

Practical Uses of Cryoplasty

A look at some of the effective applications of this nonsurgical treatment option.

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Cryoplasty is a unique nonsurgical therapy for the treatment of peripheral arterial disease that combines the application of mechanical balloon dilation and cryotherapy in a stenosed artery. Cryotherapy is a time-tested therapy that has demonstrated great efficacy in causing apoptosis of cells that tend to proliferate readily. Balloon dilation of a stenosed artery has been shown time and again both in the coronary and peripheral arterial system to be an effective treatment of arterial stenoses. Cryoplasty is the only treatment option that uses these two modalities together in treating a stenosis.

CRYOPLASTY DEVICE AND ITS MECHANISM OF ACTION

Cryoplasty uses nitrous oxide as the dilation medium, unlike saline/contrast in conventional angioplasty. Nitrous oxide, being a gaseous medium, is easily soluble

and can cool the vessel wall up to -100°C while simultaneously dilating the vessel lumen. Besides inducing apoptosis of the smooth muscle cells in the vessel wall, it also causes plaque modification and reduces elastic recoil of the vessels by altering elastin fibers in the wall.

The PolarCath peripheral dilatation system (Boston Scientific Corporation, Natick, MA) is a coaxial, dual-balloon design and is made of Pebax (polyether block amide) material (Arkema, Colombes, France) (Figure 1). The interspace between two balloon layers has a textile fabric to ensure accurate delivery of the desired temperature to the vessel wall. Radiopaque markers enhance the visibility of the balloon under fluoroscopy during the procedure. A microprocessor-controlled cryoplasty unit integrates the cryoplasty balloon and nitrous oxide cylinder and regulates controlled release of nitrous oxide to achieve desired balloon dilation and cooling simultaneously (Figure 2). The liquid nitrous oxide expands into

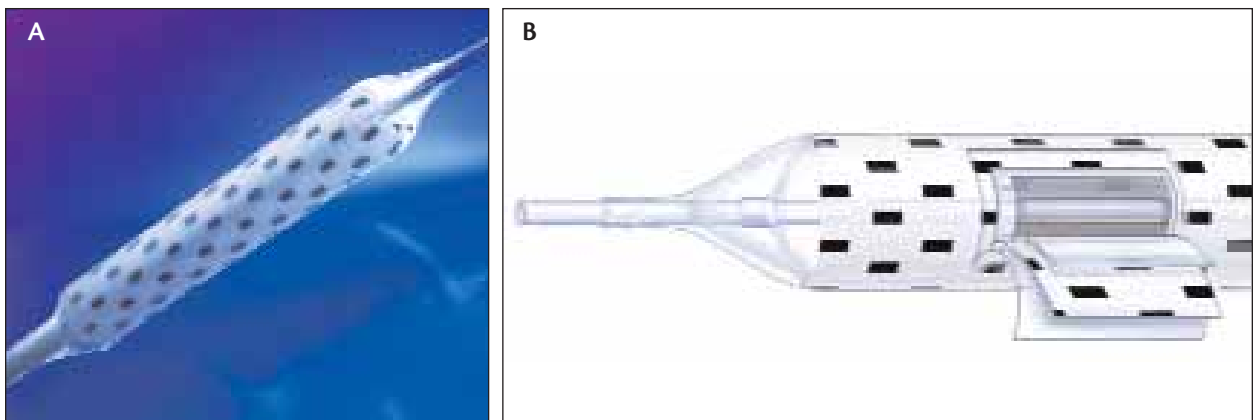


Figure 1. The PolarCath peripheral dilatation system (A). The balloon catheter is a coaxial, dual-balloon design made of Pebax Material (B). Gas is contained in the inner balloon, enhancing procedural safety. Radiopaque markings enhance the visibility of the balloon under fluoroscopy during the procedure.



Figure 2. The PolarCath inflation unit. The inflation unit contains a microprocessor to automatically control and monitor the procedure to reduce operator error. The vessel is exposed to the cold treatment for a precise amount of time to help ensure patient safety and help prevent operator error.

gas, and the temperature of the surface of the balloon cools to -10°C . Balloon inflation is preset at 8 atmospheres, 25 seconds, with a 10-second warming phase. The total treatment time is <1 minute, and if needed, multiple inflations can be done to treat long and resistant lesions.

CLINICAL DATA AND REVIEW OF CURRENT LITERATURE

The first-in-man study of cryoplasty by Fava and colleagues enrolled 15 patients with long lesions of 6.5 ± 3.2 cm; one third of these patients had chronic total occlusions.¹ An initial technical success rate of 93% and an angiographic patency rate of 83% during 14 ± 4 months of follow-up were quite promising for the PolarCath. This study was soon followed by a prospective, multicenter registry of 102 patients² that studied lesions 4.7 ± 2.6 cm in length, and nearly 20% of the lesions had chronic total occlusions. The procedural success rate was 94%, with a clinical patency rate of 82% at 9 months—a benefit that persisted even over a long term, with a patency rate of 75% at 3 years.³ Cryoplasty thus afforded a new modality in the armamentarium of endovascular interventionists.

Encouraged by these initial studies, McNamara et al led a prospective, multicenter study⁴ involving 111 patients with critical limb ischemia. Their procedural success rate was an amazing 97%, with an equally exciting outcome

showing a limb salvage rate of 94% at 5-month follow-up.

CLINICAL USE OF CRYOPLASTY

Cryoplasty is indicated in the treatment of stenosis involving peripheral vasculature (iliac, femoral, popliteal, infrapopliteal, renal, and subclavian arteries) and for the treatment of obstructive lesions of polytetrafluoroethylene-access grafts or native arteriovenous dialysis fistulae. It may also be used for postdeployed stent expansion of self-expanding peripheral vascular stents. Lesions of iliac artery bifurcation in which the internal iliac artery may need to be preserved offer a great option for cryoplasty. Similarly, lesions of the common femoral or profundafemoral bifurcations are also very attractive for cryoplasty because stenting of these lesions can yield suboptimal results and is therefore not readily performed. Critical limb ischemia and limb salvage cases are probably the most promising lesion subsets for cryoplasty because the outcome data for these really complicated patients are very

encouraging. We describe the unique role of cryoplasty in the superficial femoral artery (SFA), the popliteal artery, and the peroneal artery in the following three cases.

Case 1

A 70-year-old woman with a history of hypertension, anemia, and peripheral arterial disease, with stenting of the right SFA presented with a nonhealing ulcer of the right foot. The baseline ankle-brachial index (ABI) was 0.4. A diagnostic angiogram showed severe 90% SFA disease with in-stent restenosis, severe popliteal artery disease, and only anterior tibial runoff with 50% proximal disease. The SFA was crossed with a .035-inch stiff straight wire and exchanged for a .014-inch wire. Cryoplasty of the SFA was performed with a 5- X 100-mm balloon. The 90% severe baseline SFA lesion was reduced to a $<30\%$ lesion with no residual flow-limiting dissection. The popliteal artery was also treated with cryoplasty. The anterior tibial artery was treated with balloon angioplasty.

Case 2

A 69-year-old woman with hypertension, diabetes mellitus, hypercholesterolemia, and obesity presented with osteomyelitis of the left toe. Amputation was scheduled, and the baseline ABI was 0.82 in the left leg. Left lower extremity angiography was performed to evaluate the arterial anatomy and treat the stenosis to assist in wound

ADVANTAGES AND DISADVANTAGES OF CRYOPLASTY

Advantages	Disadvantages
Controlled, reduced mechanical injury and medial dissection	Additional time to set up the equipment
Stand alone balloon angioplasty and less stenting	Cryoballoon may not be able to cross severely calcified lesions
Less restenosis	Short inflation times
Superior patency rates	Pain experienced by patients during cooling and rewarming

healing. No preoperative duplex was performed. Angiography showed 70% eccentric popliteal artery disease. The lesion was crossed with a .018-inch wire and a 5- X 40-mm cryoballoon, followed by a 6- X 40-mm cryoballoon, and cryoplasty was performed. The 70% lesion was reduced to <30% residual lesion with no flow limitations.

Case 3

A 79-year-old man with hypertension, diabetes mellitus, hypercholesterolemia, renal artery stenosis, and peripheral arterial disease presented with left leg rest pain. The ABI in the left leg was noted to be 0.41. Baseline angiography showed severe 80% SFA disease, popliteal disease, and single-vessel runoff via the peroneal artery, with short-segment proximal occlusive disease. The lesions were crossed with a .018-inch wire and exchanged for a .014-inch wire. Cryoplasty of the peroneal artery was performed with 2.5- X 60-mm balloon followed by a 3- X 60-mm balloon. The short total occlusive lesion in the peroneal artery was reduced to <30%. The SFA and popliteal artery were treated with a 5-X 100-mm cryoballoon. The 80% lesion was reduced to a <30% residual lesion with no flow limitations.

PRECAUTIONS AND LIMITATIONS OF CRYOPLASTY

A thorough understanding of the PolarCath dilatation system should be obtained before using this device. The proximal end of the PolarCath or PolarCath inflation unit should not be submerged in water or saline. The catheter should not be moved while the warming light is illuminated. A balloon-artery ratio of 1:1 should be used for the PolarCath system. Although focal treatment is the basis of a conventional angioplasty balloon system, PolarCath caters to diffuse, longer lesions. Cryoplasty adds significant expense to a procedure.

FUTURE ROLE OF CRYOPLASTY IN ENDOVASCULAR INTERVENTIONS

Cryoplasty offers a promising outlook in the management of peripheral arterial disease in the contemporary

era of aggressive endovascular interventions. Prolonged inflation times and lower crossing profile are the modifications that are underway. Adjuvant stenting or debulking with cryoplasty may further reduce restenosis.

SUMMARY

Cryoplasty is simple to use and is useful for treatment of various lesion subsets, including patients with long segments of stenosis, lesions in the "no-stent" zones, and also critical limb ischemia from infrapopliteal disease with acceptable initial procedural success. ■

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