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# Perioperative warming, oxygen, and Ilomedin on oxygenation and healing in infrainguinal bypass surgery



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## ABSTRACT

**Background:** Perioperative adjuncts are utilized across surgical specialities with the goal of improving patient outcomes. High-dose oxygen and extended warming are shown to increase wound collagen deposition during abdominal surgery. Prostacyclin is shown to improve limb salvage and patency rate in infrainguinal bypass (IIB) surgery. This study evaluated the impact of these adjuncts on healing and perfusion post IIB surgery.

**Methods:** This randomized controlled study allocated patients undergoing IIB surgery into three treatment arms (perioperative high-dose oxygen, extended warming, and a synthetic prostacyclin) or a control group. The primary outcome was accumulation of hydroxyproline (OHP, collagen surrogate marker) as collected in polytetrafluoroethylene implants on day 5. Secondary outcomes included levels of growth factors and cytokines, and tissue oxygenation of the wound and foot as measured by hyperspectral technology and ankle-brachial pressure index. Clinical outcomes were observed to day 30, with long-term follow-up of 12 mo.

**Results:** Seventy-one patients completed the study. Comparing treatment groups with the control at day 5, there were no differences in OHP, growth factors or cytokines levels, or improvement in tissue oxygenation at the surgical incision. However, there was more flow to the foot (HT-SUM (%) change) in the Ilomedin group compared to control (0% versus -14.6%,  $P = 0.045$ ). HT-deoxy was higher at the peripheries in the oxygen and temperature groups, suggesting decreased tissue oxygenation.

**Conclusions:** The perioperative treatments did not dramatically improve oxygenation or healing of the surgical wound in IIB surgery; however, Ilomedin may result in greater flow to the peripheries.

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## Introduction

Optimizing tissue perfusion is a key component of wound healing, especially in compromised patients with comorbidities

that influence healing such as peripheral vascular disease and diabetes. Surgical wound complications following infrainguinal bypass (IIB) surgery can be up to 40% and can render the revascularization procedure a failure.<sup>1</sup> Previous studies have

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suggested that peripheral vascular perfusion can be enhanced perioperatively by supplemental oxygen, administration of a vasodilator drug, such as Ilomedin (synthetic prostacyclin analogue), or by active warming to enrich thermoregulation by vasodilation.<sup>2-5</sup> The effects of these adjuncts on wound healing and tissue oxygenation in IIB among vascular patients are unknown.

The aims of this study were to examine the roles of key molecular markers in wound healing, namely hydroxyproline (OHP) and growth factors during vascular surgery. In addition, to determine how these markers and peripheral tissue oxygenation were influenced by thermal or chemical vasodilation, and oxygen.

The primary end point was wound healing, assessed by incorporation of OHP into embedded polytetrafluoroethylene (PTFE) implants. Secondary end points included analyses of growth factors in the wound tissue and tissue oxygenation. The hypothesis was that perioperative high-dose oxygen, extended warming, and perioperative Ilomedin would improve tissue oxygenation and wound healing during IIB surgery.

## Methods

The protocol and informed consent for this randomized control study was approved by the local Northern Y ethics committee (NTY/08/04/032), and all participants gave informed consent.

### Eligibility

Patients undergoing IIB surgery at Waikato Hospital, Hamilton, New Zealand from January 2009 to July 2011 were considered for inclusion. Patients were excluded if they had untreated critically stenotic lesions proximally (e.g., aortoiliac segment), chronic obstructive pulmonary disease with retention of carbon dioxide, previous exposure to bleomycin, use of Ilomedin, corticosteroids, or immunosuppressant's 4 wk before surgery, sensitivity to Ilomedin, or a history of methicillin-resistant *Staphylococcus aureus*.

### Randomization methods

Participants were randomly allocated into four groups:

- Oxygen group (FiO<sub>2</sub> 80% without extended warming and Ilomedin)
- Temperature group (FiO<sub>2</sub> 30% with preoperative and postoperative warming using Bair Hugger and without Ilomedin)
- Ilomedin group (FiO<sub>2</sub> 30% with Ilomedin injected intra-arterially intraoperatively and one single dose immediately postoperatively, without extended warming)
- Control group (FiO<sub>2</sub> 30% without extended warming or Ilomedin)

Participants were blinded as to their group allocation, although concealment was difficult for the temperature group. Randomization codes were formulated by Statistical Package for the Social Sciences software (SPSS, version 22 [IBM

Corporation, Armonk, NY, USA]) on a 1:1 basis. The results were placed in an envelope, which was opened by the anesthetist at least 2 h before induction of anesthesia.

### Power calculation

A minimum of 76 patients were required, with 19 participants in each group, to detect a mean increase of 0.075- $\mu$ g OHP per cm tubing at day 5 in each treatment group compared with controls with a power of 80% and a significance level of 5%. A 25% absolute increment in OHP content was deemed to be clinically significant.

### Number of participants

One hundred and five patients underwent IIB involving a medial calf incision during the recruitment period. Eighty-five were invited to participate after considering the inclusion and exclusion criteria (Fig. 1). Eighty patients were consented for the study; however, nine patients were further excluded during the study. Three did not have successful IIB during surgery, three had revisions of the bypass graft before day 5, and two patients violated protocol (had higher FiO<sub>2</sub> than prescribed by the study). One patient allocated to the oxygen group had a cardiac arrest and died on day 1. No participation was terminated as a result of complications during the study.

Seventy-one patients completed the study on day 5 when the PTFE implant was removed to evaluate the primary outcome. Recruitment was slower than predicted.

### Study design

After the collection of demographic data, the number of patent crural vessels, or "run-offs", was determined. This preoperative imaging utilized digital subtraction arteriography as preferred imaging, or magnetic resonance angiography, computed tomographic angiography, and arterial duplex scan if no superior modality was available. Patients were scored out of 3, with a score of 1 allocated per patent crural vessel without critical stenosis; 0.5 per vessel with one or more critical stenosis; and zero per vessel with any length of chronic total occlusion regardless of the presence of collateral flow.

At least 2 h before surgery, under standardized conditions, the ankle-brachial pressure index (ABI) was recorded by hand-held Doppler, and transcutaneous tissue oxygenation was quantified using the OxyVu (HyperMed Inc, Boston, MA). This device utilizes hyperspectral technology and was validated by the author previously. The locations for repeat measurement were the medial aspect of the knee where the skin incision would lie, and the plantar foot over the head of the first metatarsal. OxyVu yielded oxygen saturation (HT-sat, %), oxyhemoglobin (HT-oxy), and deoxyhemoglobin (HT-deoxy) in arbitrary units (AU) and skin temperature in degrees Celsius. HT-sum (sum of HT-oxy and HT-deoxy) quantified the amount of hemoglobin at the skin capillaries.

Each patient was given chlorhexidine and alcohol (Chloraprep) for skin preparation and a standard protocol for antibiotic prophylaxis on induction. Antibiotics continued for 24 h (1-g cefazolin intravenously or erythromycin if

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