Preclinical evaluation of a new self-expanding device for closure of muscular ventricular septal defects in a pig model.

OBJECTIVES: Aim of our study was the preclinical evaluation of a new self-expanding device for interventional closure of muscular ventricular septal defects (mVSDs) in an acute pig model. BACKGROUND: Devices currently in use for closure of mVSDs still have their limitations. The deployment of the disks is dependent from the expansion of the stent, which can be associated with problems for sufficient closure of the mVSDs. This was the reason for developing a modified device with only one disk.

MATERIALS AND METHODS: The device was constructed in a single wire technique with a unique configured retention disk. mVSDs were created in six pigs with a specially designed punch instrument, and subsequently closed with our new device during the same session using a jugular or femoral vein approach. Potential residual shunting volumes were estimated by echocardiography and hemodynamic measurements. After closure, animals were sacrificed, and hearts were harvested for macropathologic evaluation. In two animals, MRI was performed for additional noninvasive evaluation.

RESULTS: Devices were successfully implanted in all animals with good alignment of the disk to the left ventricular septum, even if the stent was oversized. Echocardiography, hemodynamics, angiography and macropathology revealed complete...
closure of all mVSDs. MRI and echocardiography showed a good visibility of the device.

CONCLUSIONS: Our preclinical study shows successful closure of iatrogenic created mVSDs without residual shunting. The device is characterized by a more controlled deployment, an independent deployment of disk and waist, and a good alignment of the left ventricular disk to the muscular septum.

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