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Australia and New Zealand Horizon Scanning Network

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Horizon Scanning Technology Prioritising Summary

Cryotherapy for peripheral arterial disease

September 2006
(Updated October 2007)



ASERNIP(S)

**Australian
Safety
and Efficacy
Register
of New
Interventional
Procedures -
Surgical**



**Royal Australasian
College of Surgeons**



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Name of Technology:

Cryoplasty utilising the PolarCath™ peripheral dilation system (Cryovascular Systems Inc., California, USA).

Purpose and Target Group:

The PolarCath peripheral dilation system is indicated to dilate stenosis within the peripheral vasculature (iliac, femoral, popliteal, infrapopliteal and renal arteries).

Stage of Development (in Australia):

- Experimental
- Investigational
- Nearly established
- Established
- Established but changed indication or modification of technique
- Should be taken out of use
- Not yet emerged

The PolarCath peripheral dilation system is not available in Australia, and hence is not listed or registered in the Australian Register of Therapeutic Goods database.

International Utilisation:

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely diffused
United States		✓	
Europe		✓	

Impact Summary:

Background

Peripheral arterial disease (also known as peripheral vascular disease) refers to the blockage of arteries outside the heart and brain due to atherosclerosis. The atheroma (or lesion) consists of a core of cholesterol joined to proteins with a fibrous intravascular covering. This process can eventually lead to complete occlusion or medium and large arteries (Singh and Cousin 2005).

To date, percutaneous transluminal angioplasty (PTA) is the preferred minimally invasive method of treating infrainguinal arterial disease. Despite the advances in angioplasty, this technique continues to be limited by significant degrees of localized dissection, vascular recoil, and suboptimal long-term patency. Studies have revealed that 30% to 80% of peripheral arterial disease cases will suffer from restenosis following PTA. Reported 5-year success rates following iliac angioplasty for stenosis is 53.4%, while for femoropopliteal



disease, the 1-month patency rate is 88.8% falling to 35.7% six years after treatment (Karthik *et al.* 2006). A recent metaanalysis provides further confirmation on the inadequate patency rates achieved with femoropopliteal angioplasty, where the 1-year patency rate among multiple lesion subsets was a mere 59% (Kandarpa *et al.* 2001).

Restenosis occurs as a result of elastic recoil, neointimal hyperplasia, vessel remodeling, dissection of the treated vessel, residual atherosclerotic burden at the site of intervention, and progression of atherosclerosis. Neointimal hyperplasia in particular plays an important role in the occurrence of restenosis; it is caused by platelet activation at the site of arterial injury followed by migration and proliferation of smooth muscle cells (Karthik *et al.* 2006). It is due to aggressive neointimal proliferation rates that stent implantation of femoropopliteal arteries have done very little to extend the patency of endovascular interventions, therefore limiting their use to 'bail-out' or last-resort indication (Laird *et al.* 2005). In an effort to decrease the rate of restenosis following revascularisation, Kataoka *et al.* (2002) proposed the use of controlled freezing, otherwise known as cryotherapy.

On the surface, cryotherapy appears to be very similar to conventional angioplasty. However, the key difference is that cryotherapy is performed using nitrous oxide as a dilation medium for the balloon as opposed to a saline and contrast mixture. The nitrous oxide utilized in this technique is not released into the arterial compartment; instead it is harnessed to cool the interface between the delivery balloon and the vessel wall to -10 °C. This abrupt drop in temperature induces apoptosis in the cells that are typically believed to contribute to the process of restenosis. Cell death or apoptosis is triggered by the freezing process which forms intracellular ice, forcing water out of the cell and causing the internal environment to become substantially hypertonic. In addition to this, the compliance differences between the plaque and vessel wall are mitigated due to the freezing process, therefore allowing the lesion to release in a more benign fashion and with lower risks of deep vessel wall tears (Joye 2005).

The system designed specifically for cryotherapy is the PolarCath peripheral dilatation system. The PolarCath balloon is outwardly similar to a conventional balloon, but in actual fact is comprised of two balloons in parallel. The space between the two balloons houses a textile fabric which acts as an insulator to deliver the desired temperature more accurately. The dual balloon configuration also acts as a safety feature, a vacuum is created between the balloons due to expansion; any loss of vacuum would therefore be interpreted as balloon rupture, resulting in immediate automatic shutdown of the system. The inflation procedure is automated and regulated by a cryoinflation unit, a microprocessor controlled device that integrates the PolarCath balloon and the nitrous oxide cylinder (a disposable 14g cartridge) (Joye 2005).

Clinical Need and Burden of Disease

In 2004 to 2005, there were 25,682 hospitalisations where peripheral vascular disease was the principal diagnosis (0.4% of all hospitalisations) in Australia. Of the hospitalisations for



cardiovascular disease, peripheral vascular disease accounted for 6%. Atherosclerosis of the peripheral arteries accounted for 63% of the hospitalisations (16,046) (AIHW 2006).

Estimated Speed, Geographic and Practitioner Use, Patterns of Diffusion in the Health System

The PolarCath peripheral dilation system received 510k approval from the FDA for marketing purposes in 2002. In Europe, the system was cleared for marketing in 2002 (Cryovascular Systems Inc. 2006).

Revascularisation with angioplasty is the current gold standard minimally invasive treatment for peripheral arterial disease. If cryoplasty is proven to be safe and substantially more effective compared to conventional angioplasty, it is likely to be adopted rapidly into the Australian healthcare system.

Existing Comparators

- Conventional percutaneous transluminal angioplasty
- Combination of transluminal angioplasty and stent placement
- Atherectomy catheters
- Laser assisted angioplasty

Estimated Cost Impact

Cryoplasty is substantially more expensive compared to conventional angioplasty. A standard PTA catheter costs approximately £50, while the PolarCath costs £300 and the inflation cooling unit costs £200. Furthermore, cryoplasty requires the use of an 8 Fr puncture instead of a 4 to 6 Fr puncture used in conventional angioplasty, further increasing its cost (Karthik *et al.* 2006). The large increase in cost compared to conventional angioplasty has to be justified if cryoplasty is to be adopted into the Australian healthcare system. The Medicare Benefits Schedule reimbursement fees for procedures related to peripheral arterial disease treatments are listed in Table 1:



Table 1 Medical Benefits Schedule of fees for procedures related to peripheral arterial disease (Medicare Australia 2006)

Category	Item Number	Benefit (AUD)	Number of Claims (July 2005 to June 2006)
Transluminal balloon angioplasty of 1-peripheral artery or vein of 1 limb, percutaneous or by open exposure. Excluding associated radiological services or preparation, and excluding aftercare.	35300	\$446.10	2120
Transluminal balloon angioplasty of aortic arch branches, aortic visceral branches, or more than 1 peripheral artery or vein of 1 limb, percutaneous or by open exposure. Excluding associated radiological services or preparation, and excluding aftercare.	35303	\$571.90	2208
Peripheral laser angioplasty including associated balloon dilatation of 1 limb, percutaneous or by open exposure. Excluding associated radiological services or preparation, and excluding aftercare.	35315	\$747.80	5

Efficacy and Safety Issues

List of Studies Found

Total number of studies	5
Case series studies	5

The studies included in this summary are highlighted in bold in the reference list.

Safety and efficacy data from all five case series studies have been selected for inclusion in this summary.

Safety

The large multicentre trial by Laird *et al.* (2005) (n = 102) reported 2 cases (2%) of patient death which occurred during the course of the trial, one death was caused by squamous cell lung carcinoma while the other suffered from multiple-organ failure with pneumonia, both were deemed by the authors to be unrelated to cryotherapy. Over the course of this 9 month study, two other patients (2%) required prolonged hospitalisation for hypothyroidism and hyperthyroidism respectively. Seven patients (6.8%) experienced minor vascular access complication whilst five patients (4.9%) required target vessel revascularisation at sites different from the target lesion treated with cryoplasty. Endovascular procedures were conducted in 11 patients (10.8%) in vessels remote from the cryoplasty-treated vessels and seven patients (6.9%) underwent coronary revascularisation. Dissection grades of C or



greater (in accordance to the National Heart, Lung and Blood Institute scale for dissection) rates were noted in 6.9% of patients. Extended follow up data (Laird *et al.* 2006) reported 4 patient deaths from the same patient cohort in Laird *et al.* (2005); it is unclear if these patient deaths were in addition or inclusive of the initial 2 patient deaths reported in Laird *et al.* (2005). Once again, all deaths were deemed to be distinct to cryotherapy treatment (Laird *et al.* 2006).

Vascular complications (guidewire dissection and PTA-induced dissection of a tandem lesion) at sites remote to the cryoplasty treatment site were reported in two patients (13.3%) in the study by Fava *et al.* (2002). Meanwhile, one patient (Cryotherapy failed in this patient) from the case series by Karthik *et al.* (2006) suffered from pain at a remote site which is suspected to be neurogenic in origin.

Efficacy

Laird *et al.* (2005) recruited 102 patients (61 men, 41 women) in a FDA-approved multicentre trial to determine the safety and efficacy of cryoplasty in the treatment of *de novo* or restenotic lesions of the superficial femoral artery or popliteal artery that were amenable to endovascular intervention. Complete clinical data up to final follow-up at 9 months post-treatment were available from 90 patients. The overall technical success rate, defined as the ability to cross and dilate the target lesion with no greater than 30% residual angiographic stenosis and less than 50% residual narrowing by arterial duplex imaging (performed no greater than 7 days post-cryoplasty), was 85.3%. Whereas the procedural success rate, defined as technical success rates plus results after adjunct/‘bail-out’ stenting, was 94.1% (bail-out stent* rate of 8.8%, 9 patients). Following successful cryoplasty, the residual percent diameter stenosis, $11 \pm 11\%$, was significantly less compared to baseline, $87 \pm 10\%$ ($p < 0.05$). Improvement of blood flow was quantified utilising the resting ankle-brachial index (ABI), with significant improvement from 0.72 ± 0.17 (baseline) to 0.88 ± 0.17 at 3 months post-cryotherapy ($p < 0.05$). ABI remained consistent (0.88 ± 0.16) at the 9 month final assessment ($p < 0.05$ vs baseline). With respect to claudication, patient-based subjective improvement was reported in 75% of patients at 3 month post-cryotherapy and 89% of patients 9 months post-cryotherapy. Clinical patency rate[†] was 82.2%, as 16/90 patients which completed the follow-up required repeat revascularisation during the study period. Meanwhile, primary patency rate[‡] was 70.1%, as 23 patients had systolic velocity ratios (SVR) greater than 2.0 (indicating narrowing of the artery possibly due to restenosis).

In a subset of diabetic patients ($n = 32$), Laird *et al.* (2005) reported similar technical and procedural success rate to non-diabetic patients (84.4% and 96.9% respectively). At the final mid-term follow-up examination (9 months), 89% of diabetic patients reported

* Refers to patients requiring the insertion of a stent due to inadequate cryoplasty.

† Defined as freedom from target lesion revascularisation within the study period (in this case 9 months)

‡ Determined by duplex ultrasound examination; a method of measuring blood flow.



improvement of claudication while 80% experienced sustained ABI improvement. The overall primary patency rate at 9 months for this subset was 88.9%. In another patient subset, consisting of 15 patients which had complete occlusion of the target vessel, technical success and procedural success was 67% and 100% (includes 5 patients who required bail-out stenting) respectively. Subjective improvement of claudication was reported in all patients of this subset while 89% achieved sustained ABI improvement. The primary clinical patency rate at 9 months was 92.3% in these patients (Laird *et al.* 2005). The results for both subsets indicates that cryoplasty appears to be effective in patients which have underlying characteristics (diabetes and occlusion of target vessel) that are considered to be 'difficult' compared to other patients.

Extended follow-up results (> 2 years post-cryoplasty) for 70 patients from the same cohort discussed above (Laird *et al.* 2005) were recently published by Laird *et al.* (2006). Post-treatment residual stenosis was similar to those in the initial patient group, with mean \pm SD of $10.7\% \pm 10.4\%$ (range from 65% to 100%). A total of 5 patients (7.1%) required stenting. Overall procedural success rate was 92.9% and the stand-alone technical success rate was 85.7%. Clinical patency rate (determined as freedom from target lesion revascularisation) for this cohort was 83.2% (utilising the Kaplan-Maier method) after the original follow-up of > 9 months (300 days) and 75% after 3.4 years (1253 days). However, this extended follow-up study lacked duplex ultrasound evaluations that were used in the original study, therefore clinical patency (freedom from target lesion revascularisation) had to be utilised as the end-point measurement for the procedural success (Laird *et al.* 2006).

The case series (abstract only) by Kasper and Clark (2006) reported similar results to Laird and colleagues when cryoplasty was used to treat primary stenotic lesions in the lower extremities of 71 patients (81 lesions). ABI improved from 0.55 ± 0.18 to 0.78 ± 0.23 at follow-up (mean follow up = 10.8 months). Primary and secondary patency rates were 85% (69/81) and 89% (72/81) respectively, however details on how these results were quantified was not presented in the abstract. As the methodology was not adequately presented; therefore the connotation of the reported 'primary' and 'secondary' patency rates could not be elucidated. A total of 10 stents were implanted following vascular recoil ($n = 4$, 5%) and flow limiting dissections ($n = 6$, 7%). The authors reported an additional stent placement during follow-up (no details were reported), with restenosis occurring in 15 sites (18% restenosis) (Kasper and Clark, 2006).

When cryoplasty was utilised to treat restenosis of the ilio-femoral artery in 10 patients (12 cryoplasty procedures) initially treated with conventional endovascular methods (Karthik *et al.* 2006), technical success, defined in this study as < 30% residual stenosis and/or less than grade C dissection, was achieved in all patients. However, patency results were a stark difference compared to the study by Laird and colleagues (Laird *et al.* 2005, Laird *et al.*



2006), with all 10 patients developing restenosis during follow-up at a mean duration of 6.2 months (range of 1 to 12 months) after initial cryoplasty. Seven patients (70%) suffered recurrence of short distance, lifestyle-limiting claudication and significant restenosis (determined by Doppler ultrasound). Of these patients, six were referred for further intervention while the seventh patient achieved improvement with lifestyle modifications. Two other patients (20%) underwent repeat cryoplasty within 6 months on initial cryoplasty; however symptoms resurfaced again thus necessitating conventional angioplasty at 8 and 10 months after the second cryoplasty procedure. Overall, cryoplasty failed to prevent restenosis in this select group of patients with recurrent neointimal hyperplasia. Table 2 summarises the patient outcomes in this study after the first cryoplasty procedure:

Table 2: Patient outcomes after initial cryoplasty (Karthik *et al.* 2006)

	Duration of freedom from restenosis (months)	Return of symptoms	Reintervention
Patient 1	12	Yes	Brachytherapy
Patient 2	5	Yes	2 nd cryoplasty failed; cutting PTA
Patient 3	7	No	No; on follow-up
Patient 4	3	Yes	No; on follow-up
Patient 5	12	Yes	Awaiting redo surgery
Patient 6	6	Yes	2 nd Cryoplasty failed, Re-PTA
Patient 7	6	Yes	Re-PTA
Patient 8	1	Yes	Re-PTA cutting
Patient 9	6	Neurogenic pain?	Neurology referral
Patient 10	4	No	No; on follow-up

*PTA – Percutaneous transluminal angioplasty

In the clinical study conducted by Fava *et al.* (2002) involving 15 patients (60% had diabetes mellitus, 60% were nicotine dependant) with femoropopliteal stenosis, the use of a prototype PolarCath resulted in a 93% technical success rate. The one patient (7%) which had unsuccessful cryoplasty was left with 50% residual stenosis and grade C dissection. Three patients were excluded from the final analysis (2 deaths and 1 failed cryoplasty). ABI improved significantly one day after the procedure from a baseline of 0.64 ± 0.08 to 0.95 ± 0.05 ($p < 0.05$) and was preserved at 1 and 3-months post-treatment, with ABI results of 0.94 ± 0.09 and 0.92 ± 0.10 respectively (both $p < 0.05$ vs baseline). Additionally, percent diameter stenosis improved from $86 \pm 12\%$ to $16 \pm 3\%$ immediately after cryoplasty ($p < 0.05$). Angiographic assessment at 6 months post-cryoplasty revealed no evidence of restenosis or significant change in residual stenosis from acute cryoplasty results. At 14 ± 4



months (range 9 to 24 months) post-treatment, the patency rate was 83.3% (9/12 patients), with a restenosis rate of 16.7%. Throughout the study, the majority of patients (83.3%) did not show any significant angiographic change, with the exception of two patients (13.3%) which developed late occlusion of the target vessel.

Ethical Issues

No issues were identified from the retrieved material.

Cultural or Religious Considerations

No issues were identified from the retrieved material.

Other Issues

No issues were identified from the retrieved material.

Recommendation

Current evidence for the safety and efficacy of cryotherapy is lacking. The overall success rates in patients (including those with underlying risk factors such as diabetes and occlusion of target vessel) appears to be satisfactory, with mid-term clinical patency rates of 82% to 92% (Laird *et al.* 2005, Fava *et al.* 2002). Long-term clinical patency was available from one study (Laird *et al.* 2006), which reported a 75% patency rate 3.5 years post-cryotherapy. Despite encouraging results from several studies, cryoplasty appears to be completely ineffective in preventing restenosis in the select patient cohort of Karthik *et al.* (2006) which had recurrent neointimal hyperplasia (a condition whereby cryoplasty was meant to be capable of resolving). The absence of comparative studies severely limits the arguments that cryoplasty is substantially more effective compared to conventional angioplasty with stenting. Furthermore, comparisons with historical results, although promising, is to a large extent limited due to the difference of lesions treated, poor follow-up protocols, patients of different clinical stages of peripheral vascular disease and the use of simple clinical follow-up examinations instead of medical imaging techniques. Based on the evidence available, it is recommended that the following is conducted:

- | | |
|--|--|
| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input checked="" type="checkbox"/> Monitor | <input type="checkbox"/> Archive |

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Search Criteria:

A search of MEDLINE, PubMed, *The Cochrane Library*, the Current Controlled Trials metaRegister, the UK National Research Register, the International Network of Agencies for Health Technology Assessment, relevant online journals and the Internet was conducted in August 2006.

Search terms used were: 'Cryoplasty', 'PolarCath', 'percutaneous angioplasty' and 'Cryovascular'.



2007 update

A search of relevant databases, online journals and the Internet was conducted in October 2007, following the recommendation in September 2006 that cryoplasty utilising the PolarCath™ peripheral dilation system be monitored for 12 months.

Two new case series studies were identified and retrieved.

Safety

Samson and colleagues (2007) reported the experience of one centre in which cryoplasty therapy was used to treat 47 lesions (33 limbs) in 32 consecutive patients (12 females and 20 males). The majority of lesions (94%) were located in the superficial femoral artery (SFA) while the remainder of lesions were located in the popliteal artery and autogenous nonreversed vein bypass graft (2% and 4% respectively).

Eight dissections (not requiring treatment) with subadventitial staining and no encroachment on the lumen were reported. Two further dissections resulting in minimal intimal flaps were also reported, one of which required stenting. Four deaths, not attributed to the therapy were also reported. No further adverse events including spiral dissections, acute occlusions, amputations, thrombus, distal embolisation, aneurysms or local groin complications were reported.

The use of cryotherapy in 10 patients with restenosis following ilio-femoral endovascular treatment was reported recently by Karthik and colleagues (Karthik et al. 2007). In each case the patients had experienced at least one previous episode of stenosis that had been treated by conventional endovascular methods. The site of lesion varied and included the right iliac artery (n = 3), right superficial femoral artery (n = 1), left iliac artery (n = 2), right femoropopliteal graft (n = 2), right aortofemoral graft (n = 1) and left femoral artery (n = 1). In five patients current restenosis was the indication for treatment while in the remaining five patients graft risk of restenosis was stated as the indication. Minor dissections, classified as being less than grade C were reported in two patients but did not require further treatment. No other initial complications were reported.

Effectiveness

Samson and colleagues (2007) applied cryoplasty therapy in a median of 1.5 lesions per limb (range: 1 to 3 lesions). Technical success rate, defined as residual stenosis of $\leq 30\%$ was achieved in 96% of lesions (45/47 lesions). This translated to a mean residual stenosis of 10%. In two lesions where technical success was not achieved, a stent was required to achieve 70% partial resolution of stenosis due to the presence of heavy calcification and redilation was required to achieve 30% residual stenosis. Two further lesions required stenting, one following redilation and the other resulting from minimal intimal disruption.



The median patient follow-up was 12 months (range: 1 day to 22 months) at which time freedom from recurrence for lesions and limbs was 82.2% and 84.4% respectively. Prior to treatment, the mean ABI was 0.71 (range: 0.42 – 1.01). Post-treatment this figure improved to 0.88 (range: 0.41 – 1.11). At the initial follow-up 82% of limbs (27/33) demonstrated an improvement in ABI. One month after the treatment, duplex scans of all successfully dilated lesions showed improvement with velocity profiles demonstrating absence of hemodynamic compromise. Recurrent lesions were reported in five limbs. Three lesions previously treated with standard PTA underwent successful cryoplasty but all experienced restenosis of the lesion within six months despite the cryoplasty sites being patent at 18, 20 and 22 months (Samson et al. 2007).

Twelve procedures performed over a 14 month period were reported by Karthik et al. (2007). Cryoplasty was successful in all but two instances where the procedure was successfully repeated. In this study, technical success was defined as residual stenosis of < 30% and/or less than grade C dissection and was achieved in all 12 procedures. Significant restenosis developed in all patients during follow-up (mean follow-up 6.2 months). The duration of freedom stenosis ranged from one month (one patient) to 12 months (two patients). Seven patients of the ten patients developed recurrence of short distance, lifestyle-limiting claudication following cryoplasty and significant restenosis on the follow-up arterial Doppler study. Two of these patients were referred for further treatment and underwent repeat cryoplasty within 6 months of the original procedure. However, both patients experienced further symptomatic recurrence and required conventional angioplasty at eight and ten months after the second cryoplasty (Karthik et al. 2007).

2007 HealthPACT action

The evidence on cryoplasty remains limited, however it appears that cryoplasty is feasible and at least in the short term effective in the treatment of primary lesions. Nevertheless, the evidence also suggests that cryoplasty may not be as effective in treatment of restenosis (Samson et al. 2007). Comparative studies incorporating longer follow-up periods are required to assess the safety and effectiveness of cryoplasty. Based on the lack of development in the last 12 months it is recommended that this technology be archived.

Number of studies included

Total number of studies	2
Level IV intervention evidence	2

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