

经导管主动脉瓣置换术治疗二叶式主动脉瓣狭窄与三叶式主动脉瓣狭窄疗效比较的 meta 分析

郑五强¹ 祖秀光¹ 张少娟¹

[摘要] 目的:系统评价经导管主动脉瓣置换术治疗二叶式主动脉瓣狭窄与三叶式主动脉瓣狭窄的疗效。**方法:**检索建库至 2020 年 2 月 PubMed、Embase、Cochrane 图书馆、万方数据库和中国知网的随机对照及队列研究试验,同时采用 Revman 5.3、Stata 15.1 软件对纳入试验进行荟萃分析。**结果:**纳入 17 项研究,共分析 132333 例患者。荟萃分析结果显示:BAV 组与 TAV 组在 30 d 死亡率($OR=1.13, 95\%CI: 0.89 \sim 1.44, P=0.32$)、1 年死亡率($OR=0.91, 95\%CI: 0.77 \sim 1.06, P=0.22$)、脑卒中($OR=1.26, 95\%CI: 0.94 \sim 1.68, P=0.12$)、瓣周漏($OR=1.17, 95\%CI: 0.95 \sim 1.44, P=0.15$)、大出血事件($OR=0.84, 95\%CI: 0.66 \sim 1.06, P=0.13$)、血管并发症($OR=0.77, 95\%CI: 0.59 \sim 1.00, P=0.051$)、冠脉阻塞($OR=1.83, 95\%CI: 0.93 \sim 3.60, P=0.08$)、术后心梗($OR=1.14, 95\%CI: 0.63 \sim 2.06, P=0.66$)、急性肾损伤($OR=1.02, 95\%CI: 0.76 \sim 1.37, P=0.89$)术后并发症方面差异无统计学差异。在手术成功率($OR=0.59, 95\%CI: 0.39 \sim 0.94, P=0.03$)上低于 TAV 组。中转开胸($OR=2.88, 95\%CI: 1.61 \sim 5.18, P=0.0004$)及起搏器植入($OR=1.17, 95\%CI: 1.02 \sim 1.33, P=0.02$)方面高于 TAV 组。**结论:**与 TAV 患者相比,BAV 患者行 TAVR 治疗是可行的、有效的。两组的死亡率以及主要术后并发症无统计学差异。但 BAV 组在手术成功率上低于 TAV 组,中转开胸、新发起搏器植入事件高于 TAV 组,应该在新一代生物瓣膜中行进一步研究。

[关键词] 主动脉瓣狭窄;二叶式主动脉瓣;经导管主动脉瓣置换术;荟萃分析

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Comparing outcomes after transcatheter aortic valve replacement in patients with bicuspid aortic valve stenosis and tricuspid aortic valve stenosis: a Meta-analysis

ZHEGN Wuqiang ZU Xiuguang ZHANG Shaojuan

(Department of Cardiology, the Second Hospital of Hebei Medical University, Shijiazhuang, 050000, China)

Corresponding author: ZU Xiuguang, E-mail: zxg100109@163.com

Abstract Objective: To evaluate the efficacy of transcatheter aortic valve replacement in the treatment of bicuspid aortic valve stenosis or tricuspid aortic valve stenosis. **Method:** The randomized controlled and cohort trials

¹河北医科大学第二医院心内三科(石家庄,050000)
通信作者:祖秀光,E-mail:zxg100109@163.com

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were searched in Pubmed, Embase, Cochrane Library, Wanfang Database and China knowledge Network. At the same time, the inclusion trials were meta-analyzed by Revman 5.3 software. **Result:** The 17 studies were included and a total of 132333 patients were analyzed. The results of meta-analysis showed that there was no statistical difference in the 30-day mortality ($OR = 1.13$, 95%CI: 0.89—1.44, $P = 0.32$), 1-year mortality ($OR = 0.91$, 95%CI: 0.77—1.06, $P = 0.22$), stroke ($OR = 1.26$, 95%CI: 0.94—1.68, $P = 0.12$), paravalvular leakage ($OR = 1.17$, 95%CI: 0.95—1.44, $P = 0.15$), major bleeding ($OR = 0.84$, 95%CI: 0.66—1.06, $P = 0.13$), vascular complication ($OR = 0.77$, 95%CI: 0.59—1.00, $P = 0.051$), coronary artery obstruction ($OR = 1.83$, 95%CI: 0.93—3.60, $P = 0.08$), myocardial infarction ($OR = 1.14$, 95%CI: 0.63—2.06, $P = 0.66$) and AKI ($OR = 1.02$, 95%CI: 0.76—1.37, $P = 0.89$) between The two groups. The surgical success rate ($OR = 0.59$, 95%CI: 0.39—0.94, $P = 0.03$) in the BAV group was lower than that in the TAV group. The events of conversion to surgery ($OR = 2.88$, 95%CI: 1.61—5.18, $P = 0.0004$) and pacemaker implantation ($OR = 1.17$, 95%CI: 1.02—1.33, $P = 0.02$) in the BAV group were higher than those in the TAV group. **Conclusion:** Compared with TAV, the application of TAVR in BAV patients is feasible and effective. There was no statistical difference in the mortality and major postoperative complications in two groups. The surgical success rate in the BAV group was lower than that in the TAV group. The events of conversion to surgery and pacemaker implantation in the BAV group were higher than those in the TAV group.

Key words aortic stenosis; bicuspid aortic valve; transcatheter aortic valve replacement; meta-analysis

主动脉瓣狭窄(AS)是一种进展性疾病,部分患者由于禁忌无法行手术治疗,经导管主动脉瓣置换术(TAVR)的问世改善了这一困境。国内一项研究显示接受TAVR治疗人群中二叶式主动脉瓣狭窄(BAV)患者比例接近50%^[1]。在TAVR开展早期阶段,BAV患者特殊的解剖结构导致术后病死率增加,早期临床研究将BAV患者作为排除标准^[2-3]。随着器械及技术进步,国内外TAVR中心已经为相当多的BAV患者实施了TAVR治疗,近期发表于JACC、JAMA杂志的两项研究^[4-5]显示BAV患者行TAVR治疗,主要临床终点并不劣于三叶式主动脉瓣狭窄(TAV)患者。现就相关研究进行荟萃分析,系统评价BAV患者与TAV患者行TAVR治疗的疗效比较。

1 对象与方法

1.1 对象纳入与排除标准

纳入标准:①临床试验研究类型为BVA与TAV行TAVR术后疗效比较的随机对照试验或队列研究。②研究对象为行TAVR的BAV患者。③实验组为BAV行TAVR治疗患者,对照组为TAV行TAVR治疗患者。④参考瓣膜学术研究协会对TAVR的临床终点事件的标准化定义^[6]。

临床终点分为主要结局指标:死亡率(30 d死亡率,1年死亡率),脑血管事件。次要结局指标:瓣周漏、大出血事件、血管并发症、冠状动脉(冠脉)阻塞、围术期心肌梗死、急性肾损伤、中转开胸、手术成功率、瓣周漏、永久性起搏器植入。

排除标准是非随机对照试验及队列研究、会议摘要、除外中、英等其他语言文献、无法获取全文的文献。

1.2 文献检索方法

以transcatheter aortic valve replacement、transcatheter aortic valve implantation、TAVR、

Bicuspid、bicuspid aortic valve搜索英文文献,以经导管主动脉瓣置换术、二叶式主动脉瓣狭窄搜索中文文献。采取主题词与自由词相结合的方法,检索自建库至2020年2月PubMed、Embase、Cochrane、万方数据库和中国知网的研究,同时还对已发表研究的参考文献进行审阅,以寻找潜在文献。

1.3 文献提取方法

两名研究者独立进行资料提取:①基线资料:文献作者、发表年限。入选人群年龄、性别、试验组及对照组人数、美国胸外科医师协会(STS)评分、瓣膜植入类型等。②主要临床结局指标:死亡率(30 d死亡率,1年死亡率)、脑血管事件。次要结局指标:瓣周漏、大出血事件、血管并发症、冠状动脉(冠脉)阻塞、围术期心肌梗死、急性肾损伤、中转开胸、手术成功率、瓣周漏、永久性起搏器植入。两位研究者依据上述标准筛选出符合条件的文献,交叉核对,不一致处进行讨论,无法统一者由第3方决定。

1.4 文献质量评价

随机对照试验文献质量评价采取Jadad量表。总分为5分,评分为0~2分的视为低质量,3~4分为高质量,5分为最优质。队列研究质量评价采用NOS量表,总分≥7被认为是良好质量。由两位研究者进行质量评价,并交叉核对,不一致处进行讨论,无法统一者由第3方决定。

1.5 统计学处理

采用Revman 5.3、Stata 15.1统计软件进行。二分类资料选用OR值,连续变量资料选用WMD。判断异质性采用Q值统计量检验及 I^2 检验。若异质性较小($P \geq 0.1$, $I^2 < 50\%$),采用固定效应模型合并效应量;若异质性较大($P < 0.1$, $I^2 \geq 50\%$),则行敏感性分析,行单项排除法、亚组分析、采用随机效应模型合并效应量解决。对于纳入

文献数量大于10篇的临床结局指标绘制漏斗图直观评价发表偏倚,再行Egger检验定量评价。

2 结果

2.1 文献筛选结果

从上述数据库初步检索文献422篇,初步阅读文献标题及摘要350篇。除外综述、病例报道、评论文章、排除术后血流动力学主题、瓣膜类型、植入深度、尺寸类型、扩张方式及单独二叶式狭窄研究等文献333篇。最终17篇队列研究入选。详见图1。

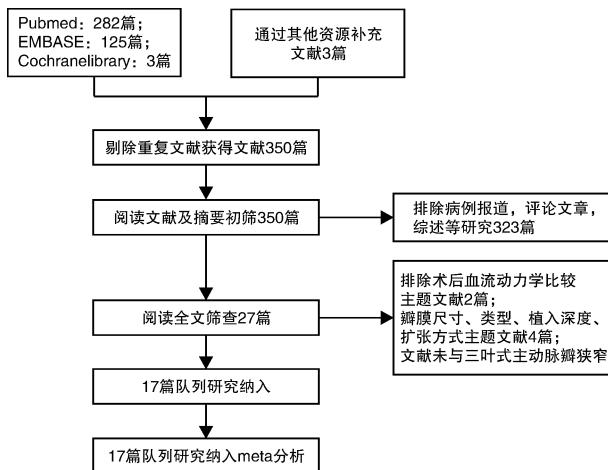


图1 文献筛选流程图

Figure 1 Flow diagram for study selection

2.2 文献质量评价及概况

入选文献17篇,均为队列研究,使用NOS量表行质量评价,总体上 ≥ 7 认为是质量优良。结果

详见表1。

2.3 荟萃分析结果

BAV组与TAV组在30 d死亡率($OR = 1.13, 95\%CI: 0.89 \sim 1.44, P = 0.32$)、1年死亡率($OR = 0.91, 95\%CI: 0.77 \sim 1.06, P = 0.22$)、脑卒中($OR = 1.26, 95\%CI: 0.94 \sim 1.68, P = 0.12$)、瓣周漏($OR = 1.17, 95\%CI: 0.95 \sim 1.44, P = 0.15$)、大出血事件($OR = 0.84, 95\%CI: 0.66 \sim 1.06, P = 0.13$)、血管并发症($OR = 0.77, 95\%CI: 0.59 \sim 1.00, P = 0.051$)、冠脉阻塞($OR = 1.83, 95\%CI: 0.93 \sim 3.60, P = 0.08$)、术后心梗($OR = 1.14, 95\%CI: 0.63 \sim 2.06, P = 0.66$)、急性肾损伤($OR = 1.02, 95\%CI: 0.76 \sim 1.37, P = 0.89$)术后并发症方面差异无统计学差异。

BAV组在手术成功率($OR = 0.59, 95\%CI: 0.39 \sim 0.94, P = 0.03$)上低于TAV组。中转开胸($OR = 2.88, 95\%CI: 1.61 \sim 5.18, P = 0.0004$)及起搏器植入($OR = 1.17, 95\%CI: 1.02 \sim 1.33, P = 0.02$)方面高于TAV组。详见图2~4,表3。

2.4 纳入文献的发表偏倚

对于文献入选大于10篇临床终点初步采用Revman 5.3软件绘制漏斗图判断有无发表偏倚,显示基本对称,同时采用STATA 15.1软件行Egger回归法定量分析,显示30 d死亡率($P = 0.719$)、手术成功率($P = 0.593$)、瓣周漏($P = 0.725$)、脑血管事件($P = 0.478$)、血管并发症($P = 0.221$)、新发起搏器植入($P = 0.703$)等关键临床终点事件方面不存在发表偏倚。

表1 纳入文献基本特征

Table 1 Basic characteristics of included literatures

研究	年度	例数/例 (BAV组/TAV组)	男性占比/% (BAV组/TAV组)	平均年龄/岁 (BAV组/TAV组)	STS评分 (BAV组/TAV组)	NOS 评分
Hayashid ^[7]	2013	21/208	57/53	82/83	—	7
Bauer ^[8]	2014	38/1357	45/42	81/82	—	7
Costopoulos ^[9]	2014	21/447	57/47	77/80	8/8	6
Kochman ^[10]	2014	28/84	46/48	78/79	—	7
Liu ^[11]	2015	15/25	60/68	75/76	6/6	6
Liao ^[12]	2017	81/65	58/64	73/74	8/9	7
Arai ^[13]	2017	10/143	43/7	81/83	—	6
Yoon ^[4]	2017	546/546	63/61	77/77	4.6/4.3	7
Sannino ^[14]	2017	88/735	60/53	80/82	7.4/7.6	7
Biase ^[15]	2018	83/166	69/66	81/83	5.1/5.1	7
Andabili ^[16]	2018	32/96	67/56	69/74	6.08/6.01	8
Xiong ^[17]	2018	67/49	60/57	74/75	6.5/8.3	7
Mangieri ^[18]	2018	54/54	39/57	80/81	4.7/4.69	8
Makkar ^[5]	2019	2691/2691	60/61	74/74	4.9/5.1	7
Tchetche ^[19]	2019	88/88	65/46	72/84	11.3/7.6	6
Nagaraja ^[20]	2019	359/359	35/38	68/68	—	7
徐原宁 ^[21]	2018	131/117	68/74	73.56/74.34	7.56/8.78	6

表2 BAV组及TAV组植入瓣膜类型及占比

Table 2 Types and proportions of implanted valves in BAV and TAV groups

研究	BAV组瓣膜类型百分比/%	TAV组瓣膜类型百分比/%
Hayashid ^[7]	Sapien 52	Corevalve 48
Bauer ^[8]	Sapien 32	Corevalve 68
Costopoulos ^[9]	Sapien 38	Corevalve 62
Kochman ^[10]	Sapien 15	Corevalve 85
Liu ^[11]	Sapien 67	Venus 33
Liao ^[12]	Corevalve Venus 100	Corevalve Venus 100
Arai ^[13]	Sapien 3 100	Sapien 3 100
Yoon ^[4]	Sapien XT 28.4	Corevalve 30
	Sapien 3 29.3	Lotus 7.9
	Evolut R 4.2	Evolut R 2.9
Sannino ^[14]	—	—
Biase ^[5]	Sapien 3 60	Evolut R 19
	Lotus 4	Lotus 4
Andabili ^[16]	SapienXT 47	Corevalve 22
	Sapien 3 31	Sapien 3 42
Xiong ^[17]	Corevalve 36	Venus 58
	Lotus 6	Corevalve 33
Mangieri ^[18]	Acurate Neo 100	AcurateNeo 100
Makkar ^[5]	Sapien 3 100	Sapien 3 100
Tchetche ^[19]	Sapien 3 65	Evolut R 20
	Lotus 10	Acurate Neo 7
	Abbott Portico 1	Direct Flow 1
Nagaraja ^[20]	—	Abbott Portico 7
徐原宁 ^[21]	—	—

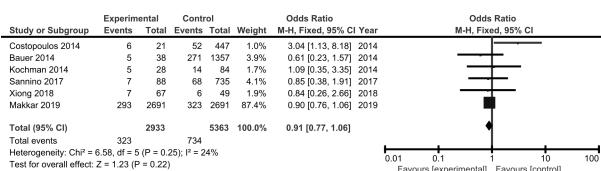


图2 30 d 死亡率的森林图

Figure 2 Forest plot for 30-day mortality

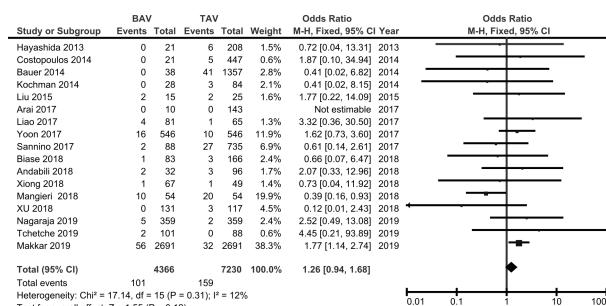


图4 脑血管事件的森林图

Figure 4 Forest plot for stroke

3 讨论

本研究纳入了迄今为止最大规模的BAV患者与TAV患者行TAVR治疗疗效对比研究。结果显示接受了TAVR治疗的BAV患者与TAV患者,在短中期死亡率上没有显著差异。没有发现在脑血管事件、大出血、血管并发症、冠脉阻塞、围术期心肌梗死、急性肾损伤术后并发症的差异。国内的一项荟萃分析,同样印证了TAVR治疗BAV患者的有效性及安全性^[22]。

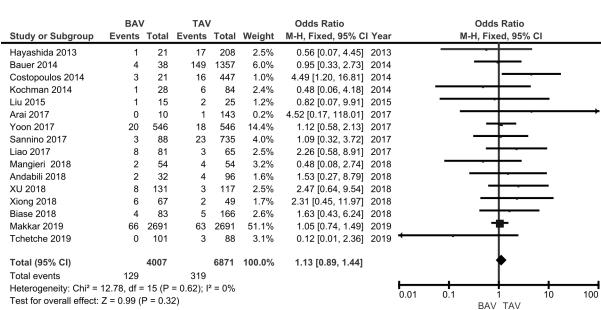


图3 1年死亡率的森林图

Figure 3 Forest plot for 1-year mortality

表 3 术后并发症及成功率荟萃分析结果
Table 3 Postoperative complications and success rate

并发症	纳入研究	异质性检验	效应模型	OR	P 值
瓣周漏	队列研究 ^[4-5,7-19,21]	$I^2 = 32\%$	固定	1.17	0.15
大出血事件	队列研究 ^[4,7,9,11-12,18-21]	$I^2 = 39\%$	固定	0.84	0.13
血管并发症	队列研究 ^[4-5,7,9-14,17-21]	$I^2 = 27\%$	固定	0.77	0.051
冠脉阻塞	队列研究 ^[4-5,7,9,11,18,21]	$I^2 = 0\%$	固定	1.83	0.08
术后心梗	队列研究 ^[5,7-11,19-20]	$I^2 = 0\%$	固定	1.14	0.66
急性肾损伤	队列研究 ^[4-5,7-11,13-14,20]	$I^2 = 0\%$	固定	1.02	0.89
手术成功率	队列研究 ^[4-5,7-11,13-15,20]	$I^2 = 52\%$	随机	0.59	0.03
中转开胸	队列研究 ^[4-5,7-11,20]	$I^2 = 0\%$	固定	2.88	0.0004
起搏器植入	队列研究 ^[4-5,7-21]	$I^2 = 19\%$	固定	1.17	0.02

但是我们发现 BAV 患者手术成功率较低,更易发生中转外科开胸,同时在永久性起搏器植入上更多见。在死亡率、起搏器植入及中转开胸关键临床终点事件上,近期荟萃分析结果与本文类似^[23-26]。一项关于术后瓣周漏的 Meta 分析表明,瓣周漏在 TAVR 后很常见,是短期和长期生存的不利预后指标^[27]。但我们在瓣周漏事件上却得出了与上述 4 项荟萃分析相反的结果。我们发现这主要与 Yoon、Makkar 等^[4-5]研究相关, Yoon、Makkar 研究表明在使用 Sapien 3、Lotus 新型生物瓣膜后,瓣周漏的发生率显著下降,BAV 与 TAV 组的瓣周漏发生率无统计学差异。而美国的一项 BAV 患者使用新一代生物瓣膜行 TAVR 治疗的国际性大型、多中心、观察性注册研究同样佐证了这一点,Sapien 3、Lotus 等新一代生物瓣膜的应用与瓣周漏事件的减少相关,增加了手术的成功率,但是 Sapien 3 植入深度及植入尺寸过大导致了永久性起搏器植入的增加^[28]。

本研究具有以下局限性:①纳入研究均为观察性研究,虽大部分为倾向评分匹配研究,实验设计良好,但由于实验数据的限制,未根据瓣膜类型行亚组分析。器械更新、瓣膜尺寸及植入位置、手术技巧改进,少数临床终点定义不同,这可能造成了不可避免的偏倚。②由于各研究随访时间均为短中期,无法行长期临床终点评价,且无法判断生物瓣膜耐久性对于预后的影响。③关于 BAV 患者行 TAVR 治疗的卫生经济学文献罕见,本研究无法行成本效益分析,无法探讨 BAV 和 TAV 患者行 TAVR 治疗的卫生经济学负担。

综上所述,与 TAV 患者相比,BAV 患者行 TAVR 治疗,是安全有效的,死亡率以及主要术后并发症无差异,随着新一代瓣膜器械更新,瓣周漏事件上无差异。但由于永久起搏器植入及中转外科开胸事件的增加,手术成功率,对于改进器械、手术技巧、更好的瓣膜影像学评估及植入深度方面提出了挑战,需要在新一代生物瓣膜中行进一步研

究。同时期待更长时间试验随访结果以及卫生经济学数据方面的研究。

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