

经导管三尖瓣置换装置Lux-Valve与Lux-Valve Plus治疗重度三尖瓣反流患者的疗效比较

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[摘要] **目的:** 比较应用Lux-Valve与Lux-Valve Plus行经导管三尖瓣置换术(TTVR)治疗重度三尖瓣反流患者术后6个月的疗效。**方法:** 回顾性分析2019年8月至2023年11月因重度三尖瓣反流于空军军医大学第一附属医院行TTVR的28例患者的资料。按照置入瓣膜类型将患者分为Lux-Valve组和Lux-Valve Plus组, 各14例。所有患者于TTVR术前及术后6个月行经胸超声心动图检查, 比较患者TTVR术前与术后6个月以及Lux-Valve组与Lux-Valve Plus组各项指标。**结果:** 与Lux-Valve组比较, Lux-Valve Plus组术中出血量减少、术后住院时间缩短(均 $P<0.05$)。TTVR后6个月, 两组患者均无少量以上三尖瓣瓣内反流; Lux-Valve Plus组有1例患者出现夹持件与三尖瓣前叶分离, 其余患者均无中量及以上瓣周漏, Lux-Valve Plus组瓣周漏的发生率(14.29%, 2/14)较Lux-Valve组(64.29%, 9/14)下降($P<0.05$)。与术前比较, 两组患者术后6个月时右心房容积、右心室中段横径均减小(均 $P<0.05$), 三尖瓣跨瓣峰值血流速度、三尖瓣最大跨瓣压差、三尖瓣跨瓣平均血流速度、三尖瓣平均跨瓣压差和三尖瓣血流速度时间积分均增加(均 $P<0.05$), 下腔静脉直径、左心室射血分数、右心室面积变化分数均无明显变化(均 $P>0.05$); 术后6个月时Lux-Valve Plus组较Lux-Valve组左心室射血分数升高($P<0.05$), 其余指标两组间差异无统计学意义(均 $P>0.05$)。**结论:** 应用Lux-Valve与Lux-Valve Plus行TTVR治疗重度三尖瓣反流患者的疗效相近, 术后6个月时患者均发生右心逆重构。Lux-Valve Plus较Lux-Valve更微创, 但在瓣膜的选择上应考虑器械的特点并遵循患者的个体化差异。



[关键词] 三尖瓣反流; 经导管三尖瓣置换术; Lux-Valve; Lux-Valve Plus; 超声心动图; 临床疗效

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Efficacy of the transcatheter tricuspid valve replacement for patients with severe tricuspid regurgitation: Lux-Valve versus Lux-Valve Plus

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[**Abstract**] **Objective:** To compare the efficacy of transcatheter tricuspid valve replacement (TTVR) using Lux-Valve and Lux-Valve Plus in patients with severe tricuspid regurgitation. **Methods:** A total of 28 consecutive patients with severe tricuspid regurgitation who underwent TTVR with Lux-Valve ($n=14$) or Lux-Valve Plus ($n=14$) in the First Affiliated Hospital of the Air Force Medical University from August 2019 to November 2023 were enrolled. Transthoracic echocardiography was performed in all patients before and 6 months after the TTVR. The ultrasound indexes were compared before and 6 months after the TTVR in all patients and between Lux-Valve and Lux-Valve Plus groups. **Results:** Compared with the Lux-Valve group, the Lux-Valve Plus group showed significantly reduced intraoperative bleeding and shorter postoperative hospital stays (both $P<0.05$). Six months after the TTVR, none of the patients exhibited more than a mild tricuspid valve regurgitation, and none of the patients had moderate or above perivalvular leakage except for one patient in the Lux-Valve Plus group who had a separation of the clamping member from the anterior tricuspid leaflet. The incidence of perivalvular leakage was significantly lower in the Lux-Valve Plus group (14.29%, 2/14) than in the Lux-Valve group (64.29%, 9/14, $P<0.05$). At 6 months after operation, the right chamber volume and right ventricle middle transverse diameter were reduced (both $P<0.05$); the peak blood flow velocity across the tricuspid valve, peak pressure gradient across the tricuspid valve, mean blood flow velocity of tricuspid valve, mean pressure gradient across the tricuspid valve and velocity time integral were increased in both groups (all $P<0.05$). Compared with the Lux-Valve group, the Lux-Valve Plus group showed higher left ventricular ejection fraction at 6 months postoperatively ($P<0.05$), while the rest of the indicators were not statistically different (all $P>0.05$). **Conclusions:** The efficacy of using Lux-Valve and Lux-Valve Plus for TTVR in patients with severe tricuspid regurgitation is comparable. Six months after the TTVR, the right side of the heart has undergone reverse remodeling. While Lux-Valve Plus offers greater minimally invasive benefits, valve selection should consider device-specific characteristics and differences in individual patients.

[**Key words**] Tricuspid regurgitation; Transcatheter tricuspid valve replacement; Lux-Valve; Lux-Valve Plus; Echocardiography; Clinical efficacy

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[**缩略语**] 经导管三尖瓣置换术(transcatheter tricuspid valve replacement, TTVR);有效反流口面积(effective regurgitant orifice area,EROA);近端等速表面积(proximal isovelocity surface area,PISA);右心房容积(right chamber volume,RAV);右心室中段横径(right ventricle middle transverse diameter,RVD);面积变化分数(fractional area change,FAC);三尖瓣环收缩期位移(tricuspid annular plane systolic excursion,TAPSE);左心室射血分数(left ventricular ejection fraction,LVEF);三尖瓣跨瓣峰值血流速度(peak blood flow velocity across the tricuspid valve,Vmax-TV);美国胸外科医师学会(Society of Thoracic Surgeons,STS);氨基末端B型脑钠肽前体(N-terminal pro-B-type natriuretic peptide,NT-proBNP);下腔静脉直径(inferior vein cava diameter,IVCD);三尖瓣最大跨瓣压差(peak pressure gradient across the tricuspid valve,PG-TV);三尖瓣跨瓣平均血流速度(mean blood flow velocity of tricuspid valve,Vmean-TV);三尖瓣平均跨瓣压差(mean pressure gradient across the tricuspid valve,MG-TV);三尖瓣血流速度时间积分(tricuspid valve velocity time integral,VTI-TV)

三尖瓣反流是临床上常见的瓣膜疾病,重度三尖瓣反流尤其是左心瓣膜手术后的重度反流对患者的远期存活率存在重要影响^[1]。孤立性三尖瓣手术存在心律失常、出血、急性肾损伤等风险,且患者死亡风险高^[2-3]。目前,TTVR已成为治疗重度三尖瓣反流的有效途径。Lux-Valve(宁波健世科技股份有限公司产品)是我国自主研发的经右心房入路的TTVR瓣膜装置,4年随访结果显示其效果令人满意^[4-6]。近两年,该公司又推出了Lux-Valve Plus,其在Lux-Valve的基础上进行改良,经颈静脉入路,以减小对心脏的创伤,但其疗效与Lux-Valve是否存在差异尚需探讨。TTVR的术前病例筛选及术后效果评价主要依赖经胸超声心动图。经胸超声心动图不仅可以清晰显示心脏结构,也能准确评估人工瓣膜的位置、轴向和功能。本研究旨在应用经胸超声心动图观察和分析两种瓣膜装置治疗重度三尖瓣反流的中期疗效。

1 对象与方法

1.1 研究对象

回顾性分析2019年8月至2023年11月因重度三尖瓣反流于空军军医大学第一附属医院行TTVR的28例患者的资料,其中应用Lux-Valve 14

例(Lux-Valve组),应用Lux-Valve Plus 14例(Lux-Valve Plus组)。所有患者均符合重度三尖瓣反流的判定标准:缩流颈彩宽7 mm及以上、反流束面积10 cm²及以上、EROA在0.4 cm²及以上、PISA半径超过9 mm^[7]。患者年龄54~84岁,平均年龄(64.68±9.25)岁,其中男性10例(35.7%),女性18例(64.3%),行左心瓣膜置换16例(57.1%)。

1.2 仪器和器械

Philips EPIQ 7C超声诊断仪、S5-1探头为美国Philips公司产品;Lux-Valve和Lux-Valve Plus系统为宁波健世科技股份有限公司产品。

1.3 手术方法

Lux-Valve组行右侧第5肋间切口,装置由肋间切口穿刺进入右心房;Lux-Valve Plus组首先进行颈静脉造影明确颈内静脉宽度是否大于10 mm,而后瓣膜装置由右侧颈内静脉通过上腔静脉进入右心房。两组装置进入右心房后均在经食管超声心动图及数字减影血管造影引导下调整角度,使输送系统垂直三尖瓣瓣环水平,并于三尖瓣中央进入右心室;经食管超声心动图监测下缓慢释放夹持件,轻柔调整输送器,待夹持件与三尖瓣前叶接触良好,缓慢释放右心房盘面;在经食管超声心动图监测下观察人工瓣架位置和瓣周反流量并微调人工瓣膜,当瓣周反流最

少时将锚定键插入室间隔,彻底释放瓣膜,撤出输送系统,缝合手术切口。TTVR成功的定义:成功植入TTVR装置,人工瓣位置正常,固定良好,瓣叶启闭自如,术后即刻无轻度以上瓣内反流、无中度以上瓣周漏,术后30 d内无死亡及严重心血管事件、未转至外科行换瓣或成形术。

1.4 经胸超声心动图评估各项指标

使用 Philips EPIQ 7C 多普勒超声诊断仪(S5-1探头,探头频率1~5 MHz)进行超声心动图检查。所有患者左侧卧位或平卧位,超声检查由两名有经验的超声科医生完成,所有结果取三次测量平均值。测量患者术前及术后6个月的三尖瓣反流PISA半径(基线Nyquist极限为28 cm/s)、EROA、RAV、RVD、FAC、TAPSE、LVEF、肺动脉收缩压和 $V_{\max}$ -TV;观察患者术后6个月右心大小、人工瓣膜位置和功能、是否存在瓣周漏。通过上述指标评价患者TTVR后6个月的疗效。

1.5 统计学方法

采用SPSS 23.0软件进行统计分析。符合正态分布的计量资料采用均数±标准差($\bar{x} \pm s$)表示,组内比较采用配对样本 t 检验,组间比较采用独立样本 t 检验;非正态分布的计量资料采用中位数(上下四分位数)[$M(Q_1, Q_3)$]表示,组内比较采用非参数

Wilcoxon检验,组间比较采用Mann-Whitney U检验;计数资料用例数(n)或百分比(%)表示,两组间比较采用 χ^2 检验Fisher's确切概率法。上述检验均以 $P < 0.05$ 为差异有统计学意义。

2 结 果

2.1 两组基线资料比较

Lux-Valve组与Lux-Valve Plus组术前年龄、STS评分、NT-proBNP、三尖瓣环最大径、TAPSE、右心室FAC、PISA半径、EROA、肺动脉收缩压、RAV、RVD、LVEF、IVCD无明显差异(均 $P > 0.05$),提示两组患者术前基线资料具有可比性,见表1。

2.2 两组手术情况比较

28例患者均成功实施TTVR,两组患者置入瓣膜型号分别为Lux-Valve组28-50[#] 1例、28-55[#] 3例、30-50[#] 10例;Lux-Valve Plus组30-40[#] 4例、30-50[#] 6例、30-55[#] 4例。Lux-Valve组和Lux-Valve Plus组手术时长分别为130(107, 160)和105(88, 140)min,差异无统计学意义($Z = 1.337, P > 0.05$)。与Lux-Valve组比较,Lux-Valve Plus组术中出血量减少[分别为(125.46±77.38)和(48.50±35.12)mL, $t = 2.882, P < 0.05$]、术后住院天数缩短[分别为8.50(7.00, 10.25)和6.50(5.25, 7.00)d, $Z = 0.294$,

表1 两组基线资料比较

Table 1 Baseline parameters compared between the two groups

[$\bar{x} \pm s$ 或 $M(Q_1, Q_3)$]						
组 别	n	年龄(岁)	STS评分(%)	NT-proBNP(μ mol/L)	三尖瓣环最大径(mm)	TAPSE(mm)
Lux-Valve组	14	64.14±6.26	5.66(4.78, 11.19)	950(514, 1114)	42.93±4.74	16.27±4.80
Lux-Valve Plus组	14	65.21±11.74	9.15(6.03, 13.35)	593(230, 1628)	42.85±6.08	17.69±3.77
t/Z 值	—	0.301	1.441	1.019	0.043	0.863
P 值	—	>0.05	>0.05	>0.05	>0.05	>0.05
组 别	n	右心室FAC(%)	PISA半径(mm)	EROA(cm^2)	肺动脉收缩压(mmHg)	
Lux-Valve组	14	36.24±9.33	11.49±5.24	0.75±0.45	41.43±7.90	
Lux-Valve Plus组	14	39.21±6.75	10.06±2.54	0.80±0.34	41.64±11.28	
t/Z 值	—	0.966	0.922	0.341	0.058	
P 值	—	>0.05	>0.05	>0.05	>0.05	
组 别	n	RAV(mL)	RVD(mm)	LVEF(%)	IVCD(mm)	
Lux-Valve组	14	162.81±92.30	33.07±6.98	56.64±3.59	22.59±3.55	
Lux-Valve Plus组	14	127.26±49.34	32.86±3.48	58.36±4.38	21.50±5.93	
t/Z 值	—	1.271	0.103	1.133	0.588	
P 值	—	>0.05	>0.05	>0.05	>0.05	

—:无相关数据。STS:美国胸外科医师学会;NT-proBNP:氨基末端B型钠尿肽前体;TAPSE:三尖瓣环收缩期位移;FAC:面积变化分数;PISA:近端等速表面积;EROA:有效反流口面积;RAV:右心房容积;RVD:右心室中段横径;LVEF:左心室射血分数;IVCD:下腔静脉直径。1 mmHg=0.133 kPa。

$P<0.05$ 〕。术后6个月两组患者均无少量以上三尖瓣瓣内反流。Lux-Valve Plus组1例患者出现瓣膜夹持件与三尖瓣前叶分离,伴大量瓣周漏,其余27例患者均无中量及以上瓣周漏发生。Lux-Valve Plus组瓣周漏的发生率(14.29%,2/14)较Lux-Valve组(64.29%,9/14)下降($P<0.05$)。结果提示,采用Lux-Valve Plus行TTVR治疗重度三尖瓣反流患者术中出血少、术后住院时间短,瓣周漏发生率低。

2.3 两组超声心动图参数测量结果比较

与术前比较,术后6个月时两组患者RAV和RVD均减小(均 $P<0.05$),Vmax-TV、PG-TV、Vmean-TV、MG-TV、VTI-TV均增加(均 $P<0.05$),IVCD、LVEF、右心室FAC无明显变化(均 $P>0.05$)。术后6个月时,Lux-Valve Plus组较Lux-Valve组LVEF明显增高($P<0.05$),其余指标两组间差异无统计学意义(均 $P>0.05$)。见表2。结果提示,采用Lux-Valve和Lux-Valve Plus行TTVR治疗重度三尖瓣反流后6个月两组均发生右心房、右心室逆重构,无明显差异。

3 讨论

我国自主研发的LuX-Valve及Lux-Valve Plus瓣膜装置均有独特的锚定装置,不完全依赖径向支撑力,且三尖瓣叶夹持件、室间隔锚定键、较大的右心房盘片和裙边设计可以有效地稳定瓣膜位置并防止瓣周漏发生^[8]。Lux-Valve Plus是在

LuX-Valve的基础上对材料及手术入路方面进行改进,提高了术中人工瓣膜装置经食管超声心动图下的显示效果。本文资料显示,两种瓣膜装置用于基线情况相近的患者,在手术时长方面无明显差异,但Lux-Valve Plus组较LuX-Valve组瓣周漏的发生率低、出血量明显减少、术后住院时间缩短,一方面可能与Lux-Valve Plus组手术医师已经经过一代器械的植入而对二代器械操作更加熟练有关;另一方面,Lux-Valve Plus为经颈内静脉入路,术中出血少、循环稳定,有利于术者对瓣膜释放位置的精细调节,减少瓣周漏发生。本研究中Lux-Valve Plus组有1例患者术后1个月因夹持件与前叶分离出现了大量瓣周漏,考虑与以下因素有关:①人工瓣膜型号与三尖瓣环的匹配度不够,可能导致瓣膜位置过高,致使夹持件对三尖瓣前叶的牵拉过度,造成瓣叶撕裂;②瓣膜释放过程中,由于同轴性不佳,调节器械使三尖瓣环受力不均,造成三尖瓣前叶过度牵拉;③患者三尖瓣瓣口与室间隔成角偏小,室间隔锚定后,造成对三尖瓣前叶过度牵拉;④三尖瓣瓣叶较长或人工瓣偏小,夹持件未达瓣根,或三尖瓣瓣叶质量差,造成三尖瓣撕裂。

与术前比较,两组患者在术后6个月右心房、右心室均发生逆重构,Vmax-TV、PG-TV、Vmean-TV、MG-TV、VTI-TV均明显增加,且两组间无明显差异,说明两种瓣膜装置对右心形态及三尖瓣血流的影响是积极且一致的。然而,两组右心室

表2 两组经导管三尖瓣置换术前及术后6个月经胸超声心动图参数测量结果比较

Table 2 Transthoracic echocardiographic parameters between two groups before and 6 months after transcatheter tricuspid valve replacement

		[$\bar{x}\pm s$ 或 $M(Q_1,Q_3)$]					
组别	<i>n</i>	IVCD(mm)	LVEF(%)	RAV(mL)	RVD(mm)	右心室FAC(%)	
Lux-Valve组	术前	14	22.59±3.55	56.64±3.59	162.81±92.30	33.07±6.98	36.24±9.33
	术后6个月	14	23.07±4.76	56.50±4.86	108.14±38.19*	29.36±5.09*	38.64±10.21
Lux-Valve Plus组	术前	14	21.50±5.93	58.36±4.38	127.26±49.34	32.86±3.48	39.21±6.75
	术后6个月	14	20.06±5.65	60.00±3.53 [#]	115.93±51.89*	29.35±5.68*	39.36±5.14
组别	<i>n</i>	Vmax-TV(cm/s)	PG-TV(mmHg)	Vmean-TV(cm/s)	MG-TV(mmHg)	VTI-TV(cm)	
Lux-Valve组	术前	14	91.46±30.63	3.64±2.68	49.29±16.14	1.0(1.0,2.0)	28.67±14.73
	术后6个月	14	121.36±19.4*	6.00±1.80*	66.43±17.39*	2.0(2.0,3.0)*	39.23±14.99*
Lux-Valve Plus组	术前	14	86.50±27.26	3.58±2.06	48.07±16.03	1.0(1.0,2.0)	22.89±9.53
	术后6个月	14	115.36±22.67*	5.07±1.64*	62.14±12.98*	2.0(1.5,2.5)*	36.84±6.07*

与同组术前比较,* $P<0.05$;与Lux-Valve组术后6个月比较,[#] $P<0.05$ 。IVCD:下腔静脉直径;LVEF:左心室射血分数;RAV:右心房容积;RVD:右心室中段横径;FAC:面积变化分数;Vmax-TV:三尖瓣跨瓣峰值血流速度;PG-TV:三尖瓣最大跨瓣压差;Vmean-TV:三尖瓣跨瓣平均血流速度;MG-TV:三尖瓣平均跨瓣压差;VTI-TV:三尖瓣血流速度时间积分。

FAC及IVCD均无明显改善,原因可能为:①TTVR瓣膜装置固定于三尖瓣环,对三尖瓣环运动有一定影响^[9];②右心室形态复杂,仅通过从心尖四腔心切面测定右心室FAC评估右心室整体功能比较局限;③TTVR后三尖瓣由大量反流转变为少量以下甚至无反流,右心室前负荷加重,对右心室功能产生了一定影响;④患者术前进行药物治疗主要为利尿剂,因此术前测得IVCD数值偏低,对统计结果存在一定影响。

综上所述,Lux-Valve Plus与Lux-Valve的治疗效果相近,但Lux-Valve Plus更微创。然而,并非所有患者均适用Lux-Valve Plus。Lux-Valve Plus瓣膜装置由颈静脉通过右心房进入右心室时必须调弯,对患者右心房的尺寸要求更为严格;而Lux-Valve则可以通过指压试验选择最佳角度刺破右心房进入右心室。此外,Lux-Valve Plus不适用于右侧颈内静脉过细或有病变、损伤的患者。因此,临床选择器械时还应考虑器械的特点和患者个体化情况,而术前超声心动图的准确评估有助于临床最终决策。

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Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the First Affiliated Hospital of the Air Force Medical University (QX20191018-1, KY20212224-C-1), and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This research exemption from informed consent

利益冲突 所有作者均声明不存在利益冲突

Conflict of Interests The authors declare that there is no conflict of interests

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