The clinical efficacy of VERSAJET® in the limb salvage of diabetic patients following minor amputation

Luca Dalla Paola, Enrico Brocco, Antonella Senesi, Daniele De Vido, Maurizio Merico, Sasa Ninkovic

Diabetic Foot Department - Foot & Ankle Clinic, Abano Terme Hospital, Padua, Italy

Introduction

In diabetic patients presenting with seriously infected forefoot and/or midfoot, the decision to perform a minor lower limb amputation distal to the ankle joint is regarded as the ultimate therapeutic approach and, therefore, it comes after any conservative treatment option is felt impracticable.

Unlike lower limb major amputations (under- or above-the-knee), minor amputations allow the retention of a sufficient plantar support, thereby effectively reducing the degree of disability and post-operative morbidity. In fact, minor amputation procedures are performed under local-regional anaesthesia, with fewer hemodynamic risks and less blood loss. Clinical conditions requiring such treatments include gangrene, deep compartmental syndromes, and phlegmon with or without abscess distal to the Chopart joint. All these surgical procedures are to be regarded as emergency interventions.

After the initial correction of any ischemic component, these clinical conditions require a complex, multi-step surgical approach to the management of the infection, as healing by first intention is very rarely achieved. First of all, a radical surgery of necrotic tissues must be considered, rather than facing the choice of the final amputation level. At this stage, the unsalvageable bone tissue must be removed, the infected material must be drained, and the necrotic tissue at the margins of vital tissue must be excised. Then, antiseptic medications are used and daily routines of debridement are performed over a period of days, until the level of amputation can be defined and the surgical closure performed.

However, according to data from the literature the incidence rate of minor amputation failure using this kind of approach may range between 20%-40%.

Aim of the study

The purpose of the study was to assess the efficacy of a new equipment for surgical debridement (VERSAJET®, Smith & Nephew) in patients presenting infective dehiscence following minor amputation.

VERSAJET is a tool for surgical debridement based on an innovative technology that, by using a waterjet system, excises and aspirates necrotic, infected soft tissues.

Before using VERSAJET for the surgical debridement of wound dehiscence, patients were subjected to a first line treatment of the infection and were treated for any ischemic component (by performing either surgical or endoluminal revascularization); the use of VERSAJET was combined with proper systemic antibiotic and local antiseptic treatments.

Our study population treated with VERSAJET was compared with a previously evaluated population group treated with conventional procedures of surgical debridement (using scalpel-curette) combined with pulse lavage system.

In order to assess the efficacy, we evaluated the rate of limb salvage, healing time, number of surgical interventions per patient, average operative time, and rate of re-amputation (more proximal to the original level of amputation).

Materials and methods

We studied a group of 12 diabetic patients presenting with a stub dehiscence following minor amputation. As a control group we evaluated an historical comparable population group.

Prior to the amputation, 10 out of 12 patients were subjected to a revascularization procedure consequent to an obstructive arteriopathy (PVD) anamnesis (Table 1).

Transmetatarsal amputation was performed in 5 patients; Lisfranc-level and Chopart-level amputations were performed in 3 and 4 patients, respectively.

This population study (V) was compared with a previously studied population group (C) treated with standard surgical debridement procedures combined with pulse lavage (Table 2).

In order to assess the efficacy, we evaluated the following parameters: rate of limb salvage, healing time, number of surgical interventions per patient, and average operative time.

Results

Neither patients treated with VERSAJET® (V, n = 0/12) nor control-group patients (C, n = 0/12) had major amputations.

The healing time was 39.2 ± 12.5 days in the treatment (V) group, versus 58.6 ± 19.12 days in the control group ($p < 0.05$).

In the group of patients treated with VERSAJET, 2,1 ± 1,2 surgical interventions per patient were performed, and 3,5 ± 1,8 interventions per patient were carried out in the control group ($p = 0.05$).

The average operative time per patient was 3.5 ± 2.2 hours in the V group, versus 7.4 ± 3.1 hours in the C group. Two patients of the VERSAJET group needed surgical revision leading to a more proximal re-amputation; such a procedure was performed in 4 patients of the C group ($p = 0.05$) (Table 3).

Discussion

The main objective of the management of acute diabetic foot problems is to reduce the number of major surgeries. An attempt to achieve this goal is the progression towards the implementation of standardized procedures, through diagnostic and therapeutic approaches well outlined in the literature. PVD and infection are poor prognostic factors that have to be treated.

The conservative treatment implies the possibility of a need for reintervention on the stump, due to the vicinity of the original infection foci. However, a proper and aggressive treatment for relapse of infection should allow to achieve significant outcomes in limb salvage. In our experience, the use of this new VERSAJET system for surgical debridement enabled to shorten the healing time and allowed to reduce the number of surgical interventions in the strategy for limb salvage.

Table 1

	N.	Age (years)	M/F	Diabetes duration *Years)	PVD	Neuro-pathy	Wound Type (T.U.C. score)
VERSAJET	12	69.7 ± 7.5	8/4	20.1 ± 10.3	10/12	11/12	IIIB/C/ D12/12
Controls	12	69.9 ± 8.3	9/3	19.8 ± 11.7	9/12	10/12	IIIB/C/ D12/12

Table 2

	N.	TMA	LISFRANC Amp.	CHOPART Amp.
VERSAJET	12	5	3	4
Controls	12	5	4	3

Table 3

	N.	Healing time (days)	Surgical interventions (N)	Surgical time (hours)	Re-amputations (N)
VERSAJET	12	39.2 ± 12.5	2.1 ± 1.2	3.5 ± 2.2	2
Controls	12	58.6 ± 19.2	3.5 ± 1.8	7.4 ± 3.1	4
		p = 0.005	p = 0.05	p = 0.005	p = 0.05

Case 1

Case 2

smith&nephew
VERSAJET◇
Hydrosurgery System

The clinical efficacy of VERSAJET in the limb salvage of diabetic patients following minor amputation

Luca Dalla Paola, Enrico Brocco, Antonella Senesi, Daniele De Vido, Maurizio Merico, Sasa Ninkovic

Diabetic Foot Department - Foot & Ankle Clinic Abano Terme Hospital, Padua, Italy

Wound Management
Smith & Nephew
11775 Starkey Road
P.O. Box 1970
Largo, FL 33779
USA

Customer Care Center
1 800 876-1261
T 727 392-1261
F 727 392-6914

www.smith-nephew.com

VJ-0035-0806