

 VASCULAR DISEASE

Cell therapy lowers PAD amputation risk

Critical limb ischaemia (CLI) is a potentially fatal complication of peripheral artery disease (PAD). A meta-analysis of studies that evaluated the safety and efficacy of autologous cell therapy for intractable CLI/PAD now reports that cell therapy reduces the risk of amputation and improves wound healing.

The efficacy of autologous cell therapy for CLI has been tested in numerous studies, ranging from case reports to randomized, controlled trials (RCTs). Meta-analyses of such studies have so far yielded inconclusive findings. Rigato and colleagues performed a meta-analysis of 19 RCTs ($n = 837$), seven nonrandomized trials ($n = 338$), and 41 noncontrolled trials ($n = 1,177$) that assessed the efficacy of cell therapy in patients with PAD/CLI, with the primary outcome being major amputation.

According to the primary analysis (all RCTs), autologous cell therapy reduced the risk of major amputation by 37%, increased the probability of wound healing by 59%, and significantly improved the chance of amputation-free survival by 18%, with no changes in all-cause mortality. Surrogate end points such as ankle-brachial

index, transcutaneous oxygen tension, and rest pain score were also improved with cell therapy. The secondary analysis, which included all controlled trials, also yielded similar findings for the primary and surrogate end points. Furthermore, the tertiary analysis, which included all studies reporting quantitative outcomes, also demonstrated improvement in indices of perfusion and pain with cell therapy.

“Our primary analysis on RCTs appears to provide conclusive results on the efficacy of cell therapy on several objective and surrogate end points in patients with intractable CLI,” the investigators conclude. However, they emphasize that these findings must be tempered “in view of the limitations of this meta-analysis, namely low–moderate quality, high heterogeneity, publication bias, and possible lack of statistical power”.

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ORIGINAL ARTICLE Rigato, M. *et al.* Autologous cell therapy for peripheral arterial disease: systematic review and meta-analysis of randomized, non-randomized, and non-controlled studies. *Circ. Res.* <http://dx.doi.org/10.1161/CIRCRESAHA.116.309045> (2017)