O-024 OUTCOME RESEARCH IN 77 PATIENTS WITH PULMONARY ARTERIAL HYPERTENSION RECEIVING SILDENAFIL: A DOUBLE-BLIND, RANDOMISED CONTROLLED STUDY

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Purpose PAH resulting from CHD – a major cause of postoperative morbidity and death. Sildenafil: selective inhibitor of phosphodiesterase-5 - an effective and promising pulmonary vasodilator, with minor reverse effects.

Methods This monocentric, randomised placebo-controlled study evaluated the efficacy, safety, tolerability of oral Sildenafil in children with severe PAH secondary congenital shunts (simple (14 patients), mixed (35), complex (28)). 77 PAH patients (35 – repaired shunts, 31 – palliative, 11 inoperable) assigned to placebo or Sildenafil – dose of 1–2 mg/kg/day each 8h: 6–12 months. Sildenafil group: 38 (mean age 19, 9 ± 5, 3 months: 16 boys/22 girls); placebo – 39 (mean age 21, 7 ± 7, 8 months: 22 boys/17 girls). Research protocol: FC NYHA; 6-min walk test; O2 saturation; echocardiography PAPm, myocardial performance index (MPI/Tei index), right cardiac catheterisation – PVRi; questionnaire for adverse reactions was available.

Results Sildenafil patients improved FC from 3,16 ± 0,1–2, 15 ± 0,1 (p < 0,001); effort tolerance (+132,5 ± 17,4m – 6 months and +184,3 ± 21,2 m - 12 months of treatment), (p < 0,001); O2 saturation (+3,1 ± 0,5%) but placebo (+0,6 ± 0,3%), (p < 0,001); PAPm decreased: 22,0 ± 2,22 at 6 months with 19,03 ± 2,3 mmHg - 12 months (p < 0,001); PVRi decreased: 2,45 ± 0,19 UWood·m-2 (p < 0,001); Tei index with 0,15 ± 0,01(-31%) to initial (p < 0,001). In placebo group only PVRI diminished from 6,4 ± 0,1 to 5,7 ± 0,3 UW/m2 (p < 0,05). No death in the Sildenafil group, but 5 in placebo.

Conclusions Sildenafil – efficient in treating severe PAH secondary to congenital shunts, but even more effective in children after cardiac surgery. Sildenafil improves FC, effort tolerability, O2 saturation, RV global function, diminishing PAPm and PVRI comparing with placebo. Sildenafil has good safety, tolerability, favourable impact on life quality – insignificant adverse reactions.