The endovascular occlusion system for safe and immediate peripheral vessel occlusion during vascular interventions

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Abstract

Endovascular occlusion of blood vessels is an important part of interventional therapy concepts. Here, we evaluate the feasibility, procedural safety and efficacy of the novel endovascular occlusion system (EOS) in the arterial system in a porcine model. Thirteen devices were deployed in the iliac and femoral arteries (diameter: 4–5 mm) of five adult swine. Post-deployment angiography was performed at 1, 5 and 10 min and 6 h. All devices (n = 13) could be successfully delivered without any complications, such as dissection, perforation or rupture. The devices could be easily advanced to the target vessel segment, deployed at the intended target location and produced immediate and complete vessel occlusion which was confirmed to be maintained after 6 h. No leaks, recanalization or device migration was observed. In this pilot study, we demonstrate the feasibility, safety and efficacy of immediate vessel occlusion with the EOS device in the peripheral arterial system in a porcine animal model. Our data indicate that this novel device allows precise delivery without the occurrence of cardiovascular complications. Owing to its long-term safety and efficacy the EOS may represent a promising and effective alternative to currently available devices for vessel occlusion during vascular interventions.

Keywords: Vessel occlusion • Endovascular • Occlusion device • Embolization

INTRODUCTION

Endovascular occlusion of blood vessels is an essential aspect of interventional vascular therapy concepts [1–3]. However, immediate and durable vessel occlusion remains a challenge when using the currently available devices and may often necessitate use of a large number of devices as well as long interventional procedures with high radiation exposure. In the present study, we assess a novel endoluminal occlusion system (EOS) for transcatheter vessel occlusion in the peripheral arterial system and demonstrate technical feasibility and procedural safety in a porcine model.

MATERIALS AND METHODS

Device description

The EOS (ArtVentive Medical Group, Inc., Carlsbad, CA, USA) device allows percutaneous occlusion of the peripheral arterial and venous vasculature. The EOS system is comprised of an implant carrier catheter with a preloaded self-expandable implant and a guide sheath with a removable core (Fig. 1A–E). The EOS implant is made of a Nitinol scaffold covered with an impermeable expanded Polytetrafluorethylene membrane, which is composed to maintain complete impermeability in order to occlude blood flow reliably, precisely and immediately. The scaffold design is based on a flat helical structure. The EOS implant is available in two sizes: 6 mm for treatment of vessels between 3.0 and 4.8 mm in diameter, and 9 mm for treatment of vessels between 4.5 and 7.8 mm in diameter, with a calculated oversizing of at least 15%. It generates sufficient radial force to provide good vessel wall apposition and to minimize post-deployment migration (Fig. 1A–E). The device design generates low local pressure that lowers the risk of vessel damage and rupture. The device is self-expandable and highly flexible per design. It is also highly adaptable to the vessel geometry. Therefore, it actually adopts the vessel configuration as every segment of the device along its length takes shape of target vessel. The device maximum length as deployed is <20 mm. The delivery mechanism and the steps of delivery are summarized in Fig. 1B–E. The device is delivered via a 6-Fr guide sheath. The guide sheath is advanced using a 0.035 guide wire.

Animal study

To assess the acute safety and technical feasibility of the EOS, 13 devices (11 × 6 mm and 2 × 9 mm) were tested in the preclinical
setting and deployed in the iliac and femoral arteries of five adult female Landrace swine (67 ± 3 kg).

Animal care and anaesthesia

All procedures were approved by the Institutional Ethics Committee (Cantonal Veterinary Office, license no. 138/2010), and all animals received humane care in compliance with the ‘Principles of Laboratory Animal Care’ and according to the ‘Guide to the Care and Use of Experimental Animals’ published by the US National Institutes of Health. The adult swine (n = 5) were fasted overnight prior to the procedure. Anaesthesia induction was performed with an intramuscular injection of ketamine (20 mg/kg), azaperone (2 mg/kg) and atropine (0.04 mg/kg). Anaesthesia was deepened with bolus injection of propofol (1–3 mg/kg) intravenously, and the animals were then intubated. Anaesthesia was maintained with inhaled isoflurane (1–3%) in 50% oxygen. For intraoperative analgesia, buprenorphine (Temgesic; 0.005 mg/kg) was used.

Device delivery and vessel occlusion

Prior to the procedures, the animals were placed in the supine position, and an 8-Fr sheath surgically introduced into each of the common arteries. All procedures were carried out in an animal hybrid operation suite using a Philips Allura FD 20/20 Imaging System. Predeployment angiography with three-dimensional (3D) vessel reconstruction analysis was performed to define the target vessel and to define the optimal size of the EOS device. A corresponding post-deployment angiogram was performed directly after the procedure (at 1, 5 and 10 min) as well as 6 h later to assess the acute safety and efficacy of the EOS device. Under fluoroscopic guidance, the ArtVentive guide catheter was introduced through the sheath and advanced into the target vessel segment of the left or right iliac or femoral arteries. Thereafter, predeployment angiography along with 3D reconstruction and subtraction analysis was performed to assess the vasculature and to determine the vessel diameter. In total, 13 devices were used, with nominal diameters of 6 mm (n = 11) or 9 mm (n = 2). In addition, a roadmap image was acquired and used throughout device delivery and deployment. To deploy the EOS, the device was introduced into the delivery catheter, and advanced to its tip. The catheter was then withdrawn, leaving the device unsheathed but still undeployed, at the target vessel segment. Finally, the EOS device was deployed and detached utilizing a controlled, two-step release mechanism (with the proximal end opening prior to the distal end).

RESULTS

All EOS devices (n = 13) were successfully delivered into the intended segments of the left and right iliac arteries of the animals.
DISCUSSION

Endovascular vessel occlusion represents an important aspect of interventional therapy strategies for a wide range of vascular and non-vascular conditions [1–3]. However, the currently available strategies have been reported to come with a limited efficacy with regard to a complete and durable vessel occlusion. While coils have been commonly used for vessel occlusion, a large number of these devices may be necessary to achieve complete occlusion and to minimize the risk of recanalization. To overcome these limitations, new devices have been developed [4–6]; however, some of these devices require large delivery sheaths and catheters [7], have complicated delivery systems and do not always achieve a fast and durable vessel occlusion [8–10].

Here, we introduce a novel endoluminal occlusion system for transcatheter vessel occlusion. Our results demonstrate the feasibility and safety of immediate vessel occlusion in the arterial system with the EOS device in an acute porcine model. Our data indicate that this novel device allows precise delivery and deployment at the intended location site without the occurrence of cardiovascular complications, such as dissection, perforation or rupture. Due to its simple and efficient design, the EOS device technology is multifaceted and thus may have other indications in the venous and arterial system of different body regions. While this was a pilot study focusing on technical feasibility, procedural safety and acute efficacy, long-term data and comparative studies of other devices are necessary. Its long-term safety and efficacy proven, the EOS may represent a promising and effective alternative to currently available devices for vessel occlusion during vascular interventions.

SUPPLEMENTARY MATERIAL

Supplementary material is available at ICVTS online.

FUNDING

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Conflict of interest: Anthony Venbrux, Martin G. Radvany and Andre Plass are members of ArtVentive SAB. Leon rudakov and Philippe Gailloud are founders of ArtVentive.

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