李 毅, 韩雅玲*, 荆全民, 张 磊, 王效增, 马颖艳, 王 耿, 王 斌, 邓 捷, 张权宇.涂层可降解雷帕霉素洗脱支架术后6个月双联抗血小板治疗的长期疗效与安全性: CREATE研究4年随访结果分析[J].中华老年多器官疾病杂志,2012,11(2):84~88

涂层可降解雷帕霉素洗脱支架术后6个月双联抗血小板治疗的长期疗效与安全性: CREATE研究4年随访结果分析

Long-term clinical efficacy and safety of six-month dual antiplatelet therapy after biodegradable polymer-based sirolimus eluting stent implantation: results of 4-year follow-up of the CREATE Study

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中文关键词: 药物洗脱支架, 血小板聚集抑制剂, CREATE研究

英文关键词:drug eluting stent; antiplatelet drugs; CREATE Study

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中文摘要:

目的 探讨涂层可降解雷帕霉素药物洗脱支架（DES）术后应用6个月双联抗血小板治疗（DAPT）的长期疗效和安全性。方法 多中心、前瞻性CREATE研究中术后6个月随访时未发生主要不良心脏事件（MACE）的存活患者共2034例, 全部接受Excel涂层可降解雷帕霉素DES治疗, 其中1626例（79.9%)于术后6个月内停用氯吡格雷（DAPT≤6个月）, 408例（20.1%）于6个月后继续服用氯吡格雷（DAPT＞6个月）。对比两组患者在6个月至4年随访期间的MACE和支架内血栓发生率。结果 DAPT＞6个月者与≤6个月者相比, 心性死亡（2.0% vs 2.2%, P=0.753）、心肌梗死（0.2% vs 0.4%, P=1.0）和靶病变血运重建（1.7% vs 2.4%, P=0.407）发生率差异均无统计学意义。两组总的MACE发生率差异亦无统计学意义（3.7% vs 3.4%, P=0.819）。两组总的血栓事件发生率分别为1.5%和0.7%, 差异无统计学意义（P=0.128）。两组明确的及很可能的血栓累计发生率差异亦无统计学意义（0.7% vs 0.5%, P=0.469）。多因素分析结果表明, 陈旧性心肌梗死是支架内血栓的独立危险因素（OR=15.313, 95% CI: 4.02～58.25, P＜0.001）。DAPT疗程≤6个月与MACE（OR=0.987, 95%CI=0.545～1.787, P=0.965）及支架血栓事件发生率（OR=0.847, 95%CI= 0.208～3.439, P=0.816）无显著相关性。结论 4年临床随访结果表明, 冠心病患者置入涂层可降解DES术后使用6个月DAPT安全、有效, 但还需随机、对照研究进一步证实。

英文摘要:

Objective To explore the long-term clinical efficacy and safety of 6-month dual antiplatelet therapy (DAPT) after biodegradable polymer based drug eluting stent (DES) implantation. Methods In the multi-center prospective CREATE Study, a total of 2034 patients who received biodegradable polymer based sirolimus eluting stent (Excel stent) treatment and had no major adverse cardiac events (MACE) at 6-month were included. Among them, 1626 (79.9%) patients discontinued clopidogrel treatment within 6 months (DAPT≤6 months) and 408 (20.1%) prolonged clopidogrel treatment after 6 months (DAPT＞6 months). The incidences of MACE and stent thrombosis through 6 months to 4 years were compared between patients with different DAPT durations. Results There was no statistical difference between the two groups in the incidences of cardiac death (2.0% vs 2.2%, P=0.753), myocardial infarction (0.2% vs 0.4%, P=1.0), target lesion revascularization (1.7% vs 2.4%, P=0.407) and MACE (3.7% vs 3.4%, P=0.819). The overall incidence of stent thrombosis in patients with DAPT＞6 months and≤6 months was 1.5% and 0.7%, respectively (P=0.128). The incidences of definite or probably stent thrombosis were similar between the two groups (0.7% vs 0.5%, P=0.469). Multivariate analysis showed that prior myocardial infarction was an independent predictor of stent thrombosis (OR=15.313, 95% CI: 4.02?58.25, P＜0.001). However, DAPT duration of ≤6 months was neither associated with the risk of MACE (OR=0.987, 95%CI: 0.545?1.787, P=0.965) nor stent thrombosis (OR=0.847, 95%CI: 0.208?3.439, P=0.816). Conclusions DAPT for 6 months is safe and effective at four years after biodegradable polymer based DES implantation, which needs further confirmation by randomized controlled studies.

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