

OUTCOME OF TRANSCATHETER VENTRICULAR SEPTAL DEFECT CLOSURE USING NIT-OCCLUD LÊ VSD COIL VERSUS VSD NITINOL WIRE MESH OCCLUDER

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Background:

The use of *Nit-Occlud Lê VSD Coil* is as an alternative device of transcatheter Ventricular Septal Defect (VSD) closure in pediatric patients. There is no previous study to evaluate and compare the outcome of the closing of VSD between using *Nit-Occlud Lê VSD Coil* and *VSD Nitinol Wire Mesh Occluder*.

Objectives:

To evaluate the efficacy and safety of using *Nit-Occlud Lê VSD Coil* and *VSD Nitinol Wire Mesh Occluder* for percutaneous closure of VSD.

<u>Methods</u>:

An observational analytic study with a retrospective cohort design was conducted on all medical records of VSD pediatric patients who underwent definitive transcatheter VSD closure therapy at Department of Child Health, Dr. Soetomo Hospital since January 2017 until December 2018. The variables included outcome of effectiveness (successful implantation, complete closure, and closure rate), efficiency in procedures (procedure time, fluoroscopy time, amount of contrast agent, length of treatment, and cost of device), and complications (residual VSD, aortic regurgitation, tricuspid regurgitation, impairment rhythm, hemolysis, embolization, and death). Data was obtained since pre, during, and post catheterization. Post-catheterization included a 1 month, 3 months, 6 months, 9 months and 12 months follow-up after catheterization. The data were processed and statistical comparative tests were carried out.

<u>Results</u>:

There were 27 subjects, divided into 2 groups: *Nit-Occlud Lê VSD Coil* 10/27 (37%) and *VSD Nitinol Wire Mesh Occluder* 17/27 (63%). There was no significant difference in the clinical characteristics of the two groups. From the outcome of effectiveness variables, there were no



significant difference either between the two groups on the success of implantation (p = 0.274), complete closure (p = 0.059), and closure rate months 1 to 12 months post-catheterization (p = 0.163). The efficiency in the procedure variables showed no significant difference in the time of catheterization (p = 0.642), fluoroscopy time (p = 0.261), length of treatment (p = 1.000), however *Nit-Occlud Lê VSD Coil* showed more in the amount of contrast agent (p = 0.001). The cost of *Nit-Occlud Lê VSD Coil* was higher (p = 0.00). There were no significant differences between the two groups regarding the occurrence of complications, including embolization (p = 1.00) and hemolysis (p = 0.370). Tricuspid regurgitation was found immediately (p = 0.371) or when we follow-up up to 12 months (p = 0.168) similarly in both groups, but significantly different on the incidence of residual VSD (p = 0.041). There were no complications of rhythm disturbances and death in both groups.

Conclusion:

VSD closure using *Nit-Occlud Lê VSD Coil* provides result which was equal to *VSD Nitinol Wire Mesh Occluder*, except for the variables amount of contrast agent, cost of device, and residual VSD complication.