Pre-operative Sildenafil administration in children undergoing cardiac surgery; a randomized placebo-controlled preconditioning study


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Introduction: Sildenafil has strong cardiac preconditioning properties in animal studies and is known to have a safe side effect profile in children. Therefore, we evaluated the use of sildenafil preconditioning to reduce postoperative myocardial injury in children undergoing surgical ventricular septum defect (VSD) closure.

Methods:
Randomized, double blind study. Children (1-17 years) undergoing VSD closure were randomized into three groups: Placebo (Control group), preconditioning with 0.06 mg/kg (Sild-L group) or 0.6mg/kg sildenafil (Sild-H group). Measurements of cardiac injury (CK-MB and troponin I), inflammatory response (IL-6 and TNF-α), bypass and ventilation weaning times, inotropy score, and echocardiographic function were made pre-and postoperatively.

Results:
Thirty-nine patients were studied (13/group). Aortic cross clamp time was similar with 27 (18-85) and 27 (12-39) minutes in the Control and Sild-L groups, respectively, but significantly longer with 39 (20-96) minutes in the Sild-H group. Area under the curve of CK-MB release was 1105 (620-1855) ng/mL in the Control group, showed a tendency to be higher in the Sild-L group with 1672 (564-2767) ng/mL, and was significantly higher in the Sild-H group with 1695 (1252-3377) ng/mL. There were no differences in inflammatory response markers, cardiopulmonary bypass and ventilation weaning times, inotropy scores, and echocardiographic function between the groups.

Conclusion:
Sildenafil does not reduce myocardial injury in children undergoing cardiac surgery, nor does it alter cardiac function, inotropic needs, or postoperative course.
A paradoxical subclinical increase in cardiac enzyme release after sildenafil preconditioning cannot be excluded.

Clinical Trial Registration number: CTRI/2014/03/004468.