·临床研究·

国产自膨式经导管主动脉瓣置换术后严重传导损伤相关因素分析

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【摘 要】 目的 分析应用国产自膨式瓣膜行经导管主动脉瓣置换术(TAVR)后严重传导损伤的相关因素并评估其预测效能。**方法** 回顾性纳入2016年12月至2022年10月于中国人民解放军总医院第一医学中心应用国产自膨式主动脉瓣膜行TAVR患者。根据术后结果分为正常组和传导损伤组,采用logistic回归分析筛选相关因素。绘制受试者工作特征(ROC)曲线,计算预测效能并评估效能差异。采用SPSS 26.0软件进行数据分析。根据数据类型,组间比较分别采用t检验、U检验及χ^2检验。**结果** 纳入患者84例,其中正常组60例,传导损伤组24例。2组间左室流出道(LVOT)面积、LVOT面积/瓣环面积、室间隔膜部长度、室间隔膜部长度和植入深度的差值(ΔMSID)比较,差异均有统计学意义(均$P<0.05$)。多因素logistic回归分析显示,LVOT面积/瓣环面积($OR=0.874$,95%CI 0.797~0.959,$P=0.004$)、ΔMSID($OR=0.660$,95%CI 0.515~0.846,$P=0.001$)是TAVR术后严重传导损伤的独立危险因素。ROC曲线示LVOT面积/瓣环面积、ΔMSID的曲线下面积分别为0.792、0.768,二者联合的曲线下面积为0.908,DeLong检验显示单因素与二者联合指标的预测差异有统计学意义($P<0.05$)。**结论** LVOT面积/瓣环面积、ΔMSID是TAVR术后出现严重传导损伤的独立危险因素,可用于预测术后新发传导损伤的发生,二者联合较单因素预测效能更高。

【关键词】 经导管主动脉瓣置换术;左束支传导阻滞;永久起搏器植入;主动脉瓣膜
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Factors associated with severe conduction injury after domestic self-expanding transcatheter aortic valve replacement: analysis of 84 cases

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【Abstract】 Objective To analyze the factors associated with severe conduction injury after transcatheter aortic valve implantation (TAVR) with domestic self-expanding valves and assess their predictive efficacy. **Methods** A retrospective trial was conducted on the patients undergoing TAVR with domestic self-expanding aortic valves in the First Medical Center of Chinese PLA General Hospital from December 2016 to October 2022. According to their postoperative outcomes, they were divided into normal and conduction injury groups. Logistic regression analysis was used to screen the relevant factors. Receiver operating characteristic (ROC) curve was plotted to calculate their predicted efficacy and evaluate the difference in efficacy. SPSS statistics 26.0 was used for statistical analysis. Data comparison between two groups was performed using student's t test, U test or Chi-square test depending on data type. **Results** There were 84 patients being enrolled, including 60 patients in the normal group and 24 patients in the conduction injury group. Significant differences were observed in following indicators between the two groups ($P=0.005$), including left ventricular outflow tract (LVOT) area, LVOT area/annular area, septal length, and difference between septal length and implantation depth (membranous septum minus implantation depth, ΔMSID). Multivariate logistic regression analysis showed that LVOT area/annular area ($OR=0.874$, 95%CI 0.797-0.959, $P=0.004$) and ΔMSID ($OR=0.660$, 95%CI 0.515-0.846, $P=0.001$) were independent risk factors for severe conduction injury after TAVR. ROC curve analysis indicated that the area under the curve of LVOT area/annular area and ΔMSID was 0.792 and 0.768, respectively, and was 0.908 for their combination. DeLong test revealed that statistical significance was seen in the predictive efficacy of the single indicator vs their combination ($P<0.05$). **Conclusion** LVOT area/annular area and ΔMSID are independent risk factors for incidence of severe conduction injury after TAVR, and can be used to predict the occurrence of new conduction injury after surgery. The two indicators combination shows better predictive efficacy than the single one.

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【Key words】 transcatheter aortic valve implantation; left bundle branch block; permanent pacemaker implantation; aortic valve
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经导管主动脉瓣置换术(transcatheter aortic valve replacement,TAVR)已逐渐成为老年重度症状性主动脉瓣膜病患者的一线治疗手段[1-3]。研究显示约 5.9%~32.0%的 TAVR 患者因传导损伤需要植入永久起搏器[4],严重影响远期预后[5,6]。分析 TAVR 后严重传导损伤的相关危险因素,对减少传导损伤的发生和术后起搏器植入有着积极意义[7]。本研究旨在探索应用国产自膨式瓣膜 TAVR 后严重传导损伤的潜在危险因素,评价相关指标的联合预测价值,为应用国产自膨式瓣膜行 TAVR 的患者早期预测术后严重传导损伤提供参考。

1 对象与方法

1.1 研究对象

回顾性纳入 2016 年 12 月至 2022 年 10 月于中国人民解放军总医院第一医学中心应用国产自膨式瓣膜行 TAVR 手术的主动脉瓣膜病患者。根据相关指南[8,9]推荐,纳入标准:(1)成功完成 TAVR 的主动脉瓣膜病患者;(2)最终成功植入单个国产自膨式瓣膜;(3)术前接受 12 导联心电图、超声心动图检查、主动脉计算机断层扫描血管造影(computed tomography angiography, CTA)检查。排除标准:(1)患者术前心电图显示存在持续完全性左束支传导阻滞(left bundle branch block,LBBB)或二度Ⅱ型以上房室传导阻滞;(2)术前植入心脏起搏器;(3)既往主动脉瓣置换手术史;(4)术前影像学检查图像质量不达标。本研究由解放军总医院伦理委员会批准(S2 22 395-01)。

1.2 方法

1.2.1 主动脉根部结构扫描流程 所有患者均接受术前心脏 CTA 检查。扫描设备为西门子第二代双源螺旋 CT(Definition Flash, Siemens Healthcare, Germany),管电压依据体质量指数调整,机架旋转速度为 280 ms,探测器准直为 2.0 mm×64.0 mm×0.6mm,层厚 0.75 mm,层间距 0.5 mm。增强扫描方案应用心电门控螺旋扫描,采集最佳收缩和舒张期图像。患者在检查前接受屏气训练,并于扫描前 3 min 舌下含服硝酸甘油。扫描开始后采用团注追踪法经肘前静脉预置套管针,由双筒高压注射器以 5.0 ml/s 的速率注射碘对比剂[37 g(I)/100 ml,碘帕醇注射液,博莱科信谊药业有限公司,上海]。当主动脉感兴趣区的 CT 阈值达到预设的 100 HU 时触发扫描,外周股动脉入路血管评估采用增强扫描,通过手动方式扫描触发,扫描范围为升主动脉根部至两侧股动脉近端。TAVR 的图像采集由工作经验超过 5 年的影像技师完成。

1.2.2 术前评估 详细采集患者资料,包括:(1)一般资料,即基本信息、症状及既往病史;(2)术前心电图(<7 d)评价患者传导系统情况;(3)术前经胸超声心动图评估患者血流动力学指标,心脏 CTA 检查评估患者结构指标;(4)计算手术危险评分。

主动脉根部结构的 CTA 图像分析应用 Anythink 软件(思创冠宇科技,北京)完成,该软件的测量稳定性已在前期研究中被证实[10]。主动脉根部结构测量在心动周期的 30%~45%完成。手动测量冠状动脉开口高度,软件自动识别模拟确定主动脉瓣环平面、左室流出道(left ventricular outflow tract,LVOT)平面(瓣环平面下 5 mm),并测量平面的最大直径、最小直径、周长、面积。偏心率=1-(最小直径/最大直径)。室间隔膜部长度由 CT 图像冠状位于右冠状动脉窦底水平测量,详见图 1。

主动脉瓣钙化体积在造影剂增强的图像上进行测量,以 850 HU 作为阈值在感兴趣区域标记钙化。主动脉根部范围定义为瓣环平面上 30 mm 至平面下 15 mm,设备着陆区[11](device landing zone, DLZ)范围定义为瓣环平面上 3 mm 至平面下 2 mm。所有的自动测量步骤均进行人工监督,必要时手动校正。

1.2.3 经导管主动脉瓣置换术 TAVR 前决策由专业心血管病介入团队完成。在对患者完成麻醉后,经两侧股动脉分别置入动脉鞘,分别用于置入造影导管和建立轨道。应用术前置入的临时起搏器对心室快速起搏(心室率 160~200 次/min),在主动脉根部造影后将人工瓣膜精准定位并释放瓣膜。回撤释放系统,并进行主动脉瓣跨瓣测压评估手术效果,完成术后即刻造影,于无冠窦-左冠窦角度测量无冠窦瓣膜植入深度,应用室间隔膜部长度减去植入深度得到室间隔膜部长度和植入深度的差值(difference between membranous interventricular septum and implantation depth, ΔMSID)。

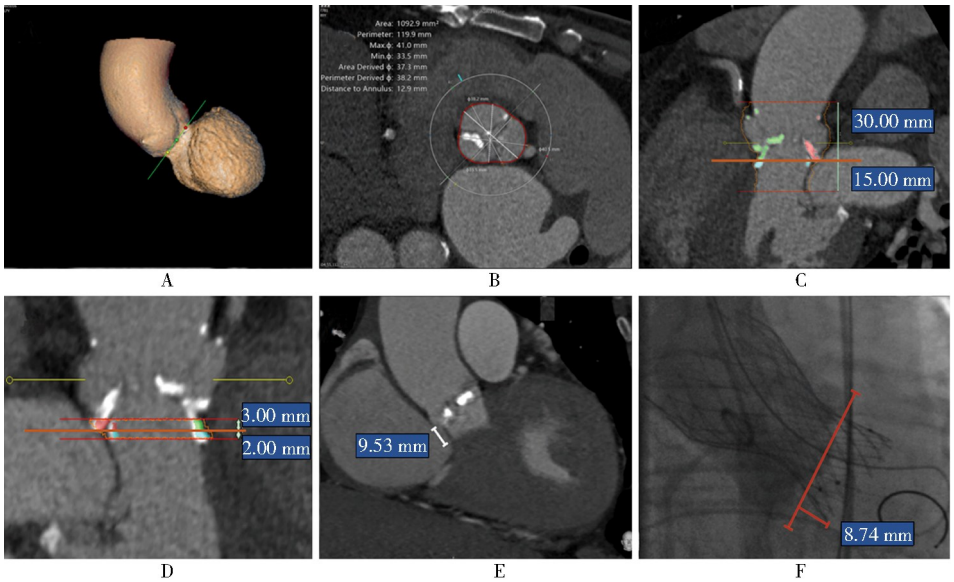

图 1　主动脉根部解剖数据的 CT 测量演示

Figure 1　CT measurement of aortic root anatomical data

A: three-dimensional model; B: flap ring data measurement reconstructed by Anythink; C: aortic root calcification measurement; D: measurement of calcification volume in the landing area of the equipment; E: length of ventricular septal membrane; F: postprocedural contrast shows implantation depth, and the long red lines represent the plane of the aortic annulus.

1.2.4　预后评价　于术后第 7 天进行标准 12 导联心电图检查,评估心脏传导系统损伤情况。将术后严重心脏传导损伤[12-14]定义为:(1)出现新发的二度Ⅱ型房室传导阻滞、三度房室传导阻滞、窦性停搏等严重心律失常,需要植入永久起搏器;(2)出现持续性 LBBB。由专业的心血管内科医师对每份心电图进行人工审核和诊断判定。

1.3　统计学处理

采用 SPSS 26.0 统计软件进行数据分析。符合正态分布的计量资料用均数±标准差($\bar{x}\pm s$)表示,采用两独立样本 t 检验;非正态分布的计量资料用中位数(四分位数间距)[$M(Q_1, Q_3)$]表示,采用 Mann-Whitney U 检验。计数资料用例数(百分率)表示,采用χ^2 检验。采用多因素 logistic 回归模型分析 TAVR 术后传导损伤的危险因素。绘制危险因素受试者工作特征(receiver operating characteristic, ROC)曲线,计算其预测传导损伤的 ROC 曲线下面积(area under curve, AUC)。应用 DeLong 检验评估各因素和联合因素预测效能的差异。$P<0.05$ 表示差异有统计学意义。

2　结　果

2.1　2 组患者基线资料比较

本研究最终纳入行 TAVR 患者共 84 例,主动脉瓣三叶型共 55 例,type 1 型二叶瓣 15 例,type 0 型二叶瓣 14 例。植入 Venus-A 瓣膜(启明医疗,杭州)患者 77 例,植入 VitaFlow 瓣膜(微创心通医疗,上海)患者 6 例,植入 TaurusOne 瓣膜(沛嘉医疗,苏州)患者 1 例。依据术后心电图结果将患者分成正常组(60 例)和传导损伤组(24 例)。2 组患者一般情况、临床症状、既往病史、危险度评分、血清学指标比较,差异均无统计学意义(表 1)。

2.2　2 组患者术前检查及手术特征比较

传导损伤组的左室舒张末(left ventricular end-diastolic, LVED)内径、LVED 容积均低于正常组,差异均有统计学意义(均 $P<0.05$);2 组其余指标比较,差异均无统计学意义(表 2)。传导损伤组包括完全性左束支传导阻滞 14 例,高度房室传导阻滞 10 例。

CTA 影像指标中,传导损伤组的 LVOT 面积、LVOT 面积/瓣环面积明显低于正常组,室间隔膜部长度明显低于正常组(均 $P<0.05$);瓣环水平数据、钙化体积无显著统计学差异。手术因素中,传导损伤组在 ΔMSID 方面明显低于正常组($P<0.05$;图 2)。

2.3　Logistic 回归分析 TAVR 后传导损伤危险因素

依据单因素分析的结果,纳入 2 组间存在显著统计学差异的变量进行多因素 logistic 回归。结果显示,经校正 LVOT 面积后,LVOT 面积/瓣环面积、ΔMSID 是 TAVR 后传导损伤的独立危险预测因素($P<0.05$;表 3)。

表 1 2 组患者基线资料比较

Table 1 Comparison of baseline data between two groups

Item	Normal group (n=60)	Conduction injury group (n=24)	P value
Age (years, $\bar{x}\pm s$)	72.29±9.17	78.38±6.59	0.060
Male [n(%)]	37(61.67)	14(58.33)	1.000
Height (cm, $\bar{x}\pm s$)	164.29±8.55	163.71±8.73	0.588
Body mass (kg, $\bar{x}\pm s$)	65.43±9.84	67.60±13.21	0.090
Clinical symptoms [n(%)]			
Dyspnea	59(98.33)	22(91.67)	0.666
Angina	23(38.33)	8(33.33)	1.000
Syncope	10(16.67)	6(25.00)	0.524
Pre-existing medical conditions [n(%)]			
Hypertension	21(35.00)	8(33.33)	0.964
Diabetes mellitus	8(13.33)	3(12.50)	1.000
CHD	36(60.00)	16(66.67)	0.155
Smoking	16(26.67)	6(25.00)	1.000
Alcohol drinking	11(18.33)	6(25.00)	0.546
Hazard score [points, $M(Q_1, Q_3)$]			
STS score	4.78(2.93,6.11)	4.64(2.85,6.67)	0.737
Euro score Ⅱ	5.57(3.45,7.21)	5.73(3.80,7.28)	0.680
Serological indicators [$M(Q_1, Q_3)$]			
Hematocrit (L/L)	0.36(0.32,0.39)	0.35(0.31,0.40)	0.957
WBC ($\times10^9$/L)	6.70(5.05,7.90)	6.52(4.79,7.82)	0.922
NT-proBNP (ng/ml)	2 480.85(705.88,3 496.50)	2 027.51(357.78,2 832.00)	0.105
Creatinine (μmol/L)	92.32(67.78,104.20)	86.46(71.08,99.23)	0.392

CHD: coronary heart disease; STS: Society of Thoracic Surgeons; WBC: white blood cell; NT-proBNP: N-terminal pro-brain natriuretic peptide.

表 2 经导管主动脉瓣植入术后正常组与传导损伤组患者术前检查及手术特征比较

Table 2 Comparison of preoperative examination and procedural characteristics of patients in normal group and conduction injury group after TAVR

Item	Normal group (n=60)	Conduction injury group (n=24)	P value
Preprocedural ECG characteristics			
PR interval (ms, $\bar{x}\pm s$) *	146.03±64.51	177.29±63.90	0.050
QRS duration (ms, $\bar{x}\pm s$)	104.43±25.73	107.04±27.44	0.682
RBBB [n(%)]	6(10.00)	6(25.00)	0.092
TTE characteristics ($\bar{x}\pm s$)			
V_{max} (m/s)	4.74±0.71	4.81±0.62	0.688
Mean pressure (mmHg)	56.80±19.07	57.83±14.11	0.811
LVED diameter (mm)	48.92±8.04	45.04±4.82	0.030
LVED volume (cm^3)	118.58±47.99	97.25±26.58	0.043
Ejection fraction (%)	54.45±10.68	57.83±7.77	0.163
Septal thickness	13.91±1.90	13.80±2.13	0.927
CT characteristics of aortic root ($\bar{x}\pm s$)			
Left coronary artery height (mm)	13.48±3.19	12.63±3.27	0.277
Right coronary artery height (mm)	15.85±2.77	15.27±3.47	0.427
Minimum annular diameter (mm)	20.89±2.43	20.31±2.13	0.310
Maximum annular diameter (mm)	27.27±2.84	26.74±3.24	0.458
Annular area (mm^2)	453.44±97.72	438.19±102.04	0.525
Annular perimeter (mm)	76.63±7.87	74.60±8.11	0.291
Annular eccentricity (%)	23.21±6.24	22.91±8.78	0.861
LVOT perimeter (mm)	79.55±12.09	74.53±11.18	0.083
Aortic root calcified volume (mm^3)	643.54±439.80	702.96±604.09	0.618
Procedural characteristics			
Pre-expansion [n(%)]	52(86.67)	22(91.67)	0.717
Post-expansion [n(%)]	19(31.67)	10(41.67)	0.450
Implantation depth (mm, $\bar{x}\pm s$)	4.73±3.20	5.49±2.56	0.306
Device oversizing [$M(Q_1, Q_3)$]	1.21(1.07,1.36)	1.21(1.10,1.34)	0.843

TAVR: transcatheter aortic valve implantation; ECG: electrocardiogram; RBBB: right bundle branch block; TTE: transthoracic echocardiography; V_{max}: maximum flow rate of aortic valve; LVED: left ventricular end-diastolic; LVOT: left ventricular outflow tract; device oversizing: artificial valve area divided by annulus area. 1 mmHg=0.133 kPa. * The PR interval analysis excluded 9 patients with atrial fibrillation.

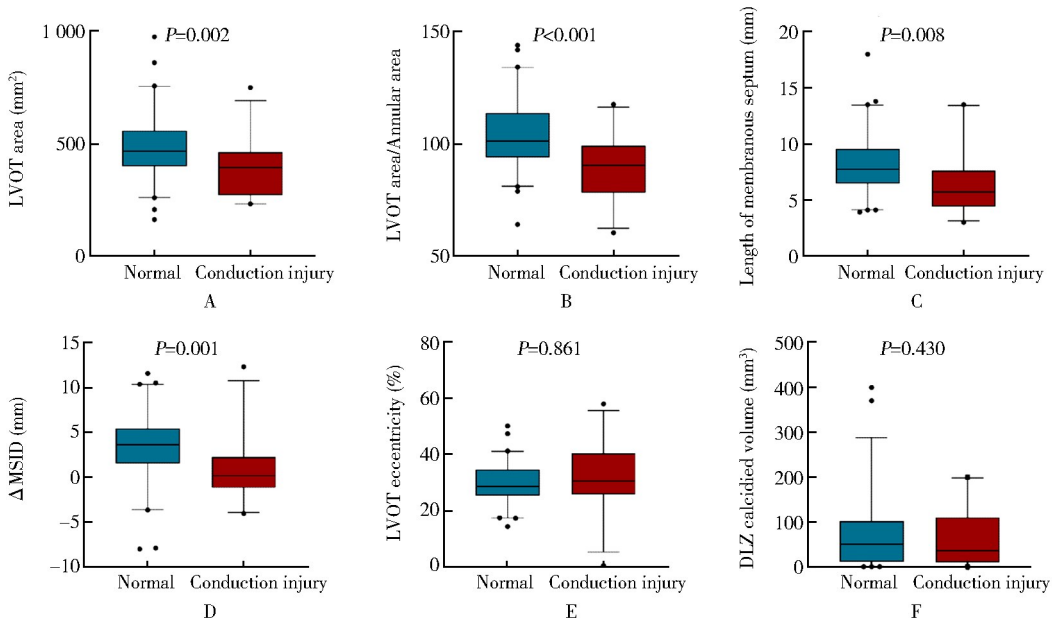

图 2 正常组与术后传导损伤组 CT 数据比较

Figure 2 Comparison of CT data between normal group and postoperative conduction injury group

LVOT: left ventricular outflow tract; ΔMSID: difference between membranous interventricular septum length and implantation depth; DLZ: device landing zone.

表 3 Logistic 回归分析 TAVR 术后传导损伤的危险因素

Table 3 Logistic regression analysis risk factors for conduction injury after TAVR

Factor	Univariate analysis			Multivariate analysis		
	OR	95%*CI*	*P* value	*OR*	95%*CI*	*P* value
PR interval	1.015	0.999-1.030	0.060	-	-	-
LVED diameter	0.917	0.846-0.993	0.033	-	-	-
LVED volume	0.984	0.970-0.999	0.037	-	-	-
LVOT area	0.993	0.988-0.998	0.003	1.000	0.992-1.009	0.938
Aortic root calcified volume	0.997	0.991-1.004	0.428	-	-	-
Length of septal membrance	0.743	0.595-0.927	0.008	-	-	-
ΔMSID	0.795	0.682-0.927	0.003	0.660	0.515-0.846	0.001
LVOT area/annular area	0.917	0.875-0.960	<0.001	0.874	0.797-0.959	0.004

TAVR: transcatheter aortic valve implantation; LVED: left ventricular end-diastolic; LVOT: left ventricular outflow tract; ΔMSID: difference between membranous interventricular septum length and implantation depth. -: no datum.

2.4 单独及联合参数预测传导损伤

以 LVOT 面积/瓣环面积、ΔMSID 分别为协变量,以术后是否发生严重传导损伤为结局变量,绘制 ROC 曲线。LVOT 面积/瓣环面积、ΔMSID 的 AUC 分别为 0.792(0.690,0.873)、0.768(0.663,0.853)。两指标联合分析结果显示 LVOT 面积/瓣环面积+ΔMSID 的 AUC 为 0.908(0.825,0.920)。采用 Delong 检验发现,两指标联合 AUC 均显著高于 LVOT 面积/瓣环面积(P = 0.045)和 ΔMSID(P = 0.006;图 3)。应用 Hosmer-Lemeshow 拟合优度检验,两指标联合预测的校准度较好(P=0.570;图 4)。

3 讨 论

本研究聚焦于国产自膨式瓣膜,以起搏器植入和新发 LBBB 作为传导损伤的研究结局,旨在探寻可预测患者 TAVR 后心脏传导系统严重损伤的相关危险因素。研究结果发现 LVOT 面积/瓣环面积和 ΔMSID 是 TAVR 后严重传导损伤的危险因素,两指标联合对于严重传导损伤具有更大的预测效能。

TAVR 目前已成为主动脉瓣膜病重要的治疗手段之一。然而,TAVR 后起搏器植入不仅会延长住院时间、增加医疗负担、降低患者生活质量,还与患者近远期不良结局密切相关[15,16]。近年来,越来越多的研究证实了术后 LBBB 与远期起搏器植入率增加、左心室功能较差相关[17-19]。随着国产自膨式瓣膜在临床中的广泛应用,识别确定其植入后严重传导损伤的相关因素成为了亟待解决的问题。

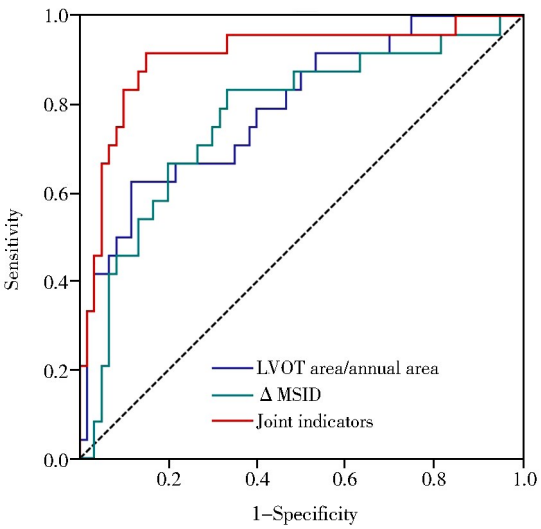

图 3 LVOT 面积/瓣环面积、ΔMSID 及 LVOT 面积/瓣环面积+ΔMSID 预测严重传导损伤的 ROC 曲线

Figure 3 ROC curves for LVOT area/annual area, ΔMSID and LVOT area/annual area+ΔMSID predicting severe conduction injury

ROC: receiver operating characteristic; LVOT: left ventricular outflow tract; ΔMSID: difference between membranous interventricular septum length and implantation depth.

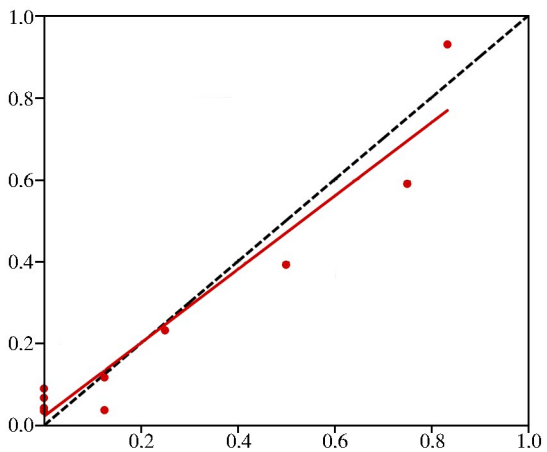

图 4 LVOT 面积/瓣环面积+ΔMSID 联合的校准曲线

Figure 4 Calibration curve of LVOT area/annual area+ΔMSID

LVOT: left ventricular outflow tract; ΔMSID: difference between membranous interventricular septum length and implantation depth.

既往国外研究曾发现 DLZ 区域钙化、室间隔膜部长度是 TAVR 术后起搏器植入的危险因素[7,20,21]。本研究中使用的国产自膨式瓣膜中，91.6%(77/84)为 Venus-A 瓣膜，其特有的标记点设计可较好地减少因手术操作失误导致的植入过深、倾斜角度过大等问题，有利于减少严重传导损伤的发生。但是，我国 TAVR 患者钙化程度高、二叶瓣比例大等特点，可能增加严重传导损伤的发生[22]。本研究结果显示，应用国产自膨式瓣膜的术后左束支传导阻滞的发生率为 16.7%(14/84)，需植入起搏器的高度房室传导损伤发生率为 11.9%(10/84)，均与既往国外自膨式瓣膜研究相仿[20,23]。此外，日本学者曾发表相关研究，证实锥形的主动脉根部结构可能是起搏器植入的危险因素之一[24]。而在本研究中，LVOT 面积/瓣环面积较小与术后传导损伤的发生相关。LVOT 面积/瓣环面积较小可能代表主动脉根部形态更倾向于锥形，更易导致 LVOT 受人工瓣膜的机械压迫。最后，ΔMSID 也对于术后传导损伤有较好的预测效果，与既往研究符合，提示导致国产自膨式瓣膜术后传导损伤的主要机制仍是手术过程、植入瓣膜对自室间隔膜部下缘穿行而出的 His 束产生的损伤。

本研究中也存在与既往研究结果不相符的情况。既往研究提示术前完全性右束支传导阻滞(right bundle branch block, RBBB)是术后起搏器植入的强预测因子[3,23]，在本研究中，60.0%(6/10)起搏器植入患者术前存在 RBBB，但传导损伤组术前右束支阻滞比例与正常组无统计学差异。这可能是因为术前存在右束支阻滞损伤并不意味着传导系统易损性的增加，仅表示患者失去右束支代偿功能。本研究中瓣膜钙化在 2 组间未表现出统计学差异，可能是由于纳入患者数量较少、未考虑钙化位置等原因。

虽然 LVOT 面积/瓣环面积、ΔMSID 对于术后严重传导损伤的发生均具有较好的预测作用，但两指标联合预测效能明显增加。这提示对于应用国产自膨式瓣膜的患者，在术前评估及手术过程中，应同时关注主动脉根部形态和 ΔMSID，从而精准预测潜在的术后严重传导损伤，通过改良 TAVR 器械及手术策略，进行更谨慎的操作，以达到改善患者预后的最终目的。

本研究仍然存在部分局限。首先，本研究为单中心、小样本、回顾性研究，不可避免地会存在选择偏倚；其次，本研究仅探讨了术后短期内传导损伤的危险因素，对于远期发生传导损伤和不良预后的危险因素还需要更大样本和更加深入的分析。

综上，LVOT 面积/瓣环面积、ΔMSID 是 TAVR 术后出现严重传导损伤的独立危险因素，可用于预测术后传导损伤的发生，二者联合较单独指标预测效能更高。对于国产自膨式瓣膜 TAVR 患者，需要密切关注 LVOT 面积/瓣环面积、ΔMSID，以减少术后严重传导损伤的发生，从而改善患者预后。

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