NOVEL TRANSRADIAL DEVICE FOR INTRA-AORTIC EMBOLIC DEFLECTION DURING TRANSCATHETER AORTIC VALVE IMPLANTATION

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BACKGROUND

Periprocedural embolic stroke is a major cause of morbidity in cardiovascular interventions. Clinical cerebrovascular event rates as high as 3-5% have been reported at 30 days following transcatheter aortic valve implantation (TAVI). Although cerebral embolic protection devices that provide partial protection of the brain during TAVI have been developed, a low profile adjunctive transradial device for complete protection of the brain is desirable.

OBJECTIVE

The aim of this study was to evaluate the safety and feasibility of a novel transradial device for intra-aortic embolic deflection in porcine experiments.

METHOD

The ProtEmbo Cerebral Protection System (Protembis GmbH, Germany) is an intra-aortic filter device to deflect embolic material arising from the aortic arch or native aortic valve away from the cerebral circulation during TAVI. The device consists of an implantable filter introduced via a 6F transradial access and which prevents the migration of embolic particles via three great branch vessels into the cerebral vasculature. The safety and feasibility of the device were tested under in-vivo conditions in porcine experiments (n=6). The animals were pretreated with aspirin and clopidogrel, and an adequate ACT level was maintained throughout the procedure (> 250 seconds) using unfractionated heparin. The device was introduced via a 6F sheath in the left subclavian artery and positioned at the target region of the aortic arch for at least 90 minutes, with subsequent removal. To measure the device's influence on cerebral perfusion, pressure measurements were conducted through an arterial line with and without device in place at implant and explant of the device. The model included two acute (follow-up after 72 hours) and four chronic (follow-up after 29 days) animal experiments, and histological examination of the heart, aortic arch, and non-target organs.

RESULTS

The device was reliably introduced, positioned and retrieved in all cases (n=6). The radioopacity of the device facilitated handling and positioning in the aortic arch. Removal of the device was uncomplicated. Initial implantation and manipulation did not reduce blood flow in the aortic side branch vessels, and the devices did not become occluded by embolic particles. Acute and chronic animal behavior after implantation and removal of the device was unremarkable. Histological investigation of

the heart, aortic arch, and non-target organs did not reveal any adverse findings. Use of the device did not create any significant safety or biocompatibility concerns.

CONCLUSION

The ProtEmbo Cerebral Protection System performed safely and reliably in a porcine model. The device is easy to deploy, is atraumatic, and effectively covers all three side branches of the aorta providing complete protection of cerebral perfusion from the aorta. Human clinical trials are planned.