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磺达肝癸钠对中国人非ST段抬高急性冠脉综合征的有效性和安全性评价

Safety and efficacy of fondaparinux in Chinese patients with non-ST elevation acute coronary syndromes

DOI：

中文关键词: 冠状动脉疾病; 磺达肝癸钠; 血管成形术, 经腔, 经皮冠状动脉

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中文摘要:

目的 评价磺达肝癸钠对中国人非ST段抬高急性冠脉综合征（NSTE- ACS）的临床疗效、安全性及预后。方法 回顾性分析2010年3月至2011年12月间, 沈阳军区总医院收治的NSTE-ACS应用磺达肝癸钠患者中随访资料完整的经皮冠状动脉介入治疗（PCI）及单纯药物保守治疗2448例患者, 男性1696例, 年龄21～90岁, 平均（68.4±12.1）岁。观察住院期间严重出血、血小板减少、住院期间和出院后1个月主要心血管事件发生率及冠状动脉病变特点,并与国外OASIS-5大型临床研究比较。结果 与OASIS-5研究比较, 本研究基本临床特征差异无统计学意义（P＞0.05）。介入治疗手术成功率97.1%（2043/2104）, PCI术中无死亡病例。与依诺肝素用于NSTE-ACS治疗后辅助抗凝的OASIS-5研究结果比较, 显示在9天、30天时死亡、心肌梗死或顽固性心肌缺血复合事件发生率有相同的临床疗效, 但9天大出血发生率磺达肝癸钠明显低于依诺肝素（P＜0.05）。磺达肝癸钠组9天时大出血发生率较OASIS-5研究依诺肝素组显著降低（1.6% vs 4.1%, 风险比0.38; 95% 可信区间0.28～0.54, P＜0.05）这些差别在30天随访中持续存在（1.4% vs 5.0%, 风险比0.65; 95% 可信区间0.45～0.93, P＜0.05）。应用替罗非班后出血并发症发生率显著高于未用替罗非班患者（25.6% vs 3.8%, P＜0.001）。肾功能损害患者冠状动脉造影显示多支血管病病变为主, PCI术后TIMI 3级血流所占比例也较低（21.0%）, 支架内血栓发生率略高（1.2%）。9天死亡、心肌梗死或顽固性心肌缺血复合事件发生率, 较肾功能正常患者显著增加（4.94% vs 1.04%, 风险比7.87; 95% 可信区间3.41~18.16, P＜0.05）。这种差别在30天随访中持续存在（5.4% vs 2.4%, P＜0.05）。磺达肝癸钠组肾功能损害患者大出血发生率均较OASIS-5 研究中依诺肝素组显著降低（2.2% vs 6.4%, P＜0.001）。结论 磺达肝癸钠在NSTE-ACS患者PCI及药物保守治疗中应用均是安全的,可以明显改善PCI术后的冠状动脉血流和心肌灌注及临床预后, 并且不增加出血风险。

英文摘要:

Objective To evaluate the clinical efficacy, safety and prognosis of fondaparinux in patients with non-ST elevation acute coronary syndromes (NSTE-ACS). Methods A retrospective analysis was performed on 2448 NSTE-ACS patients [1696 males, aged 21～90 years, mean (68.4±12.1) years] who were administrated with fondaparinux after receiving either percutaneous coronary intervention (PCI) or merely drug therapy in our department between March 2010 and December 2011 and with intact follow up . We summarized the characteristics of the patients, recorded incidence of in-hospital major bleeding, platelet reduction and incidence of major adverse cardiac events (MACE) during hospitalization and 1 month after discharge. Then we compared our results with those of OASIS-5 trial. Results There was no significant difference between our study and OASIS-5 in baseline clinical characteristics (P＞0.05). The success rate of the invention operation was 97.1% (2043/2104). There was no death during the PCI procedure. Compared with OASIS-5 trial, which used enoxaparin to assist anticoagulation for patients with NSTE-ACS, our study showed identical incidence of death, myocardial infarction and refractory ischemia at day 9 and day 30, while fondaparinux group showed significantly lower incidence of major bleeding than enoxaparin group at day 9 (P＜0.05). The incidence of major bleeding in fondaparinux group was significantly lower than that in enoxaparin group in OASIS-5 at day 9 (1.6% vs 4.1%; HR: 0.38; 95% CI: 0.28?0.54; P＜0.05), and this difference continued during the 30 days follow-up (1.4% vs 5.0%; HR: 0.65; 95% CI: 0.45?0.93; P＜0.05). Incidence of bleeding complication was significantly higher in Tirofiban-used patients than in non-Tirofiban-used ones (25.6% vs 3.8%, P＜0.001). Patients with renal impairment mainly manifested with multivessel lesions identified by coronary angiography. They also showed lower rate of TIMI grade 3 after PCI procedure (21.0%), and higher rate of in-stent thrombosis (1.2%). The incidence of death, myocardial infarction and refractory ischemia of patients with impaired renal function at day 9 were significantly higher than those in patients with normal renal function (4.94% vs 1.04%; HR: 7.87; 95% CI: 3.41?18.16; P＜0.05), and this difference sustained during the 30 days follow-up (5.4% vs 2.4%, P＜0.05). Patients with renal impairment in fondaparinux group had significantly reduced incidence of major bleeding than those in enoxaparin group of OASIS-5 trial (2.2% vs 6.4%; P＜0.001). Conclusion Application of fondaparinux is safe in NSTE-ACS patients both receiving PCI and merely drug therapy. It also significantly improves coronary blood supply and coronary perfusion after PCI procedure as well as clinical prognosis without increasing bleeding risk.

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