

· 临床研究论著 ·

自体腘绳肌腱单束与双束重建前交叉韧带临床结果的 Meta 分析

阿布都萨拉木·阿布都克力木 高志祥 买买提沙吾提阿吉·麦麦提 伊力哈木·托合提

【摘要】 目的 基于已发表的随机对照试验(randomized controlled trials, RCTs),对关节镜下采用自体腘绳肌腱单束或双束重建前交叉韧带的整体疗效比较进行 Meta 分析。方法 计算机检索 PubMed、Cochrane library、Springerlink 数据库,收集自体腘绳肌腱单束对比双束重建前交叉韧带的 RCTs,检索时间及语种不限。两名研究人员按照指定的纳入标准及排除标准独立对文献进行筛选,提取有关数据资料,并采用 Cochrane Collaboration 工具表对文献质量进行评价。采用 Revman 5.3 软件进行 Meta 分析,比较两种重建方式术后国际膝关节评分委员会(International Knee Documentation Committee, IKDC)主观评分和客观评分、Lachman 试验、轴移试验、Lysholm 膝关节评分、Tegner 膝关节评分、KT-1000 或 KT-2000 关节活动度测量仪测量的数值,评价手术疗效。结果 纳入 19 篇 RCTs,共 1 190 例研究对象,其中单束重建组 580 例,双束重建组 610 例。两组间在 IKDC 主观评分[$MD=-0.90, 95\% CI(-3.07, 1.27), P=0.42$]、IKDC 客观评分[$RR=0.98, 95\% CI(0.94, 1.02), P=0.38$]、Lachman 试验结果[$RR=0.81, 95\% CI(0.63, 1.05), P=0.11$]、Lysholm 膝关节评分[$MD=0.40, 95\% CI(-1.24, 2.05), P=0.63$]、Tegner 膝关节评分[$MD=-0.08, 95\% CI(-0.47, 0.33), P=0.74$]、KT-1000 或 KT-2000 测量值[$MD=0.30, 95\% CI(-0.05, 0.64), P=0.09$]方面,差异均无统计学意义。轴移试验结果在两组间的差异具有统计学意义[$RR=0.85, 95\% CI(0.74, 0.97), P=0.02$]。结论 对于膝关节功能恢复和前直向稳定性,用自体腘绳肌腱单束或双束重建前交叉韧带的临床结果无明显差异;而对于恢复膝关节旋转稳定性,双束重建技术优于单束重建。

【关键词】 前交叉韧带;重建;单束;双束;自体腘绳肌腱;膝关节;Meta 分析;循证医学

Single - bundle versus double - bundle anterior cruciate ligament reconstruction with autogenous hamstring tendon: a Meta-analysis. ABUDUSALAMU·Abudukelimu, GAO Zhi-xiang, MAIMAITISHAWUTIAJI·Maimaiti, YILIHAMU·Tuoheti. Department of Sports Injury, the Sixth Affiliated Hospital of Xinjiang Medical University, Urumqi 830002, China

Corresponding author: YILIHAMU·Tuoheti, E-mail: 578099038@163.com

【Abstract】 Objective Based on published randomized controlled trials (RCTs), a meta-analysis was performed on the overall efficacy of arthroscopic reconstruction of the anterior cruciate ligament using single or double hamstring tendons. **Methods** PubMed, Cochrane library, Springerlink and other databases were searched. The RCTs of single-bundle and double-bundle reconstruction of anterior cruciate ligament were obtained. Date and language were not limited. According to the criteria, the literature was screened and data were extracted by two reviewers independently, and the Cochrane Collaboration's risk of bias tool was used to assess the quality of literature. RevMan 5.3 software was used to perform the Meta analysis, including the contrast of International Knee Documentation Committee (IKDC) scores, Lachman testing, pivot-shift testing, Lysholm scores, Tegner scores, KT-1000 or KT-2000 arthrometer measurement. **Results** Nineteen RCTs were included, with a total of 1 190 patients (580 cases in the single-bundle group, and 610 cases in the double-bundle group). Meta-analysis results showed that there was no significant difference in postoperative IKDC objective scores [$MD=-0.90, 95\% CI(-3.07, 1.27), P=0.42$], IKDC subjective scores [$RR=0.98, 95\% CI(0.94, 1.02), P=0.38$], Lachman testing [$RR=0.81, 95\% CI(0.63, 1.05), P=0.11$], Lysholm scores [$MD=0.40, 95\% CI(-1.24, 2.05), P=0.63$], Tegner scores [$MD=-0.08, 95\% CI(-0.47, 0.33), P=0.74$], KT-1000 or KT-2000 arthrometer measurement [$MD=0.30, 95\% CI(-0.05, 0.64), P=0.09$], but the statistically significant

difference was found in the pivot-shift testing [$RR=0.85$, 95% CI (0.74, 0.97), $P=0.02$] between two groups.

Conclusion There was no significant difference in the clinical results of the anterior cruciate ligament reconstruction with single or double bundle of hamstring tendon autograft for the functional recovery and anterior straight stability of knee joint, while the double bundle reconstruction was superior to the single bundle reconstruction for the restoration of rotational stability of knee joint.

【Key words】 Anterior cruciate ligament; Reconstruction; Single-bundle; Double-bundle; Autogenous hamstring tendon; Knee joint; Meta-analysis; Evidence-based medicine

前交叉韧带重建被广泛用于恢复膝关节松弛,重建生物力学稳定,并防止长期关节退变^[1-3]。近年来,单束(SB)和双束(DB)重建技术常用于前交叉韧带重建^[4,5]。然而,尚未就双束重建技术是否优于单束重建技术达成共识。有研究报道,双束重建技术可以在膝关节稳定性和临床功能方面取得优异的成果^[6-8]。同时,也有文献表明双束重建技术可以获得更好的膝关节稳定性,但其术后功能方面与单束重建技术相当^[9-13]。另一方面,有研究发现膝关节稳定性和临床功能在两种技术前交叉韧带重建中没有显著差异^[4,12,14-18]。鉴于以往研究的不同结果,本文收集自体腘绳肌腱单束和双束重建前交叉韧带的临床随机对照试验(randomized controlled trials, RCTs),汇总数据,以比较双束重建和单束重建技术的临床结果差异,为前交叉韧带重建方式的选择提供循证参考基础。

资料和方法

一、文献检索

本研究根据 PRISMA 报告标准^[19]设计和制定。利用计算机检索 PubMed、Cochrane、Springerlink 数据库。参照 Cochrane 协作网推荐的检索策略,并追踪纳入文献的参考文献,文献检索无语种限制。检索词如下:“anterior cruciate ligament”、“reconstruction, hamstring, autograft”、“single bundle”、“one bundle”、“double bundle”、“two bundle”、“randomized controlled trial”、“clinical trial”。

二、文献纳入标准

纳入标准:①研究类型为临床 RCTs;②在关节镜下使用单束或双束重建前交叉韧带,病人性别及种族不限;③移植物为自体腘绳肌腱,忽略固定方式的差异;④随访时间 > 12 个月的研究。排除标准:①非临床 RCTs,动物或尸体研究;②前交叉韧带重建中非单束和双束重建比较的研究。

三、数据收集和管理

2 位作者分别独立按上述纳入、排除标准及观察指标进行数据提取,交叉核对,如遇到分歧协商达

成共识解决,若不能解决则交由第 3 方(联系文献作者)审核并提出意见解决。提取纳入文献中的作者姓名、发表时间、病人数量、移植物、固定方式、IKDC 评分、Lachman 试验、轴移试验、Lysholm 评分、Tegner 评分、KT-1000 或 KT-2000 测量值等数据^[20-25]。

四、文献质量评价

纳入文献采用 Cochrane Collaboration 工具^[26]评价文献质量,包括随机性、分配隐藏、盲法、资料完整性、选择性报告结果及其他偏倚。使用方法是将文献相关的叙述部分记录,分析后作出判断。将各项结果作出“低风险偏倚”、“高风险偏倚”或“风险不清楚”。

五、统计学分析

采用 Review Manager 5.3 软件(国际 Cochrane 协作网)对提取的数据进行 Meta 分析。对于二分类变量,计算效果大小的相对风险度(RR)^[27]。对于连续型变量,当使用相同的测量标准时,采用加权均数差(MD)进行统计分析,使用 95% 可信区间(CI)。统计异质性采用 I^2 检验,如果异质性较低($I^2 \leq 50\%$),则使用固定效应模型,如果异质性显著($I^2 > 50\%$),则进行敏感性分析和亚组分析找出异质性的来源。如果不能消除异质性,当 Meta 分析的结果具有临床同质性或使用描述性分析时,将使用随机效应模型。采用漏斗图分析发表偏倚,若漏斗图是对称的,则发表偏倚的可能性小;相反,发表偏倚大。

结 果

一、文献检索结果

按照检索策略,初步检索共得到 373 篇文献,其中 PubMed 86 篇、Cochrane 76 篇、Springerlink 211 篇,通过阅读文献标题及摘要排除 344 篇,剩余 29 篇。进一步阅读全文,按照纳入与排除标准,最终得到 19 篇文献进行 Meta 分析^[3,7,9,28-43]。文献筛选流程图见图 1。

二、纳入文献特征及质量评价

所有 19 篇纳入的文献均比较了用腘绳肌腱重建前交叉韧带中单束重建技术和双束重建技术的临床结果。纳入的文献中,固定方式不同,所有随访期

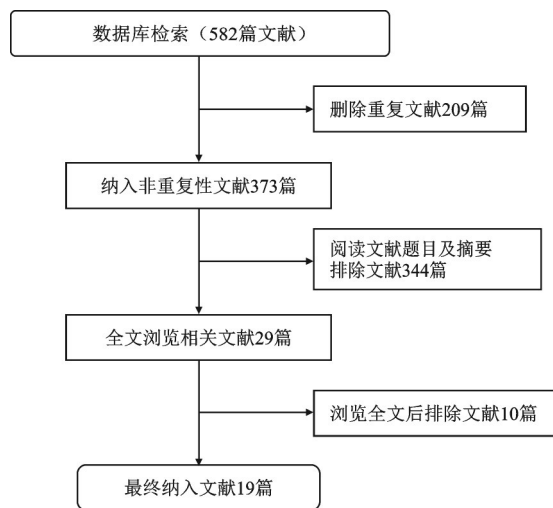


图1 文献纳入及排除流程图

均 > 12个月。共 1 190 例病人,其中单束组 580 例,双束组 610 例。采用 Cochrane Collaboration 工具对纳入的 19 篇文献进行质量评价,其中低质量文献 11 篇,高质量文献 8 篇。文献研究基本特征见表 1,文献质量评价见图 2。

三、Meta 分析结果

对纳入的 19 篇文献中报道的 IKDC 主观评分、IKDC 客观评分、Lachman 试验、轴移试验、Lysholm 评分、Tegner 评分、KT-1000 或 KT-2000 测量值进行

数据汇总,排除不全、不可用的数据后进行分析。

(一)IKDC 主观评分

6 篇文献报道了术后 IKDC 主观评分^[7,9,28,34,36,43]。各研究结果之间无异质性($P=0.18, I^2=34%$),采用固定效应模型进行分析,结果示单束重建与双束重建术后 IKDC 主观评分差异无统计学意义 $[MD=-0.90, 95% CI(-3.07, 1.27), P=0.42]$,见图 3。

(二)IKDC 客观评分

所有 19 篇文献中的 13 篇文献进行了 IKDC 客观评分^[7,9,29-31,34,37-43]。各研究结果之间无异质性($P=0.86, I^2=0%$),通过固定效应模型分析结果,单束重建和双束重建后 IKDC 客观评分差异无统计学意义 $[RR=0.98, 95% CI(0.94, 1.02), P=0.38]$,见图 4。

(三)Lachman 试验

7 篇文献报道了术后 Lachman 试验^[3,9,29,33,35,39,41],结果均为分类变量,对 Lachman 试验阴性结果分析。每项研究结果之间存在异质性($P < 0.00001, I^2=86%$),使用随机效应模型分析。敏感性分析后,异质性仍存在,显示单束重建与双束重建术后 Lachman 试验阴性结果相比,差异无统计学意义 $[RR=0.81, 95% CI(0.63, 1.05), P=0.11]$,见图 5。

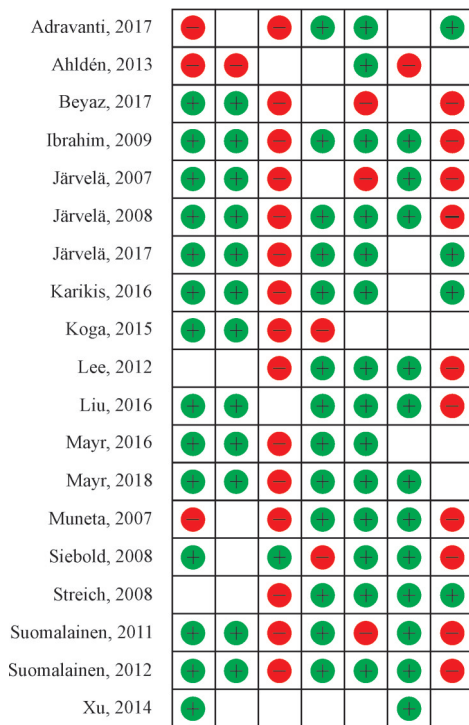
(四)轴移试验

纳入的 19 篇文献中有 16 篇报道了术后轴移试

表1 纳入文献特征表

第一作者/时间	国家	性别比(男/女)		平均年龄(岁)		例数		随访时间(月)	移植物	固定方式		主要指标*
		双束	单束	双束	单束	双束	单束			股骨	胫骨	
Ahldén/2013	瑞典	NA	NA	NA	NA	50	48	24	HT	MIS	BIS	3,4,7
Siebold/2008	德国	32/3	31/4	NA	NA	35	35	19	HT	EB	BIS	1,2,4,5,7
Lee/2012	韩国	NA	NA	NA	NA	19	18	24	HT	EB	BIS	1,2,3,4,5,6,7
Beyaz/2017	土耳其	16/0	15/0	33.53	31.06	15	16	96	HT	EB	BIS	1,5,6
Mayr/2018	德国	15/13	12/13	NA	NA	28	25	63.2	HT	NA	NA	1,2,3,4
Järvelä/2017	芬兰	NA	NA	34	30	24	23	122.4	HT	BIS	BIS	1,2,4,5,7
Adravanti/2017	意大利	NA	NA	26.4	28.3	25	25	72	HT	EB	BIS	2,5,8
Liu/2016	中国	NA	NA	NA	NA	32	34	80	HT	EB	BIS	1,4,5,6
Karikis/2016	瑞典	NA	NA	NA	NA	46	41	60	HT	MIS	BIS	3,4,5,6,7
Mayr/2016	德国	20/14	13/15	41.2	40	34	28	26	HT	BIS	IS	1,2
Koga/2015	日本	NA	NA	NA	NA	27	21	69	HT	EB	EB	3,4,5,6,7
Xu/2014	中国	24/10	25/7	30.2	33.3	34	32	16.3	HT	EB	BIS	1,4,5,7
Suomalainen/2012	芬兰	NA	NA	NA	NA	20	21	60	HT	BIS	BIS	2,4,5,7
Suomalainen/2011	芬兰	NA	NA	NA	NA	61	60	24	HT	BIS	BIS	2,4,5,7
Ibrahim/2009	科威特	50/0	48/0	NA	NA	50	48	29	HT	EB	BIS	2,3,4
Järvelä/2008	芬兰	NA	NA	NA	NA	22	21	24	HT	BIS	BIS	1,2,4,5,7
Muneta/2007	日本	20/14	14/20	NA	NA	34	34	25	HT	EB	BIS	2,3,4,5,6,7
Järvelä/2007	芬兰	NA	NA	NA	NA	30	25	14	HT	BIS	BIS	1,2,4,5,7
Streich/2008	德国	NA	NA	30	29.2	24	25	24	HT	EB	St	1,2,4,5,6,7

注: HT为半腱肌肌腱移植物; MIS为金属螺钉; EB为EndoButton固定系统; BIS为可吸收螺钉; IS为界面螺钉; St为Staple订书钉。*1, IKDC主观评分; 2, IKDC客观评分; 3, Lachman试验; 4, 轴移试验; 5, Lysholm评分; 6, Tegner评分; 7, KT-1000; 8, KT-2000



随机序列的产生(选择偏倚)
分配隐藏(选择偏倚)
实施者与参与者双盲(实施偏倚)
结局评估中的盲法(检出偏倚)
不全的结局数据(损耗偏倚)
选择性发表(报告偏倚)
其他偏倚

图2 文献质量评价图(“+”代表有,“-”代表无)

验^[3,7,9,29,30,32,33,35-43],结果均为分类变量,分析轴移试验的阴性结果。每项研究的结果之间存在异质性($P < 0.00001, I^2 = 79%$),使用随机效应模型。敏感性分析后,异质性仍存在,表明单束重建与双束重建术后轴移试验阴性结果的差异有统计学意义 [$RR = 0.85, 95\% CI(0.74, 0.97), P = 0.02$],见图6。

(五)Lysholm评分

共有12篇文献研究了术后Lysholm评分^[7,9,28,30,31,33,35-37,40,42,43],各研究组间有异质性($P = 0.02, I^2 = 51%$),采用随机效应模型分析,显示两组结果差异无统计学意义($P = 0.73$),见图7。经敏感性分析异质性主要来源于Xu等^[36],排除后无异质性($P = 0.20, I^2 = 25%$)。结果仍显示两组结果差异无统计学意义 [$MD = 0.40, 95\% CI(-1.24, 2.05), P = 0.63$]。

(六)Tegner评分

最终纳入文献中有4篇文献比较了术后Tegner评分^[9,28,33,43],各结果之间无异质性($P = 0.95, I^2 = 0%$),通过固定效应模型分析结果,单束重建与双束重建术后Tegner评分差异无统计学意义 [$MD = -0.07, 95\% CI(-0.47, 0.33), P = 0.74$],见图8。

(七)KT-1000或KT-2000测量值

13篇文献研究报道了术后KT-1000或KT-2000

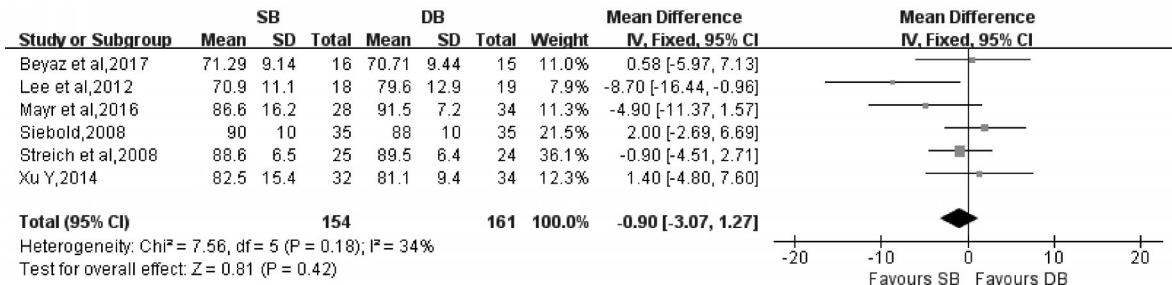


图3 单束与双束重建前交叉韧带术后IKDC主观评分比较的森林图 两组术后的IKDC主观评分差异无统计学意义

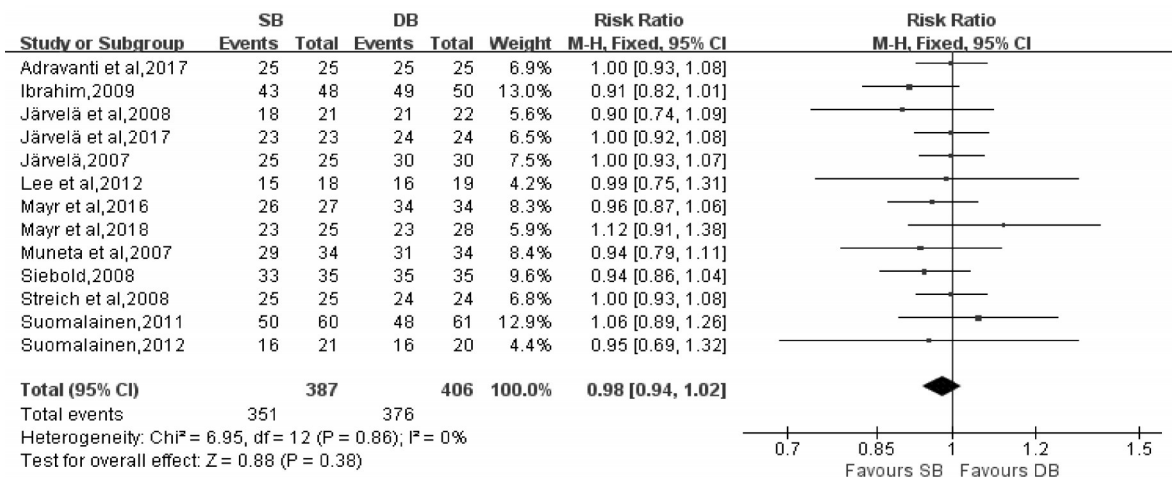


图4 单束与双束重建前交叉韧带术后IKDC客观评分比较的森林图 两组术后的IKDC客观评分差异无统计学意义

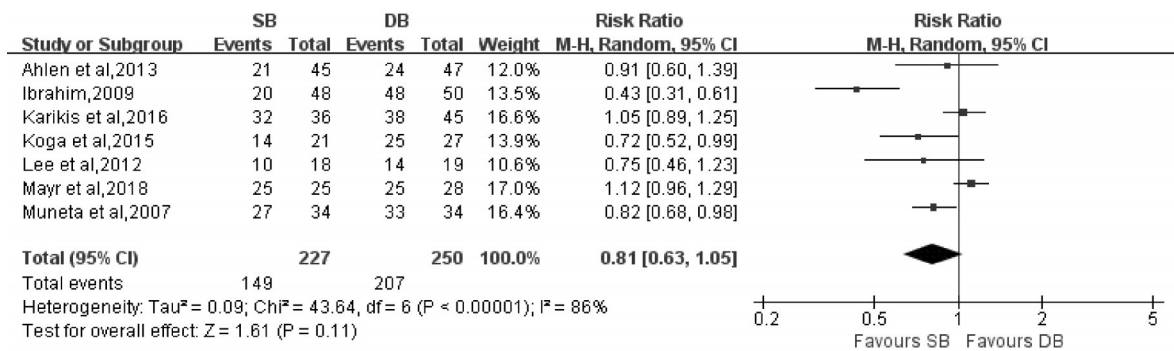


图5 单束与双束重建前交叉韧带术后Lachman 试验阴性结果比较的森林图 两组术后的Lachman 试验结果差异无统计学意义

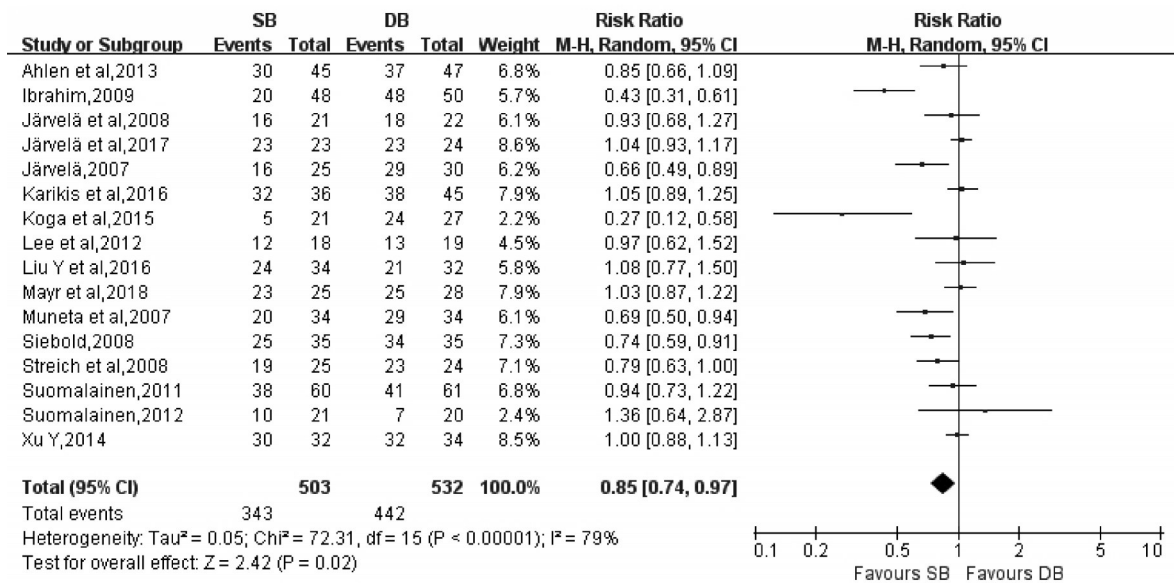


图6 单束与双束重建前交叉韧带术后轴移试验阴性结果比较的森林图 双束重建在轴移试验阴性结果上优于单束重建

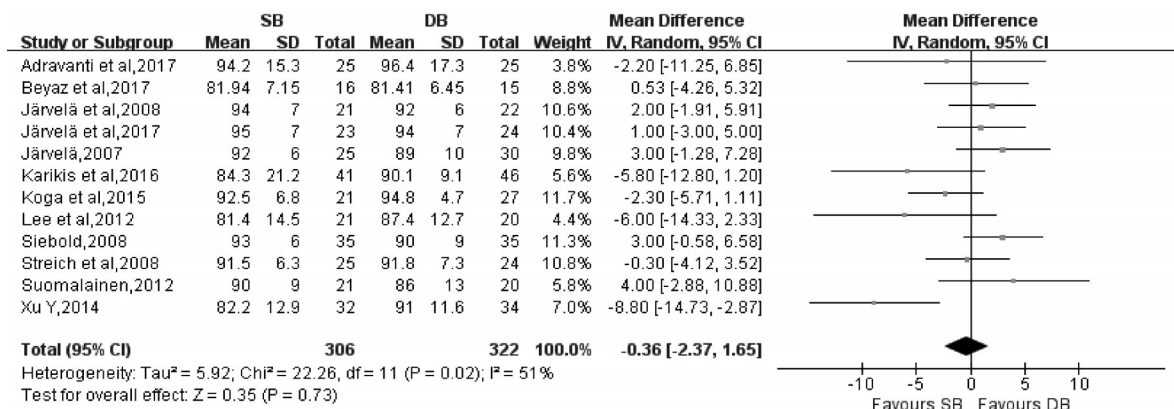


图7 单束与双束重建前交叉韧带术后Lysholm 评分比较的森林图 两组术后的Lysholm 评分差异无统计学意义

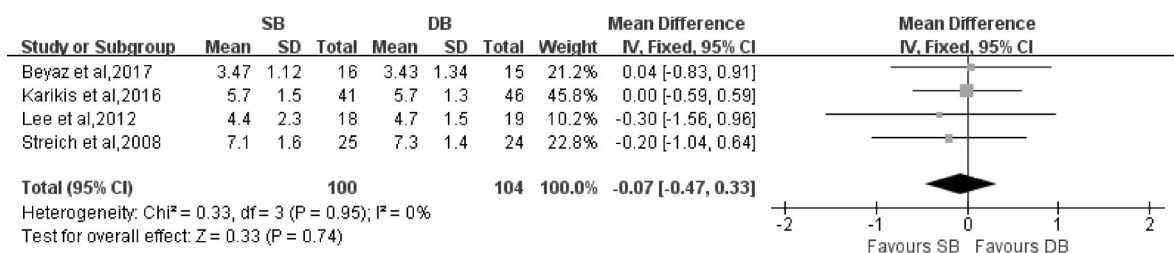


图8 单束与双束重建前交叉韧带术后Tegner 评分比较的森林图 两组术后的Tegner 评分差异无统计学意义

测量值^[3,7,9,30,31,33,35-38,40,41,43],各研究组之间存在异质性($P=0.006, I^2=56%$),采用随机效应模型。对其进行亚组分析,分为亚洲人和非亚洲人,亚洲人组纳入的4篇文献研究之间存在异质性($P=0.0003, I^2=84%$),结果显示,亚洲人组中单束重建和双束重建的KT值差异无统计学意义[$MD=0.52, 95% CI(-0.34, 1.38), P=0.24$]。非亚洲组中的9篇文献研究组之间无异质性($P=0.38, I^2=6%$),结果显示,非亚洲人组单束重建与双束重建的KT值差异无统计学意义[$MD=0.15, 95% CI(-0.13, 0.43), P=0.30$]。因分别对两组观察指标进行分析得到相对应的结果,表明单束重建与双束重建术后KT值差异无统计学意义[$MD=0.30, 95% CI(-0.05, 0.64), P=0.09$],见图9。

(八)发表偏倚

对两种重建技术术后IKDC客观评分绘制漏斗图,漏斗图对称,各纳入研究对象基本呈对称均匀分布,表明研究无明显发表偏倚,见图10。

讨 论

一、研究背景

前交叉韧带是重建频率最高的韧带之一,由于诊断技术的发展以及人们对体育运动的认识提升,临床就诊的前交叉韧带断裂的病人逐渐增多。前交叉韧带是膝关节内控制关节稳定的结构之一,若其撕裂引起膝关节不稳定,治疗不当会导致膝关节功能严重障碍^[44]。前交叉韧带断裂后行解剖重建是目

前最有效和最理想的治疗方法^[45]。随着关节镜技术的发展和成熟,关节镜下前交叉韧带重建已成为前交叉韧带断裂的常规治疗方法^[46]。然而对于选择单束重建还是双束重建,目前临床上尚无有力证据支持。本篇Meta分析通过扩大样本量来评价单束重建与双束重建前交叉韧带的临床效果。

二、单束重建和双束重建的优缺点

本篇Meta分析比较了单束和双束自体腘绳肌腱重建前交叉韧带的临床结果,显示单束重建和双束重建技术在用自体腘绳肌腱重建前交叉韧带中的差异无统计学意义。13篇文献^[7,9,29-31,34,37-43]发现前交叉韧带重建中的双束重建技术在功能参数方面并不优于单束重建技术,包括IKDC主客观评分、Lysholm评分和Tegner评分。

膝关节前直向稳定性和旋转稳定性的恢复对于前交叉韧带重建非常重要。本研究选择了Lachman试验、轴移试验、KT-1000或KT-2000测量值为指标。7篇文献^[3,9,29,33,35,39,41]显示在Lachman试验中单束重建和双束重建技术的前直向稳定性方面差异无统计学意义。纳入的13篇研究^[7,9,29-31,34,37-43]发现,在KT-1000或KT-2000测量的前直向稳定性方面也没有发现统计学差异,这与Devgan等^[4]、Kang等^[15]的研究结果一致。这些研究报道认为,单束重建和双束重建技术都可以在前交叉韧带重建中密切模仿前内侧束,从而获得较好的前直向稳定性。从理论上讲,双束重建技术还重建了后外侧束,后外侧束在膝

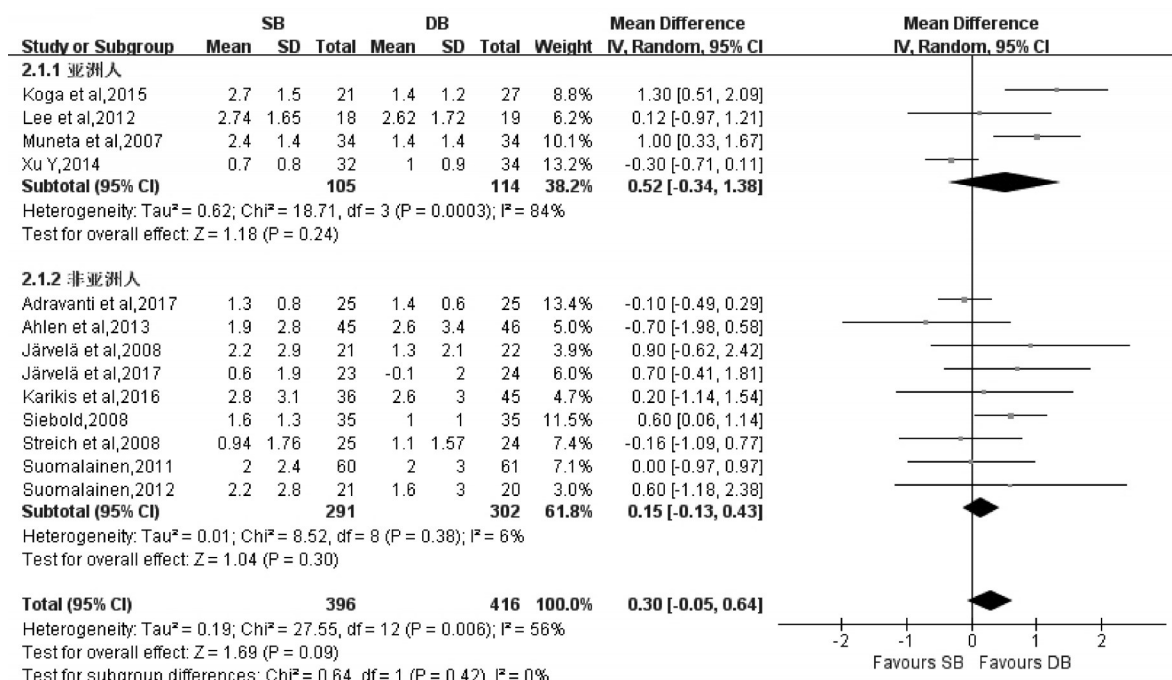


图9 单束与双束重建前交叉韧带术后KT-1000或KT-2000值比较的森林图 两组术后的KT-1000或KT-2000值的差异无统计学意义

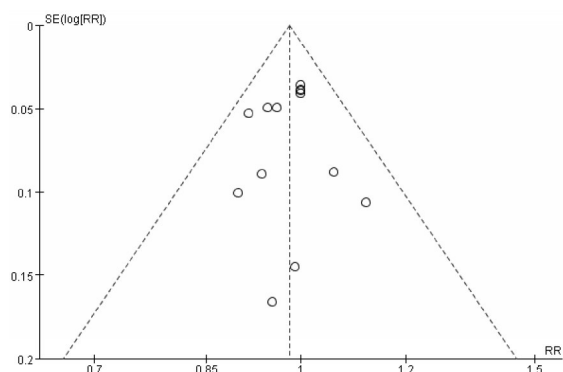


图 10 单束与双束重建前交叉韧带术后 IKDC 客观评分漏斗图 基本对称,表明无明显发表偏倚

关节伸直时对旋转稳定性的作用更大。轴移试验的测量采用等级分类,分为 4 个等级,而仅对阴性进行了 Meta 分析,此次 Meta 分析中 16 篇纳入研究^[3,7,9,29,30,32,33,35-43]结果显示,双束重建技术在旋转稳定性方面效果优于单束重建技术 $[RR=0.85, 95\% CI(0.74, 0.97), P=0.02]$ 。Hemmerich 等^[47]认为前交叉韧带可以限制膝关节的旋转,但是在孤立的扭转载荷下其对关节稳定性的作用是有限的。此外, Fanelli 等^[48]、Tsarouhas 等^[49]提出,侧副韧带和穿过膝关节肌肉组织的膝关节外周结构,与前交叉韧带在旋转稳定性中起同等重要作用。

结论:通过对 19 篇文献的 Meta 分析结果显示,用单束或双束自体腘绳肌腱重建前交叉韧带在 IKDC 主观评分、IKDC 客观评分、Lachman 试验、Lysholm 评分、Tegner 评分、KT-1000 或 KT-2000 测量值方面差异无统计学意义;而在轴移试验中,两组之间差异有统计学意义,因此对于膝关节功能和前直向稳定性恢复,单束重建和双束重建技术疗效无明显差异,而对于膝关节旋转稳定性恢复,双束重建技术优于单束重建。

三、本研究的局限性

①各研究结果指标不统一,可能影响结果。②各研究中的股骨钻孔技术和固定技术并不完全相同,这可能不足以评估单束重建和双束重建技术之间的差异。③因骨科手术很难做到完全随机和盲法,此次纳入文献中缺乏高质量文献。④纳入的文献中个别研究随访时间差异较大。

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