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Work in progress report - Experimental

Total endovascular aortic arch reconstruction via fenestration in situ with cerebral circulatory support: an acute experimental study

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Abstract

The aim of this experimental study is to evaluate the feasibility of endovascular repair of the complete aortic arch by using novel fenestration devices with simultaneous support of the cerebral circulation. Two fresh human cadavers and five Yorkshire pigs were used for the experiments. In human cadavers the thoracic aorta was pressurized using a roller pump to simulate the circulation. In animal experiments right femoral artery to right distal carotid artery bypass circuit was achieved in order to support the cerebral circulation during the stent graft deployment, fenestration and conduit fixation procedures. Commercially available Valiant Thoracic Stent Grafts, covered stents, steerable guiding catheters and dilatation balloons were used. Stent grafts were deployed successfully and two fenestrations and one conduit implantation were achieved in each cadaver. All animals survived the stent graft implantation, fenestration and conduit implantation procedures. Cadaver dissection and necropsy of the animals revealed good fixation of the conduits into the fenestrated segments of the stent gra. Endovascular repair of the total aortic arch via in situ fenestration of the stent graft using cerebral circulatory support seems to be feasible and safe. Further studies are required before clinical adoption of this procedure.

Keywords: Aortic arch aneurysm; Endovascular stent graft; Cerebrovascular circulation

1. Introduction

Conventional treatment of aneurysms, dissections and other pathologies located in the aortic arch still have high morbidity and mortality despite measures to minimize cerebrovascular complications. Both the open surgical technique and recently introduced hybrid procedures that combine supra-aortic trunk surgery with endovascular repair are still far from having reasonable morbidity and mortality rates [1–3]. Several authors described their techniques for endovascular repair of the arch but they were neither practical nor reproducible [4, 5]. These techniques require too much manipulation in the aortic arch which may cause high rates of neurological morbidity. The aim of this experimental study was to evaluate the feasibility of a new endovascular technique for complete aortic arch repair using retrograde fenestration in situ and conduit implantation with simultaneous cerebral circulatory support (Video 1 – Procedure animation).

2. Materials and methods

This study was approved by the Ethical Committee of University Hospital of Geneva, Switzerland.

2.1. Cadaver experiments

Two fresh cadavers were used for the experiments. Bilateral common carotids and left subclavian arteries were exposed. Median sternotomy and laparotomy were done in order to gain access to the ascending aorta and the suprarenal aorta. Two aortic cannulae, one to the proximal ascending aorta, and one to the suprarenal aorta were inserted and secured with purse string sutures so that a roller pump with isotonic saline could be used to pressurize the aorta. A 10 mm Dacron vascular prosthesis was anastomosed to the suprarenal aorta in end-to-side fashion for stent graft access. The whole thoracic aorta was isolated between two vascular clamps, one placed proximal to the aortic cannula and the other distal to both cannulae to prevent fluid leakage during the perfusion. The roller pump...
was started and the clots were removed from the lumens of the aorta, carotid and left subclavian arteries through arteriotomies created on the supra-aortic branches and through the distal aortic cannula. The pump created a closed perfusion system with a mean pressure of 70 mmHg. The circulating saline was heated to 37 °C in order to properly activate the nitinol memory of the stent grafts. Using aortography, the diameters of the aortic segments and supra-aortic vessels were measured. Commercially available Valiant Thoracic Stent Grafts (Medtronic CardioVascular, Santa Rosa, CA) and iCAST (Atrium Medical Corp., Hudson, NH) covered stents were used in both cadavers.

2.2. Animal experiments

Five Yorkshire pigs between 70–80 kg were used for the experiments. All animals received humane care in compliance with the guidelines of Principles of Laboratory Animal Care formulated by the National Society for Medical Research, and the Guide for the Care and Use of Laboratory Animals published by the National Institutes of Health (NIH Publication No. 88-23, revised 1985). Under general anesthesia, and right lateral decubitus position, the infrarenal aorta was exposed through the left oblique flank incision via retroperitoneal access. Intravenous Heparin 5000 U was given and a 10 mm Dacron vascular graft was anastomosed as the conduits. High pressure balloons larger than the covered stent were used for preflaring the covered stents. Final flaring was done by using spherical occlusion balloons (Video 2 – Animal study). After completing the deployments of the conduits, a control aortography was performed in the cadavers and animals. The animals were euthanized. Necropsy on animals and anatomic dissection on cadavers were performed to photograph the implants in situ.

3. Results

3.1. Cadaver experiments

The perfusion system utilizing proximal and distal aortic cannulae to pressurize the thoracic aorta and supra-aortic branches was effective in both cadavers. The left subclavian artery was occluded in the first cadaver and a bovine aortic arch anatomy was present in the other cadaver as an anatomical variant. Stent grafts were deployed into the aortic arch successfully and two fenestrations and one conduit implantation were done in each cadaver (Fig. 1). Anatomic dissection confirmed fixation and sealing in both conduits.

3.2. Animal experiments

Due to the pig’s bicarotid take off from the brachiocephalic trunk anatomy, only two conduits were planned in conduit implantation and fixation. The Valiant thoracic stent graft was implanted into the aortic arch with its proximal end just distal to the coronary ostia and with the body of the graft covering the ostia of the brachiocephalic trunk and the left subclavian artery.

2.3. Fenestration and conduit implantation

In cadaver experiments, 16 Fr introducer sheaths were used for placing the devices inside the carotid and the left subclavian arteries. In animal experiments, 14 Fr introducer sheaths were placed into the left proximal carotid artery and the left proximal subclavian artery in order to achieve the fenestration of the stent graft, conduit deployment and fixation procedures. Balloon-centered and balloon-anchored needle-dilator catheters and radio frequency (RF) plasma electrode catheters were designed and produced by the Medtronic Research and Development Department to create fenestrations. High pressure dilatation balloons were used to dilate the puncture holes on the stent graft. Peripheral covered stents, specifically the iCAST, Viabahn (W.L. Gore Associates, Inc., Flagstaff, AZ, USA), and Jostent (Jomed GmbH, Rangendingen, Germany), were used as the conduits. High pressure balloons larger than the covered stent were used for preflaring the covered stents. Final flaring was done by using spherical occlusion balloons (Video 2 – Animal study). After completing the deployments of the conduits, a control aortography was performed in the cadavers and animals. The animals were euthanized. Necropsy on animals and anatomic dissection on cadavers were performed to photograph the implants in situ.

Video 1. Video animation of total endovascular aortic arch repair.

Video 2. Fluoroscopic cine films showing the total reconstruction of the aortic arch obtained from the animal experiments.
Fig. 1. Fenestration through the left carotid artery using the RF plasma catheter. Note that the first conduit was placed through the right carotid artery (cadaver study).

Fig. 2. Final flaring of the conduits through the lumen of the Valiant stent graft by using an occlusion balloon. Arrows indicating the protrusions into the ostia of the branch conduits (animal study).

Fig. 3. The 3D reconstruction of the stent graft and the conduits (animal study); clear vision obtained after cessation of the heart beats.

Fig. 4. Necropsy showing the perfect implantation of the Valiant stent graft in the arch and good fixation of the conduits into the fenestrations (animal study).

Each pig: one to the brachiocephalic trunk and the other one to the left subclavian artery. Deployment of stent grafts was successful in all five animals. The cohort of animals presented ten possible access sites for fenestration and conduit deployment. These procedures were successful via seven access vessels. In two animals, complete arch reconstruction was accomplished (Fig. 2). All prototype fenestration systems were used successfully in the animals. Fluorographic 3D reconstruction of the implants was accomplished before and after sacrificing the animals (Fig. 3).

Necropsy confirmed that secure fixation and sealing of conduits was achieved in all cases (Fig. 4).

3.3. Fenestration and conduit implantation

Regarding the arterial access sites, all attempts to fenestrate the Valiant stent graft and implant the conduit through the carotid arteries were successful in both cadavers and in all animals except one because of the guide wire displacement during the procedure. On the other hand, it was not possible to do the fenestration through the left subclavian artery in both cadavers because of the chronic total occlusion of the artery in the first cadaver and the rigidity of the steerable needle dilation catheter in the second. The left subclavian artery could not be passed in three of the animals due to sharp angulation of the artery.
4. Discussion

Mortality and morbidity associated with aortic arch surgery is still high despite new endovascular and hybrid approaches. Ishimaru classified the aortic arch segments according to the landing zones of the stent grafts with respect to the location of the arch vessels [6]. Hybrid procedures for arch repair without sternotomy most frequently can be performed for Zone 2 or Zone 3 lesions. Usually an extra anatomic bypass or transposition of a branch to another vessel is required. In Zone 1 lesions, the hybrid methods can only be performed with partial or complete sternotomy. Bergeron et al. reported the early results of 25 cases of debranching and stent grafting of the aortic arch aneurysms and chronic dissections [7]. The major adverse event rate, including the early deaths and major strokes, was 12% and the rate of Type I endoleak was 12%. On the other hand, reports of in-hospital mortality of open aortic surgery are around 10% and most reports did not distinguish the total arch repair from the partial or hemiarch resection [8]. Some special techniques were introduced for cerebral circulation during the open surgery of the arch but the mortality and morbidity rates are still high, probably due to the associated surgical trauma [9, 10].

Inoue et al. were the first to introduce a fully endovascular technique for the repair of the aortic arch [4]. They utilized custom-made multi-branched stent grafts which required extensive catheter manipulations, contrast media and fluoroscopy use. This technique has the potential risks of cerebral embolism, and seems to be less applicable in the case of aortic dissection.

An appealing method of modular single-branch stent graft implantation for aortic arch repair described by Chuter et al. represented an intermediate path between the technique of Inoue and hybrid procedures [5]. Nevertheless, this approach requires a very large carotid artery introducer system (up to 24 Fr), supra-aortic bypass procedures, and possibly anastomosis of a vascular prosthetic graft to the innominate artery.

Kazui was one of the pioneers who widely used antegrade cerebral perfusion in open aortic arch surgery, and his concept of perfusing the brain with moderately hypothermic blood helped to prevent the side effects of deep hypothermia [9]. In the technique described in this article, the concept of performing the endovascular repair by using the simplified cerebral perfusion system prevents embolic showers from the aortic arch and allows work through the arch vessels directly in order to complete the arch reconstruction. This method may also facilitate achieving cerebral hypothermia which may attenuate potential neurological damage. In this technique, fewer surgical and endovascular manipulation skills are necessary, and the total procedure time is likely to be about three hours. Anatomical repair is the goal of this procedure and supraaortic anastomosis may be reserved only for cases of stenosis or occlusion of the branch arteries. The puncture devices and conduits described here require introducer sheaths of 8 to 12 Fr which are within the acceptable ranges of clinical use. Prototypes under development include steerable 8 Fr RF plasma electrode catheters capable of creating full-size circular fenestrations with fused edges.

Some of the arch aneurysms and aortic dissection cases which involve the ascending aorta may not have a good fixation zone for the proximal end of the stent graft. It is not possible to utilize this technique in these particular cases, but hybrid use of this endovascular repair may simplify the repair without using the deep hypothermia and total circulatory arrest technique and clamshell incision. Further developments of conduits and of percutaneous aortic valves may also allow us to repair aortic root pathologies via a single endovascular procedure.

This experimental study demonstrated the feasibility of a new endovascular repair technique which promises complete aortic arch reconstruction via retrograde fenestration and conduit implantation while using cerebral circulatory support. Improvement of the stent graft, conduits and the fenestration devices will probably accelerate the development of this technique clinically. Further experimental studies should be considered.

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References

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