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Levosimendan versus Milrinone after Corrective Open-Heart Surgery in Neonates and Infants

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Introduction: Levosimendan has been shown to improve cardiac function and hemodynamics in adults. After open-heart surgery in neonates and infants low cardiac output syndrome (LCOS) commonly complicates the postoperative course and is associated with poor outcome. Therefore, milrinone is widely used prohylactically to prevent LCOS after open-heart surgery. The aim of our study was to evaluate whether levosimendan is superior to milrinone in preserving cardiac output (CO) after open-heart surgery in infants.
Methods: After written informed consent forty children <1yr old (71 +/- 80days, 4.2 +/-1.3kg) undergoing corrective open-heart surgery (basic Aristotle score 8.9 +/-1.8) were included in a prospective single-center, double-blind, randomized pilot-study.
Exclusion criteria were <36 weeks of gestation, <3kg weight, preoperative LCOS, pretreatment with the study drugs, renal impairment and thrombocytopenia. At weaning from cardiopulmonary bypass patients received either a 24hours continuous infusion of 0.1 microg/kg/min of levosimendan (n=20) or a 24hours continuous infusion of 0.5 microg/kg/min of milrinone (n=20). The primary study endpoints cardiac output (CO) and index (CI) using transesophageal Doppler technique (Cardio-QP, Deltex Medical), hemodynamic parameters and FS were evaluated at 2, 6, 12,18, 24 and 48 hours post cardiopulmonary bypass. ANOVA was used for statistics.
Results: There were no differences in demographic data, complexity of cardiac surgery, bypass time and aortic cross clamp time. Both drugs were well tolerated and no death or serious adverse event occurred throughout the study. The duration of mechanical ventilation, stays in ICU and total hospital stay did not differ between the groups. Heart rate, systemic arterial pressure, pulmonary artery pressure, left atrial pressure, arterial to venous saturation difference, NIRS, FS, lactate levels, total volume requirement, urine output and inotrope score were similar in both groups.
In the levosimendan group compared to the milrinone group there was a statistically significant increase of cardiac output (p=0.043) over time. However, the increase in cardiac index between the groups only showed a trend (p=0.077).
Conclusions: Levosimendan was found to be safe when prophylactically given to neonates and infants following open-heart surgery. The prophylactic use of levosimendan slightly increased CI. However, this marginal hemodynamic benefit did not observably influence patients´outcome.