

## REVIEW

## Venous Arterialisation for Salvage of Critically Ischaemic Limbs: A Systematic Review and Meta-Analysis

M.A. Schreve <sup>a,\*</sup>, C.G. Vos <sup>a</sup>, A.C. Vahl <sup>b</sup>, J.P.P.M. de Vries <sup>c</sup>, S. Kum <sup>d</sup>, G.J. de Borst <sup>e</sup>, Ç. Ünlü <sup>a</sup>

<sup>a</sup> Department of Surgery, Noordwest Ziekenhuisgroep, Alkmaar, The Netherlands

<sup>b</sup> Department of Surgery, OLVG, Amsterdam, The Netherlands

<sup>c</sup> Department of Vascular Surgery, St. Antonius Hospital, Nieuwegein, The Netherlands

<sup>d</sup> Department of Surgery, Changi General Hospital, Singapore

<sup>e</sup> Department of Surgery, UMCU, Utrecht, The Netherlands

### WHAT THIS PAPER ADDS

Critical limb ischaemia (CLI) is the clinical end stage of peripheral artery disease and is associated with high amputation and mortality rates, and poor quality of life. New treatment options are being explored for patients with CLI who have no option for surgical or endovascular revascularisation, with venous arterialisation considered to be a viable alternative before major amputation. This study reviews the literature and provides pooled data on the clinical effectiveness of venous arterialisation for lower limb salvage in CLI patients without revascularisation options.

**Background:** Critical limb ischaemia (CLI) is the end stage of peripheral artery disease (PAD) and is associated with high amputation and mortality rates and poor quality of life. For CLI patients with no revascularisation options, venous arterialisation could be a last resort for limb salvage.

**Objective:** To review the literature on the clinical effectiveness of venous arterialisation for lower limb salvage in CLI patients with no revascularisation options.

**Method:** Different databases were searched for papers published between January 1966 and January 2016. The criteria for eligible articles were studies describing outcomes of venous arterialisation, published in English, human studies, and with the full text available. Additionally, studies were excluded if they did not report limb salvage, wound healing or amputation as outcome measures. The primary outcome measure was post-operative limb salvage at 12 months. Secondary outcome measures were 30 day or in-hospital mortality, survival, patency, technical success, and wound healing.

**Results:** Fifteen articles met the inclusion criteria. The included studies described 768 patients. According to the MINORS score, methodological quality was moderate to poor. The estimated pooled limb salvage rate at one year was 75% (0.75, 95% CI 0.70–0.81). Thirty day or in-hospital mortality was reported in 12 studies and ranged from 0 to 10%. Overall survival was reported in 10 studies and ranged from 54% to 100% with a mean follow-up ranging from 5 to 60 months. Six studies reported on patency of the venous arterialisations performed, with a range of 59–71% at 12 months.

**Conclusion:** In this systematic review on venous arterialisation in patients with non-reconstructable critical limb ischaemia, the pooled proportion of limb salvage at 12 months was 75%. Venous arterialisation could be a valuable treatment option in patients facing amputation of the affected limb; however, the current evidence is of low quality.

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### INTRODUCTION

Critical limb ischaemia (CLI) is the clinical end stage of peripheral artery disease (PAD) and is associated with high amputation and mortality rates, and poor quality of life.<sup>1</sup> It is estimated that 5–10% of patients with peripheral artery disease who are older than 50 years will develop severe or

\* Corresponding author. Department of Surgery, Noordwest Ziekenhuisgroep, Wilhelminalaan 12, 1815JD Alkmaar, The Netherlands.

E-mail address: [m.a.schreve@nwz.nl](mailto:m.a.schreve@nwz.nl) (M.A. Schreve).

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critical limb ischaemia (CLI) within 5 years.<sup>2</sup> Bypass surgery and more recently endovascular interventions with angioplasty and stenting have become the treatment of choice to prevent amputation and resolve rest pain. Endovascular interventions carry lower morbidity and mortality.<sup>3</sup> One prospective study 15 years ago showed that up to 50% of patients with CLI are not suitable candidates for vascular intervention because of extensive occlusions of the outflow in the crural and pedal vessels.<sup>3</sup> Nowadays more patients are suitable for vascular intervention because of progress in techniques and materials but when re-occlusion occurs, these patients will return.

In the past decade, new treatment options have been explored for patients with CLI with no option for surgical or endovascular revascularisation. These include stem cell therapy, spinal cord stimulation, and prostanoid therapy. A meta-analysis of placebo controlled trials showed no advantage for stem cell therapy on the primary outcome measures of amputation, survival, and amputation free survival in patients with CLI.<sup>4</sup> Another meta-analysis showed no benefit for prostanoid treatment or other medical treatments.<sup>5</sup> A Cochrane review concluded that there may be some benefit from spinal cord stimulation for prevention of amputation; however, evidence is considered to be very low grade, mainly because of imprecision and increased risk of bias.<sup>6</sup>

For CLI patients with no revascularisation options, venous arterialisation could be an alternative technique for limb salvage. The concept of using the disease free venous bed as an alternative conduit for perfusion of the peripheral tissues with arterial blood was first published by Halstead and Vaughan in 1912.<sup>7</sup> Flow in existing collateral vessels will increase, reversal of flow all the way through the capillaries improves tissue nutrition<sup>8</sup> and possibly stimulates angiogenesis.<sup>9</sup>

A systematic review in 2006 concluded that venous arterialisation may be considered a viable alternative before major amputation.<sup>10</sup> Nevertheless, this technique is not being widely used. This could be because of the low quality of studies. Since 2006 the evidence has grown as the number of studies doubled and the number of included patients tripled. This study reviews the literature on the clinical effectiveness of venous arterialisation for lower limb salvage in CLI patients without revascularisation options. Also, meta-analyses of the studies was conducted and pooled data provided on limb salvage.

## METHODS

This report was written in accordance with the PRISMA guidelines for reporting systematic reviews and meta-analyses.<sup>11</sup>

### Literature search

Two authors (MS, CV) independently searched the literature to identify studies investigating venous arterialisation for critically ischaemic limbs. MEDLINE, EMBASE, and CINAHL databases and the Cochrane Database of Systematic Reviews were searched for papers published between January 1966

and February 2016, using the following keywords: (Vein OR veins OR venous OR venosome) AND (arterialization OR arterialisation) AND (ischemia OR ischaemia OR ischemic OR ischaemic OR gangrene OR necrosis OR tissue loss OR ulcer OR ulcer OR ulcers OR restpain OR limb salvage). Free text words were also used instead of MeSH terms to avoid missing recent publications that have not yet been given MeSH headings. The “related articles” function in PubMed and reference lists of retrieved articles were also used to identify articles not found in the original search. The search was not restricted to any language. However, studies published in Russian and Chinese were excluded. No unpublished data or abstracts were included. A full search strategy is available on request.

### Validity assessment

After removal of duplicates, two authors (MS, CV) screened the titles and abstracts of the identified studies for relevance. Full texts of the remaining relevant studies were obtained and two authors (MS, CV) read the full text papers and made a final selection of relevant studies. Two authors (MS, CV) independently assessed the methodological quality of the articles using the Methodological Index for Non-randomised Studies (MINORS) score, with a global ideal score of 16 for non-comparative studies and 24 for comparative studies.<sup>12</sup> The MINORS score was reported as a percentage of the global ideal score. For this review a score of  $\leq 8$  was considered to be poor quality, 9–14 moderate quality, and 15–16 good quality for non-comparative studies. Cutoff points were  $\leq 14$ , 15–22, and 23–24, respectively, for comparative studies. Discrepancies between the authors during the search, selection, and quality assessment were resolved by discussion. If agreement was not reached, a third author was consulted.

### Definition

Venous arterialisation was defined as the use of the disease free venous bed as an alternative conduit for perfusion of the peripheral tissues with arterial blood.

Chronic CLI was defined according to the transatlantic inter-society consensus document (TASC II 2007), which is based on the clinical symptoms predominantly caused by peripheral arterial disease (i.e. ischaemic rest pain and/or ulceration).<sup>2</sup>

### Inclusion and exclusion criteria

**Types of studies.** The criteria for eligibility were studies describing outcomes of venous arterialisation, human studies, and full text availability. The exclusion criteria were case reports and case series ( $N < 10$ ), reviews, abstracts, animal studies, and studies published in Russian or Chinese. Additionally, studies were excluded if they did not report limb salvage, wound healing, or amputation as outcome measures.

**Types of participants.** All studies with patients who received venous arterialisation for critical lower limb

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