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Experimental Evaluation of Endovascular Fenestration Scissors in an Ovine Model of Aortic Dissection

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WHAT THIS PAPER ADDS

This experimental study describes a novel endovascular technique to achieve a controlled endovascular fenestration in an ovine model of acute aortic dissection. Endovascular scissors have been designed and tested *in vivo* to allow an accurate progression of two blades guided over two wires: one in the true lumen and the other in the false lumen. Compared with the previously described long sheath method, endovascular scissors allowed for a safe, controlled, and effective aortic fenestration.

Objective/Background: To evaluate the experimental feasibility of endovascular fenestration using specific endovascular scissor prototypes in an ovine model of acute aortic dissection (AD).

Methods: A previously described endovascular technique was used to create a model of acute type B AD in sheep. Endovascular fenestrations using either endovascular scissor prototypes or a long sheath were compared. Four prototypes of endovascular fenestration scissors were evaluated. Both validity of the experimental model of AD and technical success of endovascular fenestration were assessed by haemodynamic criteria, completion angiography, transesophageal echocardiography, and post-procedural analysis of harvested aortas.

Results: Experimental acute AD was created by endovascular means in 17 sheep, with a technical success rate of 82%. Systolic blood pressure was lower in the false lumen than in the true lumen (58 $\pm$ 5 vs. 79 $\pm$ 3 mmHg, respectively; $p < .001$). Endovascular fenestration was performed in 11 models (endovascular scissors $n = 8$; long sheath $n = 3$). Controlled endovascular fenestration was obtained by the use of endovascular scissors ($n = 5/8$), resulting in a significant rise in false lumen systolic blood pressure after fenestration (60 $\pm$ 2 vs. 67 $\pm$ 9 mmHg before and after fenestration, respectively; $p < .047$). Long sheath fenestration resulted in an uncontrolled flap motion, leading to either pseudo-coarctation syndrome or aortic rupture (58 $\pm$ 6 vs. 40 $\pm$ 2 mmHg before and after fenestration, respectively; $p < .001$).

Conclusion: In this experimental study, a reproducible AD model has been developed in sheep using endovascular procedures exclusively to evaluate endovascular fenestration techniques. Endovascular fenestration using a long sheath appeared hazardous and risky *in vivo*. Endovascular scissors constitute a dedicated and suitable tool to perform a safe controlled and effective endovascular fenestration in an ovine model.

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INTRODUCTION

Malperfusion is a life threatening complication of acute aortic dissection (AD), occurring in up to 30% of AD and associated with a high mortality rate.[1] Malperfusion syndrome usually results from the occurrence of dynamic or static mechanisms.[2] Dynamic malperfusion is directly related to the compression of the true lumen (TL) by the false lumen (FL), leading to collapse of the TL. End organ malperfusion involves serious major adverse events such as stroke, acute kidney injury, acute mesenteric ischaemia, paraplegia, and lower limb ischaemia.[3] Although thoracic endovascular aortic repair (TEVAR) has emerged as the dominant strategy for resolving malperfusion in complicated type B AD,[4,5] fenestration may still have a role in its treatment as an accessible additional tool in the emergency setting. By creating a large communication between the TL and the FL, fenestration relieves the TL from its

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compression by the FL. Initially proposed to treat malperfusion in acute AD, some authors have evolved the fenestration technique in order to create a distal sealing zone for TEVAR in chronic AD.[6–8] Fenestration may also play a role in preventing FL dilatation by providing an outflow and reducing its pressure.[9] Several endovascular fenestration techniques have been reported thus far.[10–16] Among them, endovascular fenestration using a long sheath described by Beregi et al.,[10] and the balloon fenestration technique might be the most commonly used.[15,17] However, just as with open fenestration, endovascular fenestration has some limitations, highlighting the clinical need for a dedicated endovascular fenestration device. In this context, the concept of endovascular fenestration scissors appears attractive in both indications: acute malperfusion and creation of a distal sealing zone in TEVAR.

The aim of this experimental study was to test *in vivo* new and ingenious prototypes of endovascular scissors developed for endovascular fenestration in an ovine model of AD.

METHODS

The study was approved by institutional ethics review committee from the French Ministry of Research and Education, and received authorisation for use of animals for scientific purposes (APAFiS#3102, Amendment 01379.02), following the ARRIVE guidelines.[18]

Creation of an acute AD model in sheep

In this experimental study, an exclusive endovascular model of acute type B AD was created in sheep using a minimally invasive technique previously described in swine by Okuno et al.[19] Sheep seem better suited to the evaluation of human endovascular devices because their aortic diameter (12–14 mm) is greater than that of swine. Briefly, via a femoral approach, an 8 Fr sheath was placed across the aortic bifurcation. A bolus of heparin (100 UI/kg) was administered as required to achieve an activated coagulation time of >200 s. An intimal tear was created by puncturing the aorta at the level of the infrarenal or thoraco-abdominal aorta using a stiffening metallic needle provided in the Transjugular Liver Access Set (Terumo, Somerset, New Jersey, USA). A 0.035 inch guidewire supported by a straight catheter and formed into a loop was subsequently advanced in the dissection space in a retrograde fashion to reach the aortic isthmus. A proximal reentry tear was created by puncturing the intimal flap by the use of an Outback catheter (Cordis, Milpitas, CA, USA). Finally balloon dilatation using a 4 × 20 mm Armada balloon (Abbott Vascular, Abbott Park, IL, USA) was performed to enlarge the FL, as well as the proximal and distal entry tears.

The validity of the model was assessed by haemodynamic and morphological criteria. Haemodynamic evaluation corresponded to the arterial pressure difference between the TL and FL. The systolic arterial blood pressure was measured using two catheters placed simultaneously in both lumens and connected to the anaesthetist arterial line monitor. Measurements were recorded 2 min after creation of the aortic dissection, when the values were stable, and every 3 min thereafter. A 20% variation between TL and FL blood pressure values was considered significant. Morphological evaluation was performed using angiography (Philips Veradius C-arm; Philips Healthcare, Philips Medical Systems, Best, The Netherlands) and transoesophageal echography (Mindray TE7; Mindray, Shenzhen, China). The angiographic validation was assessed by the visualisation of two different aortic lumens after arterial injection of contrast medium at the level of the aortic arch. Transesophageal echographic validation was obtained if two patent lumens were identified within the thoracic aorta. Sheep were administered an intravenous bolus of pentobarbital (75 mg/kg) and sacrificed immediately after the procedure. The entire thoraco-abdominal aorta was harvested. AD was evaluated by macroscopic examination and confirmed by histological examination. Sections of the dissected aortas were sent to the Department of Pathology for analysis. The tissues were fixed in a 4% phosphate buffered formaldehyde solution and embedded in paraffin. Serial 3 µm thickness sections were cut and stained with hematoxylin and eosin. Technical success was defined as the combination of haemodynamic, morphological, and macroscopic criteria, and confirmed by histological examination as the creation of a dissection space within the layers of the media, between the levels chosen as entry and re-entry tears.

Endovascular fenestration scissors: device design

The endovascular fenestration scissors were patented (Brevet APHP #1256751, International Publication WO2014/009554A1). It was first derived from endoscopic scissors. Endovascular scissors were formed by two blades on which two wire gutters were fixed, with a flexible 80 cm shaft and a distal manual handle able to transmit an accurate force feedback and an efficient cutting force.

Design specifications included the following requirements: the ability to progress in a smooth and regular way on 0.035 inch guidewires; a diameter compatible with a 20 Fr sheath; radio-opacity; and the capability of the device to cut a healthy sheep aorta with satisfactory transmission of the cutting force from the scissor handles to the blades. Four prototypes of endovascular fenestration scissors were evaluated in this experimental study. In the first prototype (P1), the wire gutters were added lateral to the blades and fixed by a welding point. In the second prototype (P2), the gutters were fixed along the anterior face of the blades. In the third prototype (P3), blades were shorter than in P1 and P2, and the wire gutters were directly incorporated into the blades. In the fourth prototype (P4), blades were longer than in P1 and P2 (8 mm long), with incorporated wire gutters. *In vitro* tests were performed on healthy sheep aorta samples prior to *in vivo* evaluation.

These prototypes were developed in association with two different industrial partners: Alcis (Besançon, France) for P1, P2, and P3, and Clariance (Beaurains, France) for P4.

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