No Additional Benefit from Laser in Balloon Angioplasty of the Superficial Femoral Artery

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Objectives: To evaluate the efficacy of the addition of plaque ablation by hot-tip laser to balloon angioplasty.

Design: Prospective randomised clinical trial.

Materials and methods: Patients with either occlusion or >50% diameter stenosis less than 3cm in length in the superficial femoral artery, and with two or three calf vessel run-off were eligible and randomised to receive either balloon angioplasty alone or with laser assistance. Treatment failure in follow-up was defined as reocclusion or recurrence of greater than 50% stenosis at the site of angioplasty.

Results: Ninety limbs (82 patients) were entered into the study. Forty-four patients had mild claudication, 32 more severe symptoms and 6 rest pain or ulceration. More patients with diabetes (5 of 5, p = 0.04, Fisher’s exact test) and occlusions (16 of 22, p < 0.05, χ²) were randomised to the laser group. Initial technical success was obtained in all lesions. The median duration of follow-up was 1 year.

Failure occurred in 40 limbs during follow-up. Three segments, all with initial occlusions and undergoing laser angioplasty re-occluded within 2 days, one requiring immediate thrombectomy. Another 20 limbs underwent further intervention. Overall success (± s.m.) (Kaplan-Meier) at 1 year was 67% (±5%), and at 2 years 43% (±7%). Only increased age, initial occlusion, female sex, and not smoking were significantly (p < 0.05, Cox’s proportional hazards) associated with failure; on multivariate analysis, age and occlusion were the best independent predictors. There was no significant difference (p > 0.05) in outcome between limbs undergoing laser assisted balloon angioplasty and balloon alone either overall or within the stenosis or occlusion subgroups.

Conclusions: This study found no significant benefit was gained by the addition of laser to balloon angioplasty and that the long term success was modest for lesions considered to be suitable for angioplasty.

Key Words: Laser; Balloon; Superficial femoral; Angioplasty; Randomised controlled trial.

Introduction

Percutaneous balloon angioplasty has become a popular technique for treating localised arterial disease but is limited by the development of restenosis. It has been proposed that debulking of plaque in combination with balloon angioplasty will result in higher primary patency and lower restenosis rates. Laser vaporisation of plaque, performed prior to conventional balloon angioplasty, theoretically provides such debulking of atheroma as well as preventing distal propagation of debris. Laser techniques, expensive both in hardware and disposables, have been introduced with much enthusiasm, but also readily abandoned with few controlled scientific studies. A prospective randomised clinical trial to evaluate the efficacy of laser assisted balloon angioplasty compared to conventional balloon angioplasty alone in the treatment of localised disease in the superficial femoral artery was performed.

Methods

Entry criteria and randomisation

Patients with isolated occlusions less than 3cm in length or stenoses greater than 50% in the superficial femoral artery, and with popliteal and two or three calf vessel run-off were eligible for entry. Patients with iliac or popliteal artery occlusion or significant stenosis were specifically excluded. Patient related data...
including age, sex, diabetes, ischaemic heart disease and hypertension were recorded. Patients underwent resting and exercise ankle brachial indices (ABPI), Duplex scanning and angiography prior to entry into the study. The type of lesion and run-off were confirmed by angiography prior to randomisation to receive either balloon angioplasty using standard techniques or balloon angioplasty following laser.

Procedures were performed at three University teaching hospitals either by an interventional radiologist in the angiography suite or in the operating suite by a vascular surgeon experienced in endovascular techniques. A Trimedyne Argon or Nd:YAG “over the wire hot tip” laser system was used for patients allocated to the laser group.2,3

Table 1. Univariate Cox proportional hazards analysis

<table>
<thead>
<tr>
<th>Factor</th>
<th>Number of limbs</th>
<th>Coefficient</th>
<th>s.d.</th>
<th>p</th>
<th>Odds ratio</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>90</td>
<td>0.06</td>
<td>0.02</td>
<td>0.005</td>
<td>1.06</td>
<td>1.02</td>
</tr>
<tr>
<td>Non-smoker</td>
<td>24</td>
<td>0.92</td>
<td>0.36</td>
<td>0.01</td>
<td>2.50</td>
<td>1.24</td>
</tr>
<tr>
<td>Occlusion</td>
<td>22</td>
<td>0.73</td>
<td>0.33</td>
<td>0.03</td>
<td>2.04</td>
<td>1.08</td>
</tr>
<tr>
<td>Female</td>
<td>43</td>
<td>0.68</td>
<td>0.33</td>
<td>0.04</td>
<td>1.98</td>
<td>1.04</td>
</tr>
<tr>
<td>Laser assistance</td>
<td>49</td>
<td></td>
<td></td>
<td></td>
<td>0.99</td>
<td></td>
</tr>
</tbody>
</table>

Table 2. Multivariate Cox proportional hazards analysis (best fit)

<table>
<thead>
<tr>
<th>Factor</th>
<th>Coefficient</th>
<th>s.d.</th>
<th>p</th>
<th>Odds ratio</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>0.065</td>
<td>0.022</td>
<td>0.003</td>
<td>1.07</td>
<td>1.02</td>
</tr>
<tr>
<td>Occlusion</td>
<td>0.782</td>
<td>0.331</td>
<td>0.018</td>
<td>2.19</td>
<td>1.14</td>
</tr>
</tbody>
</table>

Endpoint

Treatment failure was defined as restenosis of the original lesion to greater than 50% diameter stenosis or occlusion. Patients were reviewed immediately after the procedure, then at 1, 3 and 6 monthly intervals. Patients were also assessed noninvasively by Duplex scanning and/or resting ABPI measurements until failure or termination of the study. In cases of failure, further reintervention was determined on clinical grounds on an individual patient basis; restenoses usually being considered for repeat balloon angioplasty with or without laser assistance or stenting while reocclusions were more usually considered for bypass.

Statistical methods

Data were analysed on a PC. Statistical analysis performed using SPIDA (Statistical Package for Interactive Data Analysis, Macquarie University, Sydney, Australia). After univariate Cox proportional hazards were determined, a multivariate model was developed by the stepwise addition of significant variables. Survival curves were plotted from data from Kaplan-Meier analysis. Fisher’s exact test probabilities were calculated using a spreadsheet calculator function.

Results

Ninety limbs in 82 patients were entered into the trial. Forty-four patients were mild claudicants (Fontaine Class IIa), 32 severe claudicants (Fontaine IIb) and six had either rest pain or tissue loss (Fontaine III or IV). The mean (± s.d.) age was 69 (± 9) years. There were 22 occlusions and 68 stenoses.

All five patients with diabetes were randomised to receive laser assisted angioplasty (p = 0.04, Fisher’s exact test). Sixteen of the 22 limbs with occlusion were randomised to laser assisted angioplasty (p < 0.05, χ² = 3.94). There were otherwise no significant differences between the two groups.

Three patients died during follow-up, all with treatment success at last follow-up. No death was directly or indirectly related to limb ischaemia or the intervention. The median duration of follow-up was 350 days and, for those limbs with treatment success, the median follow-up was 430 days. Success (± s.d.) at 1 year was 67% (± 5%), and at 2 years 43% (± 7%). Treatment failed in 40 limbs during follow-up. The median time to failure was 220 days. Twenty-one limbs underwent repeat intervention comprising four thrombectomies (2 early), 11 percutaneous and six bypass procedures.

There was no significant (p > 0.05) increase in the likelihood (Cox proportional hazards) or duration (Kaplan-Meier) of success from laser assisted balloon angioplasty compared to balloon angioplasty alone. The Cox regression found that only increased age, female sex, pre-existing occlusion and never having smoked were factors positively associated (p < 0.05) with treatment failure on univariate analysis (Table 1). On multivariate analysis, only age > 75 years and initial occlusion were significant factors (Table 2). There was no significant difference in success between laser and balloon alone within the subgroups of those with and without initial occlusion (Fig. 1).
Superficial Femoral Artery: Laser vs. Balloon

100
80
60
40
20

0  6  12  18  24

Time (months)

Fig. 1. Kaplan-Meier survival curves for limbs treated with laser assisted balloon angioplasty (---) or balloon angioplasty alone (---). Figure shows data points for which the standard deviation of survival is less than 10%.

Discussion

Our early results with laser angioplasty were encouraging, suggesting that the treatment may be able to be extended to a wide range of patients with peripheral vascular disease including those who would otherwise require bypass surgery. Patients with superficial femoral artery occlusions less than 8 cm in length and with good (2 to 3 vessel) run-off had better results than patients with longer length occlusions and poor (0 or 1 vessel) run-off. However, with improvement in guide wire technology, the number of occluded segments that were able to be crossed without use of laser for initial recanalisation increased considerably, so that the main issue which needed to be resolved was whether the debulking of atheroma, theoretically associated with the use of laser, contributed to improved long-term patency.

We chose to study the effect of balloon angioplasty with and without laser in the superficial femoral segment and, in aiming for as homogeneous a population of patients as possible, restricted entry into the trial to short segment stenoses and occlusions less than 3 cm in good run-off and with no other significant disease in the superficial femoral segment or proximally in the iliac segment. We found that the number of eligible patients at each of our centres was small, as most patients requiring intervention on the basis of their clinical symptoms had much more extensive disease excluding them from the trial.

Our study confirms the findings of others, that there is no significant benefit from the addition of laser to balloon angioplasty. The nature of the lesion (occlusion vs. stenosis) or patient factors (such as age > 75 years) appear to be more important in determining the outcome of percutaneous intervention.

Three vessels occluded within 2 days of the procedure; all had had initial occlusions and had undergone laser assisted balloon angioplasty. Exclusion in the reporting of results of early "technical" failures is now recommended as invalid. However, the difference in outcome between standard balloon angioplasty and the laser assisted group was unaffected even with exclusion of these early failures.

The use of the "hot tip" laser as an adjunctive procedure for uncomplicated angioplasty cannot be recommended. It may still have a role, however, for attempted recanalisation of short segment occlusions which cannot be crossed with a guide wire, although this is now only a minority of lesions.

We were disappointed with the overall success rates of 69% at 1 year and 47% at 2 years for both groups of patients considering that these lesions were the most favourable that we could find to subject to percutaneous intervention. We would not recommend an aggressive approach to minimally symptomatic or asymptomatic localised lesions on the basis that this might prevent subsequent more extensive occlusion of the superficial femoral segment as the long-term success appears at best only modest for lesions otherwise considered to be suited to this form of intervention.

Acknowledgements

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References


