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CONTEXT AND POLICY ISSUES:

Peripheral vascular disease is a condition in which systemic atherosclerosis leads to narrowing of arteries distal to the arch of the aorta, with superficial femoral artery as the most common site. Life style therapies, medical therapies, and invasive therapies form the main treatments for peripheral vascular disease. Surgical therapeutic options include open surgery of the legs with grafts, endarterectomy, and catheter-based endovascular procedures. Catheter-based endovascular procedures include percutaneous transluminal angioplasty (PTA), balloon-expandable stents, and self-expandable stents.

This report reviews the evidence for the clinical effectiveness and cost-effectiveness of PTA plus stenting when compared to PTA alone.

RESEARCH QUESTIONS:

1. What is the clinical effectiveness of aortoiliofemoral arteriogram-guided peripheral vascular stenting for the diagnosis and treatment of patients with peripheral vascular disease as compared to percutaneous transluminal angioplasty?

2. What is the cost-effectiveness of aortoiliofemoral arteriogram-guided peripheral vascular stenting for the diagnosis and treatment of patients with peripheral vascular disease as compared to percutaneous transluminal angioplasty?

METHODS:

A limited literature search was conducted on key health technology assessment resources, including PubMed, The Cochrane Library (Issue 3, 2009), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international health technology agencies, and a focused Internet search. The search was limited to English language articles published between 2004 and September 2009. No filters were applied to limit the retrieval by study type.

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SUMMARY OF FINDINGS:

Clinical effectiveness

The literature search identified a 2009 Cochrane review that aimed to determine the effect of PTA with stenting when compared to PTA alone for lesions of the superficial femoral artery. Eight randomized controlled trials with 968 participants were included. Participants were followed up to two years. The efficacy outcome measures were patency of the vessel as determined by duplex ultrasound or angiography, ankle brachial pressure index (ABPI), and treadmill walking distance.

At 6 months follow up, there was a statistically significant improvement in angiographic patency (odds ratio [OR] 2.06, 95% CI 1.15, 3.72) and duplex patency (OR 1.71, 95% CI 1.03, 2.85) in patients treated with PTA plus stenting compared with lesions treated with PTA alone. However, at 12 months, the improvement was not conclusive for either angiographic (OR 1.31, 95% CI 0.84, 2.03) or duplex patency (OR 1.41, 95% CI 0.97, 2.04). The trend continued at 24 months, with inconclusive findings for angiographic (OR 0.70, 95% CI 0.28, 1.76) or duplex patency (OR 1.78, 95% CI 0.98, 3.24). A very small and inconclusive result was found for ABPI at 6 months (mean difference 0.07, 95% CI 0.04, 0.10), 12 months (mean difference 0.07, 95% CI 0.05, 0.09), and at 24 months (mean difference 0.03, 95% CI -0.04, 0.10) in favour of PTA with stent when compared with PTA alone. A more pronounced improvement in treadmill walking distance was observed in patients with PTA plus stent as compared to PTA alone at 12 months (mean difference 62.52 (95% CI 48.36, 76.68) but the finding was not conclusive at 24 months (p = 0.81, mean difference not reported). Overall, the authors of the systematic review concluded that stenting did offer a benefit, but stenting could not be recommended based on their analysis.

A systematic review published in 2008 compared peripheral artery stenting with other interventions for occlusive peripheral artery disease (PAD). The authors conducted a systematic search for all comparative and non-comparative studies including patients with PAD that included one study arm using stenting. The review included 1190 patients from 10 RCTs that compared PTA plus stent versus PTA alone for aorto-iliac, femoropopliteal, and infrapopliteal arteries. Main outcomes studied were mortality, major amputation, ABPI, and walking distance. The authors conducted a meta-analysis of six studies and found no significant difference in mortality (risk difference 1.6 95% CI 0.9, 4.1). For major amputation, no statistically significant differences were found (OR 0.76, 95% CI 0.28, 2.05). No meta-analyses for ABPI or walking distance were performed. The evidence suggested no difference in ABPI between PTA plus stent or PTA alone, and insufficient data was available to provide evidence about a change in walking distance. The authors concluded that there is no evidence to suggest that primary stenting results in better clinical outcomes than PTA alone.

Cost-effectiveness

The literature search identified a 2004 cost-analysis study comparing in-hospital costs of PTA plus stent implantation with PTA alone. Two hundred and sixty-six patients with femoropopliteal arteries occlusion were randomized to PTA plus self-expanding Nitinol stent or PTA. There were no statistically significant differences between the stent group and the PTA group in either subacute closure (0.07% versus 1.5%, p >0.05), or abrupt closure (0% versus 1.5%, p >0.05). Differences in major adverse events or any other complications were also inconclusive.
between the two groups (p > 0.05). Stent placement increased procedure duration, equipment costs, and physician services. Hospital costs were approximately US$3,500 higher for patients randomized to the Nitinol stent, compared with PTA alone (US$8,435 versus $4,980; p < 0.001). The authors’ concluded that because there were no substantial differences in subsequent outcomes between the two treatments, the increase in initial costs would unlikely be offset by savings in follow up costs.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING:

Although one systematic review found that stenting resulted in better outcomes than PTA alone, the other systematic review found insufficient data to suggest that stenting was superior to PTA alone. Limited findings suggested that a routine stent implantation in patients undergoing PTA is not optimal on economic grounds. Guidelines from the Transatlantic Intersociety Consensus (TASC)\(^8\) stated that the evidence was insufficient to recommend stenting as a primary treatment for patients with PAD of the femoropopliteal or tibial arteries, and that if PTA produced suboptimal results, stents were indicated. The limited information may be a consideration for the use of PTA plus stenting for patients with peripheral vascular disease

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