LABORATORY INVESTIGATIONS

A New Rotational Thrombectomy Catheter: System Design and First Clinical Experiences

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Abstract

Purpose: To describe a new catheter for the percutaneous mechanical removal of fresh and organized thrombi, and to assess its efficacy and safety in vitro and in vivo.

Methods: The catheter consists of a coated stainless steel spiral that rotates at 40,000 rpm over a guidewire inside the whole length of an 8 Fr, single-lumen, polyurethane catheter, driving a dual-blade cutting crown. Abraded occlusion material is sucked into the catheter head through distal side holes and transported by the spiral into a reservoir at the proximal end. The efficacy of the device was tested in arterial models and fresh bovine carotid arteries (n = 72). In a clinical pilot study 10 patients (8 women, 2 men; mean age 70.6 ± 10.1 years) with occlusions of the superficial femoral artery (2–12 cm, mean 5.8 cm), not older than 4 weeks, underwent thrombectomy with the new catheter.

Results: In arterial models and bovine cadaver arteries the catheter completely removed fresh thrombi. Occlusion material of higher consistency was cut into particles of 100–500 µm and transported outside. Thrombectomy was successful and vessel patency restored in all 10 patients. The ankle/brachial pressure index significantly (p < 0.0005) increased from 0.41 ± 0.18 before intervention to 0.88 ± 0.15 after 48 hr and to 0.84 ± 0.20 after 3 months. Two recurrences occurred within 14 days after the intervention.

Conclusion: Thrombectomy with the new device appears to be feasible and safe in patients with acute and subacute occlusions of the femoropopliteal artery.

Key words: Thrombectomy—Catheter—Thrombosis—Femoropopliteal artery

The drawbacks of conventional nonsurgical treatment of thrombotic arterial occlusions, such as long procedure time, bleeding, vessel wall injury and peripheral embolization, have stimulated the development of devices for mechanical removal of thrombi in the last decade [1–3]. Several systems have entered clinical practice, while others were described as prototypes. Each device has its own limitations, including restriction to fresh thrombi only, incomplete clot removal, vessel wall damage, or design complexity. The ideal instrument should be wire-guided to avoid vessel perforation, remove fresh and organized thrombi, and transport them to the outside without risk of peripheral embolization. With this aim in view a rotational catheter was constructed and is described here for the first time.

Materials and Methods

The system has three components: the Rotarex catheter (Straub Rotarex, patent pending, Straub Medical, Wangs, Switzerland), a 40 W DC electric motor drive, and an electronic control unit (Fig. 1A). Inside the whole length of the 8 Fr polyurethane catheter rotates a coated stainless steel spiral, which slides over a 0.020-inch guidewire (Schneider Europe, Bülach, Switzerland). The catheter head consists of two cylinders that fit over each other (Fig. 1B, C). The outer rotating cylinder is fixed to the spiral, the inner one is attached to the catheter shaft. Each cylinder has two oval slits. The blunt tip of the outer cylinder is perforated for the guidewire. Catheter and motor drive are connected by a magnetic clutch. The motor rotates the spiral at 40,000 rpm, resulting in 80,000 cuts/min. The high frequency of revolution creates a negative pressure at the catheter head of 5.8 kPa (=43.5 mmHg). When the catheter is activated, soft and solid occlusion material is caught in the slits, transported by the spiral to the proximal sideport, and discharged into a plastic bag. No additional suction is required. The transport of the occlusion material is done exclusively by the rotating spiral. The catheter is for one-time use, while the motor drive and the connecting cable to the electronic control unit can be sterilized.
Preclinical Studies

The catheter was tested in an arterial model made of silicon tubing and in fresh bovine carotid arteries. Translucent silicon tubing of 4, 6, and 8-mm inner diameter and length 15–30 cm served as an arterial model, allowing the observation and the video documentation of the catheter function. The tubes were bendable to test the behavior of the catheter at various angles. The tubing was filled with occlusion material of different consistencies: (a) bovine blood that was allowed to coagulate for 48 hr or 2 weeks and stored at 4°C; (b) stamp cylinders of “black pudding”, a mixture of thrombus, muscle, fat, and connective tissue, 4, 6, and 8 mm thick, and 15 cm long, simulating organized thrombus; (c) strips of bovine arteries (3 cm long, 1 mm broad) sutured intraluminally to the vessel wall, imitating intimal flaps. The tubing was clamped at one end and connected to an infusion line on the other, where a mixture of saline and glycerine could be infused under a continuous pressure of 120 mmHg. In this infusion tube an 8 Fr sheath (Cook, Bjaerverskov, Denmark) was introduced, a 0.020-inch Teflon coated guidewire threaded through the occlusion material, and the catheter advanced.

In a second test series (n = 72) the silicon tubing was replaced by fresh bovine carotid arteries with an average length of 20 cm and a diameter of 6–7 mm. The side branches were ligated and the arteries filled with the above-mentioned occlusion material. During catheter activation tubes and arteries were either kept straight or bent in different angles up to 50°. Occlusion of the arteries was achieved by tightening a 5-mm-wide rubber band around the vessel, completely interrupting the flow of perfusate. The occlusion was passed with the catheter over the wire. All tests were recorded on video. The time of catheter activation was recorded, the volume of the aspirated fluid measured, and the fluid passed through different filters for analysis of particle size. The arteries were cut open and examined visually and histologically for remnants of occlusion material and possible intimal damage.

Clinical Studies

Based on the results of the preclinical tests the institutional review board of the Department of Internal Medicine, University Hospital Basel, accepted the protocol of a pilot study for the evaluation of the device for the treatment of thrombotic occlusions in femoropopliteal arteries in humans. Ten patients (8 women, 2 men; age 58–87 years, mean 70.6 ± 10.1 years) with acute or subacute occlusion of the femoropopliteal artery with an estimated age of less than 4 weeks and patent proximal segments of lower leg vessels, were included in the study. All patients were informed in detail about the procedure and gave their written consent. Patients with aneurysms of the popliteal artery, severe coagulation disturbances or a history of adverse reactions to contrast media were excluded.

Seven patients suffered from critical ischemia (rest pain) and three from peripheral arterial occlusive disease (PAOD) stage II (intermittent claudication). The estimated age of the lesions was between 2 and 28 days. The mean length of the occluded segments was 5.8 cm (range 2–15 cm). The diagnosis was established by clinical examination, oscillography, Doppler pressure recordings,