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冠心病三支病变置入 Firebird 2 术后 3 年的随访研究*

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摘要 目的:通过对冠心病三支病变患者置入 Firebird 2 支架术后 3 年的随访,探讨 Firebird 2 支架的性能。**方法:**收集 2009 年 1 月~2012 年 12 月在解放军总医院住院行冠脉造影确诊为冠心病且首次置入 Firebird 2 支架患者的临床资料,按术后随访时间不同分为术后 3 年组(70 例)与术后 1 年组(69 例),比较两组的临床资料及术后 MACE 的结果。**结果:**术后 3 年组再发心绞痛的比例显著高于术后 1 年组(33.8 vs 18.2)%,差异有统计学意义($P < 0.05$)。而两组间性别、年龄、体重指数、SYNTAX 积分、LVEF、优势血管(右)、既往史、诊断、NYHA 心功能分级、MACE、再次血运重建、总死亡、非致死性心肌梗死及造影复查比例,支架总数及前降支、回旋支和右冠置入支架数比较均无统计学差异($P > 0.05$)。**结论:**冠心病三支病变置入 Firebird 2 术后 3 年主要心血管不良事件的发生情况与术后 1 年相当,但还需大规模、多中心继续随访研究。

关键词:冠心病;Firebird 2;随访研究

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3-year Follow-up after Firebird 2 Stent Implantation of Coronary Heart Disease patients with Three Lesions*

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ABSTRACT Objective: To explore the performance of Firebird 2 stents through the 3-year follow-up of coronary heart disease (CHD) patients with three lesions treated by Firebird 2 stents. **Methods:** From Jan. 2009 to Dec. 2009, the clinical data of CHD patients who underwent coronary angiography and were treated with Firebird 2 stents for the first time in our department were collected. According to the follow-up time, 70 patients were divided into 3-year group and 69 patients were divided into 1-year group. The major adverse cardiac or cerebrovascular events (MACCE) were compared between the two groups. **Results:** The recurrence of angina pectoris in 3-year group was significantly higher than that of 1-year group (33.8 vs 18.2) %. No significant difference was found in the gender, age, body mass index, SYNTAX score, LVEF, advantage blood vessels (right), past medical history, diagnosis, NYHA heart function classification, MACE, revascularization, total death, nonfatal myocardial infarction, proportion of repeated angiography, number of total stents, number of stents in LAD, LCX and RCA between the two groups ($P > 0.05$). **Conclusion:** CHD patients presenting with 3-vessel lesions had the same occurrence rate of adverse cardiac events at 1st year and 3rd year post-operation. Further large and multicenter follow-up studies were still required.

Key words: Coronary heart disease (CHD); Firebird 2; Follow-up study

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前言

冠状动脉旁路移植术 (coronary artery bypass grafting, CABG) 及经皮冠状动脉介入治疗 (percutaneous coronary intervention, PCI) 是目前治疗冠心病的两种主要手术方式。药物洗脱支架 (drug eluting stent, DES) 使支架内再狭窄率下降至 10% 左右^[1-3], 使 PCI 术适应症范围更广。自国产第一药物洗脱支架 Firebird (微创医疗器械(上海)有限公司) 性能逐渐被认可, 2009 年国产第二代药物洗脱支架 Firebird 2 (微创医疗器械(上海)有限公司) 的上市更为我国药物洗脱支架的前景带来了曙光, 但

对其中长期性能研究较少。本研究旨在通过对冠心病三支病变置入 Firebird 2 术后 3 年的随访, 探讨 Firebird 2 支架的性能。

1 资料与方法

1.1 一般资料

收集 2009 年 1 月~2012 年 12 月在解放军总医院住院且冠状动脉造影检查确诊为冠心病三支病变首次置入 Firebird 2 支架患者的临床资料, 按随访时间不同分为术后 3 年组(70 例), 共置入支架 171 枚 (LAD 75 枚, LCX 42 枚, RAD 54 枚), 及术后 1 年组 (69 例), 共置入支架 160 枚 (LAD 63 枚, LCX 40

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枚,RAD 57 枚)。所有患者的资料完整且均来源于我院住院患者的原始资料。纳入标准:①年龄大于 18 周岁;②造影显示三支病变且靶血管狭窄程度不小于 85%;③首次置入 Firebird 2 (微创医疗器械(上海)有限公司)。排除标准:①既往已行 PCI、CABG 或行急诊 PCI、CABG 术者;②首次置入其他类型支架或裸支架者及单纯球囊扩张术者;③造影显示优势血管呈均衡型;④存在恶性肿瘤、结缔组织及免疫系统疾病或严重感染及肝肾功能不全者;⑤近期(6 个月)有活动性溃疡,脑出血、卒中及双抗禁忌症者。

1.2 介入治疗

所有患者术前均按指南^[4]常规给予阿司匹林、氯吡格雷等药物口服,按介入手术要求给予冠脉造影和支架置入术。手术成功标准:最终血管残余狭窄小于 20%,且血流 TIMI 达到 3 级,无严重并发症(例如:恶性心律失常、严重心肌梗死、死亡等)。术后常规给予阿司匹林 100 mg 1/d 口服至终生(如机体条

件许可)、氯吡格雷 75-150 mg 1/d 至少服用 1 年,他汀调脂药(依据肝功情况调整)。积极遵循指南要求控制如血压^[5]、血脂^[6]、血糖^[7]、体重^[8]、吸烟^[9]等危险因素。

1.3 冠心病及冠脉病变的评定标准

用 Judkins 法进行冠状动脉造影判定有无冠心病^[10]。用 SYNTAX 积分系统^[11]对每 1 位造影患者计算 SYNTAX 积分,最后结果取 2 次积分的平均值。

1.4 随访终点

所有患者通过电话、门诊或住院进行随访,评估术后 1 年、3 年患者主要不良心血管事件(MACE,包括全因死亡、非致命性心肌梗死、血运重建)的发生情况,术后 3 年组随访中位时间 42.19 个月,术后 1 年组随访中位时间平均随访 15.6 个月。

1.5 统计学分析

采用 SPSS 19.0 统计软件分析数据,正态计量资料以均数±标准差($\bar{x} \pm s$)表示,组间比较采用 t 检验;非正态计量资料

表 1 Firebird 2 术后 3 年组与术后 1 年组的临床资料比较(例, %)

Table 1 Comparison of the clinical data between 3-year follow-up group and 1-year follow-up group(n, %)

Items	3-year follow up group(n=70)	1-year follow-up group(n=69)	t(X ²)	P
Gender(male)	52(74.3)	48(69.6)	0.384	0.536
Age	64.41± 10.23	61.03± 11.30	0.662	0.066
BMI	25.8	25.4	0.416	0.678
SYNTAX score	41.25	45.5	0.930	0.354
LVEF	57	57.5	0.690	0.491
Advantage blood vessels (right)	63(90)	61(88.4)	0.092	0.762
Past history				
Smoking	21(30)	28(40.1)	1.704	0.192
Hypertension	48(68.6)	52(75.4)	0.794	0.373
Diabetes mellitus	24(34.3)	24(34.8)	0.004	0.951
Hyperlipidemia	18(25.7)	18(26.1)	0.003	0.960
Old Myocardial Infarction	10(14.3)	8(11.6)	0.223	0.637
Stroke	9(12.9)	11(15.9)	0.268	0.604
Coronary heart disease	12(17.1)	9(13)	0.455	0.500
Diagnosis				
Stable angina pectoris	6(8.6)	10(14.5)	1.196	0.274
Unstable angina pectoris	51(72.9)	50(72.5)	0.003	0.959
NSTEMI	2(2.9)	3(4.3)	0.001	0.987
STEMI	11(15.7)	6(8.7)	1.595	0.207
NYHA classification				
I class	0(0)	0(0)	a	b
II class	7(10)	13(18.8)	2.205	0.138
III class	33(47.1)	35(50.7)	0.178	0.673
IV class	30(42.9)	21(30.4)	2.308	0.129

Note: LVEF: Left Ventricular Ejection Fraction; NYHA: New York Heart Association;

BMI: Body Mass Index; NSTEMI: Non ST segment elevation myocardial infarction;

STEMI: ST segment elevation myocardial infarction;a,b: no X² was used in Fisher exact probability in 2× 2 table.

用中位数(M)表示,组间比较用秩和检验;用百分比(%)表示计数资料,通过 X^2 检验进行组间比较,以 $P<0.05$ 为差异有统计学意义。

2 结果

2.1 Firebird 2 术后 3 年组与术后 1 年组的临床资料比较

Firebird 2 术后 3 年组与术后 1 年组的性别、年龄、体重指数、SYNTAX 积分、LVEF、优势血管(右)、既往史、诊断、NYHA

心功能分级方面比较差异均无统计学意义($P>0.05$),见表 1。

2.2 Firebird 2 术后 3 年组与术后 1 年组术后不良心血管事件发生情况的比较

术后 3 年组再发心绞痛的比例显著高于术后 1 年组(33.8% vs 18.2%),差异有统计学意义 ($P<0.05$),而两组 MACE、再次血运重建、总死亡、非致死性心肌梗死及造影复查比例比较差异均无统计学意义($P>0.05$),见表 2。

表 2 Firebird 2 术后 3 年组与术后 1 年组术后不良心血管事件发生情况的比较(例, %)

Table 2 Comparison of the incidence of postoperative adverse cardiac events between 3-year follow-up group and 1-year follow-up group(n, %)

Items	3-year follow up group(n=70)	1-year follow-up group(n=69)	t(X^2)	P
MACE	7 (10.7)	7(10.6)	0.009	0.976
Revascularization	6 (9.2)	7(10.6)	0.069	0.792
Total mortality	1(1.5)	0(0)	a	0.496
Nonfatal myocardial infarction	3(4.62)	0(0)	b	0.237
Angiography	41(63.1)	36(54.5)	0.984	0.321
Angina pectoris Recurrence	22(33.8)	12(18.2)	4.181	0.041

Note: MACE: major adverse cardiac events; a,b; no X^2 was used in Fisher exact probability in 2×2 table.

2.3 Firebird 2 术后 3 年组与术后 1 年组置入支架数目的比较

Firebird 2 术后 3 年组与术后 1 年组置入支架总平均数,前

降支、回旋支及右冠置入支架的平均数目比较差异均无统计学意义($P>0.05$),见表 3。

表 3 Firebird 2 术后 3 年组与术后 1 年组置入支架数目的比较(n)

Table 3 Comparison of the number of coronary stent between 3-year follow-up group and 1-year follow-up group (n)

Items	3-year follow up group	1-year follow up group	t(X^2)	P	95% CI
Total	2	2	0.565	0.573	-0.31~0.56
LAD	1	1	0.974	0.332	-0.16~0.48
LCX	0	1	0.163	0.871	-0.23~0.27
RCA	0	1	0.331	0.741	-0.38~0.27

Note: LAD: Left Anterior Descending;LCX: left circumflex coronary artery; RCA Right Coronary Artery.

3 讨论

药物洗脱支架的问世已使支架内再狭窄率明显降低^[1-3],作为国产第一代药物洗脱支架的 Firebird 经国人多年研究^[12,13]逐渐被认可。随着技术的发展,国产第二代药物洗脱支架 Firebird 2 也登上时代的舞台,因其以 L605 钴铬合金为药物平台而具有更好的可视性、不透光性及径向支撑力,聚乙烯丁烯-聚乙烯聚合物的涂层使雷帕霉素的释放时间延长,改善了支架的通过性,提高了操控性^[14]。Firebird 2 早期及近期的临床随访研究^[15,16]结果随之而出,但关于其中、长期性能的研究甚少。本研究旨在通过回顾性分析在我院首次置入 Firebird 2 支架的三支病变冠心病患者术后 3 年的随访结果,进一步评价此支架的性能。

本研究结果显示置入 Firebird 2 支架后 1 年和 3 年患者的性别、年龄、体重指数、SYNTAX 积分、LVEF、优势血管(右)、既

往史、诊断、NYHA 心功能分级等方面比较差异均无统计学意义($P>0.05$),临床诊断以不稳定型心绞痛为主(72.9 vs 72.5)%, NYHA 分级以Ⅲ级(47.1 vs 50.7)%、Ⅳ级(42.9 vs 30.4)%为主,不排除与三支血管病变有关。术后 3 年组再发心绞痛的比例显著高于术后 1 年组(33.8 vs 18.2)%,而 MACE、再次血运重建、总死亡、非致死性心肌梗死及造影复查的比例无显著性差异。初步考虑再发心绞痛比例高的原因与 PCI 术后不能完全再血管化有一定关联。术后 3 年组与 1 年组无一例脑卒中发生,术后 1 年组随访无心源性死亡及非致死性心肌梗死出现,术后 3 年组 1 例(1.5%)患者猝死,考虑心源性死亡可能性大。术后 3 年组 70 例患者共置入支架 171 枚,其中 LAD 75 枚、LCX 42 枚、RAD 54 枚;术后 1 年组 69 例患者共置入支架 160 枚,其中 LAD 63 枚、LCX 40 枚、RAD 57 枚,手术成功率 100%。两组置入支架总数,前降支、回旋支及右冠状动脉置入支架的数目均无统计学差异。虽然术后 3 年组与术后 1 年组 MACE 及再次

血运重建比例比较无统计学差异,但术后3年组与术后1年组较既往研究所占比例较高(10.7 vs 10.6)%,与刘玲等^[17]在复杂及多支病变12个月的心脑血管不良事件发生率是10.4%相似,而Ge等^[18]在Firebird 2置入术后30天及6个月的主要心血管不良事件比率分别是1.2%、1.8%,张文全等^[19]在术后6个月的随访中主要心血管不良事件是5%,Li等^[20]在急性心肌梗死患者术后1年主要心血管不良事件是5.1%,甘舜进等^[21]在不稳定型心绞痛患者术后38.6个月的不良心血管事件是1.4%。本研究主要不良心血管事件比例较高的原因初步考虑:①入选冠脉病变均为三支血管,SYNTAX积分分析均为重度,病变重,预后差;②术后3年组的随访率稍低(92.9%),整体病例数偏少(共139例),存在一定的偏倚;③再次血运重建率高,间接使MACE的发生比例升高。因此,在以后的研究中可着重从以上原因入手,尽量减少偏倚。

综上所述,本研究结果表明冠心病三支病变置入Firebird 2术后3年主要心血管不良事件的发生情况与术后1年相当,但还需延长随访时间,扩大样本量,加强多中心合作,进一步评估其中长期效果。

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