และ Scopus (ระหว่างเดือน มกราคม พ.ศ.

แหลงขอมูลที่น้ำมาศึกษา: การศึกษานี้ใชฐานขอมูลจาก MEDLINE และ Scopus (ระหวางเดือน มกราคม พ.ศ. 2528 ถึง เดือน มีนาคม พ.ศ. 2551) และ Web of Science และ Cochrane Central Register of Controlled Trials (ระหวางเดือน มกราคม พ.ศ. 2536 ถึง เดือน มีนาคม พ.ศ. 2551)

ข้อมูลที่นำมาศึกษา: การศึกษาเชิงทดลองแบบสุ่มและมีกลุ่มควบคุมทุกการศึกษาที่เกี่ยวข้องกับการเปรียบเทียบ ผลการรักษาระหว่างการผ่าตัดสร้างเอ็นไขว้หน้าข้อเข่าด้วยวิธี single bundle และ double bundle

ผลการศึกษา: จากการศึกษาเปรียบเทียบผลการรักษาระหว่างการผ่าตัดสร้างเอ็นไขว้หน้าข้อเขาด้วยวิธี single bundle และวิธี double bundle ทั้งสิ้น 2,119 การศึกษา พบวามี 7 การศึกษาที่มีข้อมูลตรงตามเกณฑ์ที่กำหนด โดยใน 7 การศึกษานี้มีผู้ป่วยทั้งสิ้น 482 ราย (238 รายในกลุ่ม single bundle และ 244 ราย ในกลุ่ม double bundle) ผลการวัดความมั่นคงของข้อเข่า โดยเครื่องมือ KT 1000 (ใน 7 การศึกษา) พบวาวิธี double bundle ให้ความมั่นคงมากกว่าอย่างมีนัยสำคัญทางสถิติ (p<0.05) สำหรับการตรวจร่างกายโดยวิธี Pivot shift ในผู้ป่วย 374 ราย จาก 6 การศึกษา (183 รายในวิธี single bundle และ 188 รายในวิธี double bundle) พบวา วิธี double bundle ให้ความมั่นคงมากกว่าอย่างมีนัยสำคัญทางสถิติ (p<0.001) สำหรับค่า International Knee Documentation Committee (IKDC) ในผู้ป่วย 257 ราย จาก 4 การศึกษา พบวาการผ่าตัดด้วยวิธี double bundle ให้คามากกวาการผ่าตัดอิธี single bundle อย่างไม่มีนัยสำคัญทางสถิติ (p=0.17) และค่า Lysholm scores ในผู้ป่วย 174 ราย จาก 3 การศึกษา พบวาการผ่าตัดด้วยวิธี double bundle อย่างไม่มีนัยสำคัญทางสถิติ (p=0.10)

สรุป: จากการวิเคราะห์อภิมาน พบวาผลการผ่าตัดสร้างเอ็นไขว้หน้าด้วยวิธี double bundle ให้ความมั่นคงของข้อเข่า แนวหน้าหลัง และด้านการบิดหมุนของข้อเข่ามากกวาการผ่าตัดด้วยวิธี single bundle การศึกษานี้ไม่พบ ความแตกต่างอย่างมีนัยสำคัญทางสถิติของ functional scores ดังนั้นควรเลือกใช้การผ่าตัดด้วยวิธี double bundle ในผู้ปวยที่ต้องการความมั่นคงในด้านการบิดหมุนของข้อเข่าค่อนข้างมาก