DETERMINANTS OF WOUND RELATED OUTCOMES IN MILD DIABETIC FOOT INFECTION

Introduction

Diabetic foot infections (DFIs) are a major global health concern due to their potential for serious complications such as amputation, if not properly managed. This post-hoc analysis examines how patient characteristics at the start of the treatment influence wound related outcomes in mild DFIs.



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Methods

We conducted an exploratory analysis of a randomized controlled trial enrolling 30 patients diagnosed with grade 2 DFIs according to the International Working Group on Diabetic Foot (IWGDF) guidelines. Analysis was based on a trial comparing a novel wound dressing incorporating synergistic copper and silver nanoparticles (CuAgWD*) and commercially available gelling fiber silver ion dressing (AgWD*). Baseline data collected included age, sex, initial wound size, bacterial load from wound swab, pain levels (VAS scale) and quality of life scores (The Diabetic Foot Ulcer Scale). Generalized linear mixed models were used to assess the effect of baseline characteristics on the same clinical outcomes.



Inclusion criteria:
Diabetic foot ulcers ≤8 cm
Mild infection (IWGDF 2)
Age ≥18 years

Exclusion criteria: Antibiotics in prior 7 days Osteomyelitis Critical limb ischemia

Table1. Main inclusion and exclusion criteria

	Total (n=30)
Age, years	65.9±11.9
Male/Female, n (%)	19 (63.3) / 11 (36.7)
BMI, kg/m ²	30.3±5.3
Systolic BP, mmHg	142.2±15.5
Diastolic BP, mmHg	79.5±12.6
HbA1c, %	7.13±0.95
Vascular disorders, n (%)	24 (80)





Figure 2. Wound surface area in both groups on all trial visits presented as percent reduction from the initial wound size. Error bars represent standard deviation. *p-value <0.05

Results

The trial demonstrated a reduction in mean wound surface area over time, with smaller initial wounds exhibiting greater improvement. Patients presenting with higher initial bacterial loads consistently maintained higher levels throughout the study. Notably, female sex was Associated with statistically significantly higher bacterial counts compared to males, while older age was Associated with lower bacterial loads. Pain associated with the wound decreased during the trial but remained correlated with initial pain levels. The DFS score followed a similar pattern, with baseline scores strongly correlating with subsequent scores. Older patients tended to have higher DFS scores.

Wound size		<0.001	Bacterial load		p=0.11 ↔	
	P-value				P-value	
Estimate	Wald type	Type III (overall)	Parameter	Estimate	Wald type	Type III (overall)
0.003	<0.001	<0.001	Baseline total	0.411	<0.001	<0.001
0.128	0.777	0.584	bacterial load			
0.536	0.185	0.185	Treatment	0.470	0.231	0.352
-0.171	0.413	0.413	Female sex	0.569	0.021	0.021
			Age (years)	-0.282	0.025	0.025
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QoL (DFS)		p=0.15 ↔		Pain (VAS 0-10)		p=0.009	
		P-value				P-value	
Parameter	Estimate	Wald type	Type III (overall)	Parameter	Estimate	Wald type	Type III (overall)
Baseline total DFS score	0.911	<0.001	<0.001	Baseline pain intensity	0.252	<0.001	<0.001
Treatment	-1.974	0.541	0.802	Treatment	-0.088	0.575	0.121
Female sex	0.038	0.987	0.987	Female sex	-0.099	0.366	0.366
Age (years)	2.349	0.057	0.057	Age (years)	0.004	0.393	0.393

This study highlights the significant influence of baseline patient characteristics on wound related outcomes in mild DFIs. Initial wound size, bacterial load, sex, age and pain at baseline all appear to be determinants of the outcomes. Main limiting factor for further detailed analysis was small sample size and short duration of the trial, but similar analysis is planned in an ongoing trial with larger sample size and longer duration (NCT06667752).

Conclusion