The World of LeGoo Assessed: A Short Systematic and Critical Review

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It is very difficult to identify whether the use of the thermosensitive polymer LeGoo offers advantages over the use of clamps or clampless techniques for infra-inguinal bypass. This issue of the journal provides much additional information about the use of LeGoo. We have summarised all the available evidence. In a very heterogeneous patient population, with heterogeneous graft type and location, the primary technical success rate remains high at 90% [95%CI 83–99], the 3 months secondary graft patency is 71 [95%CI 58–84]% and limb salvage is 78% [95%CI 68–89%]. These promising early results need to be followed by extended follow-up of the patients and standardised outcome reporting in the future.

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INTRODUCTION

The thermosensitive polymer LeGoo is being marketed for clampless bypass on the basis that it prevents damage to vulnerable arteries (particularly those which are calcified) and therefore to theoretically improve long-term patency and minimise secondary interventions. This issue of the journal contains the experience of 2 centres, one in Switzerland and one in England in using LeGoo for the temporary occlusion of infra-inguinal vessels during bypass surgery and consolidates the previous French study reporting technical success only.1–3 To summarise these findings and place them in perspective, we undertook a systematic review of the literature and sought information from unpublished studies in elsewhere in Europe (to overcome any potential bias in favour of publishing successful studies).

Here the aims are to systematically and critically review published and unpublished data for the use of LeGoo in peripheral arterial reconstruction.

METHODS & RESULTS

A systematic review was conducted according to PRISMA guidelines using a pre-defined protocol with standard format data extraction (Supplementary data). This published literature, including clinical trial databases, has been systematically searched up and until October 2012, which identified only 4 eligible studies, contributing 83 patients.1–4 In addition we have attempted to identify unpublished patient series elsewhere in Europe through advertisements at recent vascular surgical meetings in Europe, including the European Society of Vascular Surgery in Bologna, September 2012: this identified 3 unpublished studies, albeit with limited numbers (a total of 14 bypasses in 14 patients) and limited follow-up information. In total, we identified 105 separate bypasses which used LeGoo in 100 limbs of 97 patients. Many of the cases were technically challenging, often in patients with diabetes or chronic kidney disease, usually for critical limb ischaemia and redo procedures, and used saphenous vein, arm veins and prosthetic materials for bypass conduits: therefore the patient group and type of bypass are both very heterogeneous. LeGoo was used for the distal anastomoses.

The technical success rate, reported in all studies, continues to be very high 95/105 [90% [95%CI 83–99]], although sometimes assisted success is reported (Fig. 1A). However, nearly every study identified problems with plug emboli in the first one or two cases, which led one centre to discontinue use of LeGoo. Plugs were readily removed by embolectomy. Following the peri-operative period secondary interventions to preserve graft patency was necessary in about 10% of cases but these were not reported consistently.

Across the separate studies, confidence intervals have not been reported and there have been no standardised outcomes or criteria for vessel patency and only the largest study4 reports patency and limb salvage rates to 12 months. We focused on outcomes at 3 months; summary secondary patency was 71% [95%CI 58–84], limb salvage 78% [95%CI 68–89] limbs (Fig. 1B) and survival 81% [95%CI 56–92]. No study has follow-up of 12 months or more on all patients.

DISCUSSION

The total published experience of using LeGoo to provide temporary occlusion of infra-inguinal vessels is limited and this issue of the journal provides the majority of world experience and the total world experience of outcomes beyond 30 days. Technical success rate is high, but higher in published than unpublished studies. This is probably the
result of a short learning curve in which some centres become discouraged from further use. Centres encountered residual plug emboli in the first one or two cases, since the recommended technique of plug solution by application of cold saline to the exterior of the vessel does not appear to be as effective as either intra-arterial or particularly plug injection of cold saline. The volumes of LeGoo required are usually small (less than a 0.5 ml LeGoo syringe) and the mean occlusion time is in the range 13–15 min, which usually provides adequate time to complete the anastomosis.

The patency rates and limb salvage reported at 3 months are similar to those of clamped bypasses of comparable complexity, conducted without LeGoo occlusion but in the future should be reported with associated confidence intervals. There is no proof that LeGoo provides better outcomes than the use of occlusion balloons or other techniques in either heavily calcified or other diseased infrainguinal arteries and mid and long-term results remain conspicuously absent as is the use of standardised reporting standards. Better data, from a randomised trial, are available for the use of LeGoo in coronary artery bypass. LeGoo also is being used for larger arteries e.g. femoral arteries: this too would benefit from formal evaluation.

LeGoo remains a promising adjunct technique for vascular surgeons but more comprehensive reporting, using standardised criteria, of its use and complications, with more than short term follow up is essential. Only in this way can the advantages of LeGoo be exploited appropriately. Therefore, we would be pleased to continue adding data to an on-going systematic review.

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CONFLICT OF INTEREST/FUNDING

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APPENDIX A. SUPPLEMENTARY DATA

Supplementary data related to this article can be found online at http://dx.doi.org/10.1016/j.ejvs.2012.10.021.

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