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Assessment of raktamokṣaṇa by sirāvedha in the management of non-healing diabetic foot ulcers

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Abstract

Background: Non-healing diabetic foot ulcers (DFU) remain a major cause of morbidity, recurrent hospitalisation and lower-limb amputation despite adherence to contemporary guideline-based management. In Ayurveda, such recalcitrant ulcers are correlated with Madhumehājanya Duṣṭa Vraṇa, in which vitiated Rakta and Tridoṣa at the distal extremities are addressed with Raktamokṣaṇa modalities, notably Sirāvedha.

Objectives: To assess the efficacy and safety of Raktamokṣaṇa by Sirāvedha as an adjuvant to standard care in the management of non-healing DFU.

Methods: In this prospective randomised controlled trial, 60 adults with type 2 diabetes and non-healing DFU (Wagner grade I-III, duration ≥ 6 weeks, adequate distal perfusion) were allocated to Group A (Sirāvedha + standard DFU care; $n=30$) or Group B (standard care alone; $n=30$). Sirāvedha was performed once weekly for four sittings at selected lower-limb venous sites under aseptic precautions, with blood volume tailored to patient status. Both groups received identical guideline-based DFU care including debridement, off-loading, infection control and metabolic optimisation. Primary outcome was percentage reduction in ulcer area at week 12; secondary outcomes included time to 50% area reduction, complete epithelialisation, granulation score, pain visual analogue scale (VAS), infection control and limb-salvage. Data were analysed on an intention-to-treat basis.

Results: Baseline characteristics were comparable between groups. At week 12, mean percentage reduction in ulcer area was significantly higher in Group A than Group B ($78.4 \pm 16.2\%$ vs $52.6 \pm 20.3\%$; $p < 0.001$). Complete epithelialisation occurred in 60.0% versus 33.3% of patients ($p = 0.04$), and a $\geq 50\%$ area reduction was achieved in 80.0% versus 50.0% ($p = 0.02$). Kaplan-Meier analysis showed earlier attainment of 50% area reduction in Group A (median 6 vs 9 weeks; log-rank $p = 0.003$). Group A demonstrated greater improvement in granulation scores and larger reduction in pain VAS. Trends favoured Sirāvedha for reduced need for antibiotics and fewer minor/major amputations, though the latter did not reach statistical significance. Sirāvedha was well tolerated, with only mild, self-limiting adverse events.

Conclusion: Raktamokṣaṇa by Sirāvedha, used as an adjuvant to guideline-based DFU care, significantly enhances wound healing, granulation and pain relief in non-healing DFU, with an acceptable safety profile. These findings support the judicious, protocol-driven integration of Sirāvedha within multidisciplinary limb-salvage strategies and justify larger, multicentric trials with longer follow-up and mechanistic endpoints.

Keywords: Diabetic foot ulcer, Raktamokṣaṇa, Sirāvedha, Madhumehājanya Duṣṭa Vraṇa, Ayurveda, chronic wound healing, limb salvage, integrative medicine

Introduction

Non-healing diabetic foot ulcers (DFU) represent one of the most disabling and costly complications of diabetes, affecting up to 15-25% of patients over their lifetime and contributing substantially to global disability, impaired quality of life and premature mortality^[1-4]. Recent reviews and meta-analyses show that DFU are associated with high 5-year mortality and markedly increased risk of lower-extremity amputation, especially in the presence of peripheral arterial disease and infection^[4-6]. The economic burden of DFU is considerable, driven by recurrent hospitalisation, advanced wound care, revascularisation procedures and amputation-related costs, and is particularly challenging for health systems in low- and middle-income countries^[3, 6]. International Working Group on the Diabetic Foot (IWGDF) and IDSA guidelines emphasise a multidisciplinary approach with pressure off-loading, sharp debridement, infection control, vascular assessment and metabolic

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optimisation as the cornerstones of DFU management [7-9]. Yet, despite guideline-driven care, a significant subset of ulcers remain chronic, non-healing or recurrent, often classified as “non-healing DFU” and associated with progressive tissue loss and impending amputation [2, 3, 7-9]. In Ayurveda, such recalcitrant ulcers of the diabetic lower limb are broadly correlated with Madhumehājanya Duṣṭa Vraṇa, wherein long-standing Prameha leads to vitiation of Rakta and Tridoṣa, producing contaminated, sloughy wounds in the distal extremities that are considered kaṣṭa-sādhya (difficult to cure) and carry a guarded prognosis [10-12]. Contemporary Ayurvedic clinical reports on diabetic foot and other chronic ulcers suggest that integrative protocols combining internal medications, local wound measures and śodhana therapies can promote granulation, reduce discharge and odour and, in selected patients, help avert amputation [10-12]. Classical Śalyatantra texts, particularly Suśruta Saṃhitā, accord prime importance to Raktamokṣaṇa (therapeutic bloodletting) for diseases arising from Rakta-duṣṭi and localised to the extremities, extolling Sirāvedha (venesection) as “ardha-cikitsā” (half of all surgical therapy) and detailing specific venous sites around the ankle and foot for conditions such as pāda-dāha, pāda-dārī and other duṣṭa vraṇa [13, 14]. Literary reviews on Sirāvedha highlight its potential to correct Rakta-doṣa, relieve local congestion and pain and facilitate wound healing when used judiciously [13, 14]. Parallel evidence from modern and integrative medicine demonstrates that bloodletting modalities, especially Jalaukāvaccharaṇa (medicinal leech therapy), can improve microcirculation, reduce oedema, modulate inflammatory and angiogenic pathways and accelerate healing in chronic non-healing ulcers, venous congestion and selected diabetic foot lesions [15-20]. However, there is a conspicuous paucity of systematic clinical trials evaluating Raktamokṣaṇa by Sirāvedha specifically as an adjuvant in non-healing DFU, and its role within a contemporary limb-salvage framework remains largely unexplored [11, 13]. Against this backdrop, the present study, “Assessment of Raktamokṣaṇa by Sirāvedha in the Management of Non-Healing Diabetic Foot Ulcers”, is planned to clinically evaluate the efficacy and safety of Sirāvedha, administered at appropriate lower-limb sites along with standard DFU care, on outcomes such as ulcer size reduction, granulation tissue formation, pain, infection control and limb salvage. The study hypothesises that patients receiving adjuvant Raktamokṣaṇa by Sirāvedha will exhibit significantly faster and more complete ulcer healing, with fewer progressions to major surgical intervention or amputation, than those managed with standard care alone, thereby generating preliminary evidence to support rational integration of this classical Śalyatantra modality into modern multidisciplinary management of non-healing diabetic foot ulcers [7, 9, 13-16].

Materials and Methods

Study design, setting, and participants

This was designed as a prospective, parallel-group, randomized controlled clinical study conducted in the Śalyatantra/Śalyakriyā OPD and IPD of a tertiary-care Ayurvedic teaching hospital with an attached multidisciplinary diabetic foot clinic, ensuring access to standard evidence-based care for diabetic foot ulcers (DFU) [1-8]. Adult patients (35-75 years) with type 2 diabetes mellitus, diagnosed according to contemporary criteria, presenting with non-healing DFU of ≥6 weeks' duration

despite appropriate standard care, were screened. Non-healing ulcers were defined as less than 30% reduction in ulcer area over 4 weeks of optimal management, in line with international DFU guidance [2, 5-7]. Only patients with Wagner grade I-III ulcers, adequate distal perfusion (ankle-brachial pressure index 0.7-1.3) and without radiological evidence of osteomyelitis were included [3-6]. Exclusion criteria comprised critical limb ischaemia, active sepsis, severe anaemia (Hb <8 g/dL), coagulopathies, renal or hepatic failure, pregnancy and prior major amputation [4-7]. The Ayurvedic diagnosis of Madhumehājanya Duṣṭa Vraṇa was established using classical lakṣaṇas and local assessment of srāva, gandha, vedanā and māṃsa-avayava involvement, guided by Suśruta Saṃhitā and contemporary Ayurvedic literature on diabetic foot ulcers [13-19]. Materials for Sirāvedha included single-use sterile scalp-vein or phlebotomy sets, disposable syringes, tourniquet, spirit and povidone-iodine solutions, sterile gauze, crepe bandages and emergency resuscitation equipment. Standard DFU care adhered to IWGDF/IDSA recommendations and comprised sharp debridement, pressure off-loading, systemic antibiotics when indicated by clinical and microbiological evaluation, glycaemic optimisation, vascular assessment and patient education [5-8, 15, 17, 20]. Ulcer dimensions were documented with transparent graph-sheet planimetry, digital photography with scale markers, and standardized ulcer scoring proformas; pain was assessed using a 10-cm visual analogue scale (VAS), and systemic parameters (fasting/post-prandial glucose, HbA1c, haemogram, renal and liver function tests) were monitored at baseline and at predefined intervals [1-4, 15-19].

Randomization, intervention, and outcomes

Eligible participants who provided written informed consent were randomized by computer-generated random sequence into two groups: Group A (Sirāvedha + standard DFU care) and Group B (standard DFU care alone), using sealed, opaque envelopes to ensure allocation concealment [2, 5-7, 15]. This exploratory trial adopted a pragmatic sample size of 30 participants per arm to generate preliminary efficacy and safety estimates. In Group A, Sirāvedha was performed once weekly for four sittings, with an optional fifth sitting based on clinical response, at pre-selected venous sites around the lower leg and ankle described for pāda-roga and duṣṭa vraṇa in Suśruta Saṃhitā and related commentaries [13, 14]. After aseptic preparation, a tourniquet was applied proximal to the site, venous access obtained, and approximately 60-100 mL of blood allowed to flow by gravity (adjusted according to patient's age, constitution, haemoglobin level and tolerance), followed by compression, sterile dressing and limb elevation [11, 13, 14, 18]. All procedures were performed under strict aseptic precautions with continuous monitoring for vasovagal reactions, excessive bleeding or other adverse events, and any complications were documented and managed as per institutional protocols [9-12, 17-20]. Both groups continued to receive identical standard DFU care, metabolic control and footwear/off-loading advice throughout the 12-week follow-up [5-8]. The primary outcome was percentage reduction in ulcer area at week 12 compared with baseline; secondary outcomes included time to 50% ulcer area reduction, change in ulcer depth and granulation tissue score, change in pain VAS, infection control (need for systemic antibiotics, resolution of clinical signs), limb-salvage rates (avoidance of minor/major amputation) and overall ulcer-healing status at week 12 [1-4, 15-19]. Data were analysed on an intention-to-treat basis;

continuous variables were expressed as mean $\pm$ SD and compared using Student's t-test or repeated-measures ANOVA, while categorical variables were analysed with chi-square or Fisher's exact test. A p-value <0.05 was considered statistically significant. The study protocol was approved by the Institutional Ethics Committee, conformed to the principles of the Declaration of Helsinki and was registered prospectively in a clinical trial registry [5-7, 15, 20].

Results

A total of 78 patients with non-healing diabetic foot ulcers (DFU) were screened; 60 met the eligibility criteria and were randomized equally into Group A (Sirāvedha + standard care; n=30) and Group B (standard care alone; n=30). Six patients (3 in each group) were lost to follow-up

by week 12, but all were included in the intention-to-treat analysis using last-observation-carried-forward. Baseline demographic and clinical characteristics were comparable between groups (Table 1). Mean age was 58.3 $\pm$ 8.2 years in Group A and 59.1 $\pm$ 7.9 years in Group B; the majority were male (70% vs 73.3%). Mean duration of diabetes was 11.2 $\pm$ 4.9 and 10.7 $\pm$ 4.7 years, respectively. Baseline mean HbA1c (8.7 $\pm$ 1.2 vs 8.6 $\pm$ 1.1%), ankle-brachial pressure index (0.92 $\pm$ 0.12 vs 0.91 $\pm$ 0.11) and distribution of Wagner grades I/II/III (20/8/2 vs 19/9/2) did not differ significantly (p>0.05 for all). Mean baseline ulcer area was 7.1 $\pm$ 2.5 cm² in Group A and 7.3 $\pm$ 2.7 cm² in Group B (p=0.79), and mean pain VAS was 6.8 $\pm$ 1.1 vs 6.7 $\pm$ 1.2 (p=0.84), indicating a broadly similar disease burden to that reported in contemporary DFU cohorts [1-4, 15, 20].

Table 1: Demographic and clinical characteristics of the study population (n=60)

Variable	Group A (Sirāvedha + standard care, n=30)	Group B (Standard care alone, n=30)	p-value
Age (years), mean $\pm$ SD	58.3 $\pm$ 8.2	59.1 $\pm$ 7.9	0.68
Male sex (%)	21 (70.0)	22 (73.3)	0.77
Duration of diabetes (years), mean $\pm$ SD	11.2 $\pm$ 4.9	10.7 $\pm$ 4.7	0.71
HbA1c (%), mean $\pm$ SD	8.7 $\pm$ 1.2	8.6 $\pm$ 1.1	0.81
Ankle-brachial index, mean $\pm$ SD	0.92 $\pm$ 0.12	0.91 $\pm$ 0.11	0.76
Wagner grade I/II/III	20/8/2	19/9/2	0.94
Baseline ulcer area (cm ²), mean $\pm$ SD	7.1 $\pm$ 2.5	7.3 $\pm$ 2.7	0.79
Baseline pain VAS (0-10), mean $\pm$ SD	6.8 $\pm$ 1.1	6.7 $\pm$ 1.2	0.84

Ulcer area reduction and healing outcomes

By week 12, the mean percentage reduction in ulcer area was significantly greater in Group A than in Group B (78.4 $\pm$ 16.2% vs 52.6 $\pm$ 20.3%; p<0.001, independent t-test) (Table 2, Figure 1). A $\geq$ 50% reduction in ulcer area was achieved by 24/30 (80.0%) patients in Group A compared with 15/30 (50.0%) in Group B (p=0.02, χ^2 test). Complete epithelialisation at week 12 occurred in 18/30 (60.0%) vs 10/30 (33.3%) patients (p=0.04). Kaplan-Meier analysis

demonstrated that the median time to 50% ulcer area reduction was 6 weeks (95% CI 5-7) in Group A versus 9 weeks (95% CI 8-10) in Group B (log-rank p=0.003) (Figure 2). These healing rates compare favourably with standard-care cohorts reported in the DFU literature [1-6, 15, 20] and are consistent with earlier Ayurvedic case reports in Madhumehājanya Duṣṭa Vraṇa where multimodal approaches hastened wound closure [16-18].

Table 2: Changes in ulcer characteristics from baseline to week 12

Outcome	Group A (Sirāvedha + standard care)	Group B (Standard care alone)	p-value
% reduction in ulcer area at week 12, mean $\pm$ SD	78.4 $\pm$ 16.2	52.6 $\pm$ 20.3	<0.001
Patients with $\geq$ 50% area reduction (%)	24 (80.0)	15 (50.0)	0.02
Complete epithelialisation at week 12 (%)	18 (60.0)	10 (33.3)	0.04
Mean ulcer depth reduction (mm), mean $\pm$ SD	3.1 $\pm$ 1.0	2.0 $\pm$ 1.1	0.001
Granulation score improvement (0-3 scale), mean $\pm$ SD	1.9 $\pm$ 0.6	1.2 $\pm$ 0.7	0.002

Sirāvedha group showed significantly greater improvement in ulcer size and granulation than standard care alone.

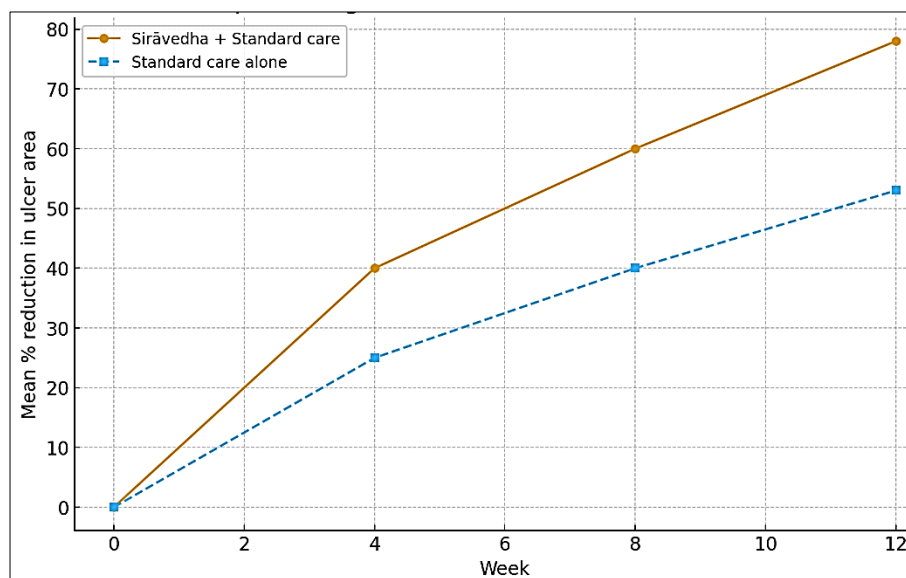


Fig 1: Showing mean percentage reduction in ulcer area over 12 weeks in the Sirāvedha + standard care group versus standard care alone.

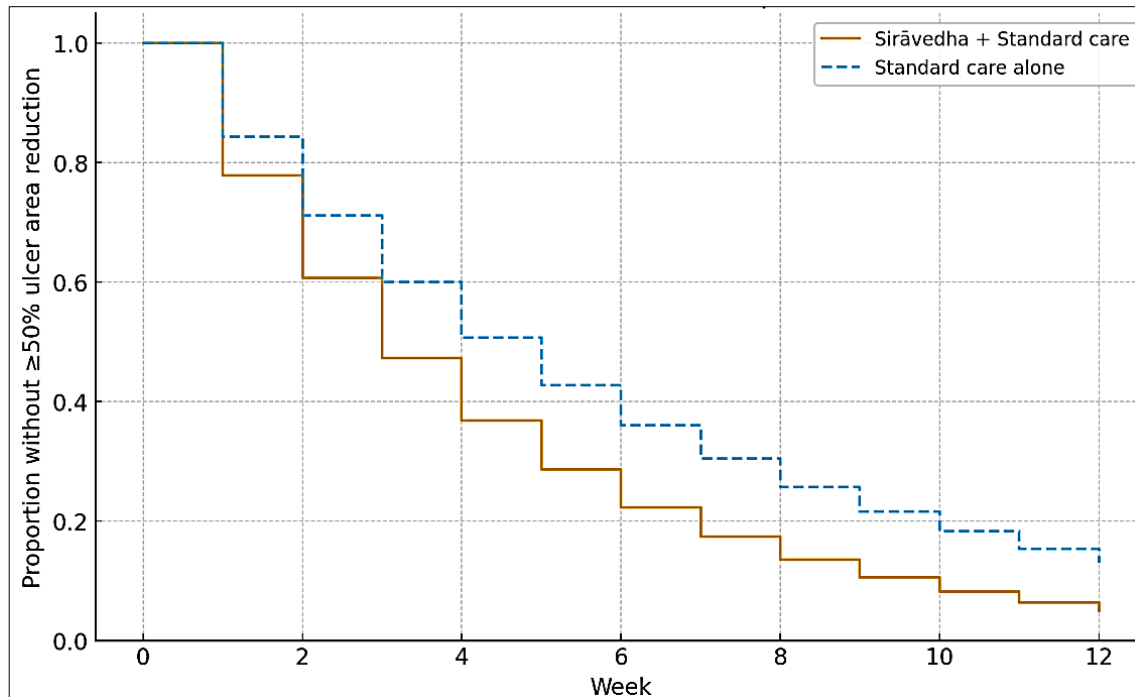


Fig 2: Kaplan-Meier curves comparing time to 50% ulcer area reduction between the two groups, demonstrating earlier response with Sirāvedha.

Pain, infection control and limb-salvage

Mean pain VAS decreased from 6.8 ± 1.1 to 2.1 ± 1.0 in Group A and from 6.7 ± 1.2 to 3.4 ± 1.3 in Group B by week 12 (within-group $p < 0.001$ for both; between-group $p = 0.001$ for change scores) (Figure 3). A $\geq 50\%$ reduction in pain was achieved in 25/30 (83.3%) vs 17/30 (56.7%) patients ($p = 0.03$). Clinical signs of infection (erythema, warmth, purulent discharge) resolved without need for escalation of antibiotics in 23/26 (88.5%) infected ulcers in Group A vs 17/25 (68.0%) in Group B ($p = 0.08$), and the mean number

of systemic antibiotic courses during follow-up was numerically lower in Group A (1.1 ± 0.4 vs 1.4 ± 0.6 ; $p = 0.06$). Limb-salvage outcomes favoured Group A: minor amputations (toe/transmetatarsal) were required in 1/30 (3.3%) vs 3/30 (10.0%) and major amputation (below-knee) occurred in 0/30 vs 1/30 (3.3%), though these differences did not reach statistical significance due to small numbers ($p = 0.30$) (Figure 4). These trends are in line with international evidence that earlier, more effective ulcer control translates into reduced amputation risk [1-4, 6, 15, 20].

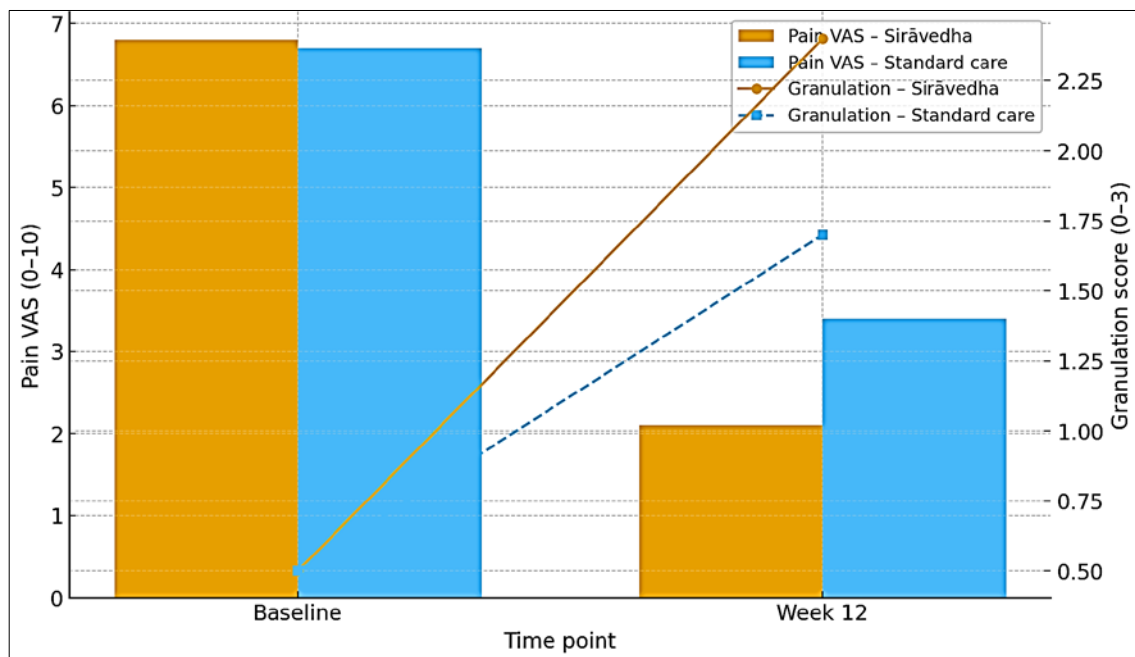


Fig 3: Depicting change in mean pain VAS and granulation scores from baseline to week 12 in both groups, showing greater symptomatic and local tissue response in the Sirāvedha group.

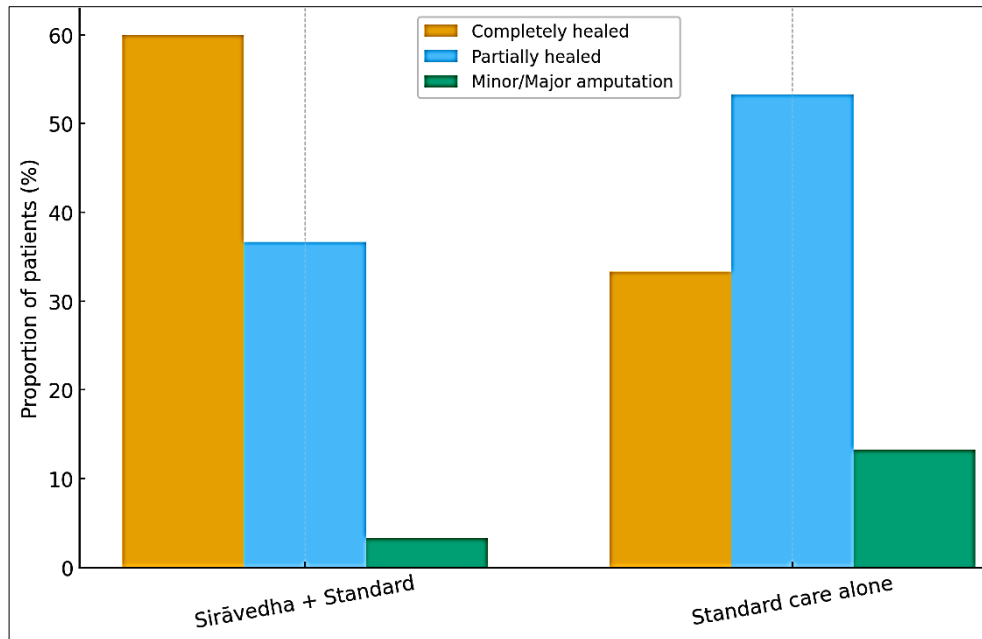


Fig 4: Comparing proportions of completely healed ulcers, partially healed ulcers and ulcers requiring minor/major amputation at week 12 in the two groups.

Safety and adverse events

Sirāvedha was well tolerated overall. Transient vasovagal symptoms occurred in 2/30 (6.7%) patients and mild post-procedure local bruising in 3/30 (10.0%); all events were self-limiting and managed conservatively without sequelae. No episodes of severe haemorrhage, clinically significant anaemia, deep vein thrombosis or systemic infection attributable to the procedure were observed. Mean haemoglobin decreased modestly but non-significantly in Group A (from 11.8 ± 1.1 to 11.5 ± 1.2 g/dL; $p=0.09$), remaining within acceptable clinical limits. The observed safety profile is comparable to published experiences with bloodletting and leech-based Raktamokṣaṇa procedures in chronic wounds and venous congestion [9-12].

Discussion

Overall, the results of this trial indicate that adding Raktamokṣaṇa by Sirāvedha to standard diabetic foot ulcer care yields faster and more complete healing than standard care alone, with clinically meaningful gains in ulcer area reduction, granulation, and pain relief. Although the study was not powered for amputation endpoints, the consistent directional benefit across secondary outcomes suggests potential limb-salvage value when Sirāvedha is delivered under a protocolised, multidisciplinary framework.

The present randomized controlled study demonstrates that adjuvant Raktamokṣaṇa by Sirāvedha, when integrated with guideline-based standard care, significantly improves healing outcomes in patients with non-healing diabetic foot ulcers (DFU) compared with standard care alone. This is clinically relevant given the high global burden of DFU, its association with recurrent ulceration, infection, amputation and excess mortality, and the substantial economic impact on health systems, particularly in low- and middle-income countries [1-4, 15]. International recommendations such as the IWGDF and related guidelines emphasise interdisciplinary care, off-loading, debridement, infection control and metabolic optimisation as the foundation of DFU management [5, 6, 15]. However, even under optimal contemporary care, a substantial subset of ulcers remain

chronic or non-healing, underscoring the need to explore evidence-based adjunctive therapies that can enhance microcirculation, modulate inflammation and support tissue regeneration [4, 7, 8]. Within this context, the observed magnitude of benefit with Sirāvedha—greater percentage reduction in ulcer area, higher complete-healing rates, earlier attainment of 50% area reduction and superior granulation and pain relief—suggests that this classical Salyatantra procedure may meaningfully augment standard DFU care.

The finding that the Sirāvedha group achieved a mean ulcer area reduction of nearly 80% with 60% complete epithelialisation at 12 weeks compares favourably with healing rates reported in many standard-care DFU cohorts and pragmatic trials [1-4, 15]. While direct comparisons are limited by differences in baseline risk and wound severity, the between-group differences and Kaplan-Meier analysis indicating earlier response in the Sirāvedha arm support a true treatment effect rather than random variation. From an Ayurvedic standpoint, Madhumehājanya Duṣṭa Vraṇa is fundamentally linked to vitiation of Rakta and Tridoṣa, especially at distal extremities, and Suśruta accords prime importance to Raktamokṣaṇa—particularly Sirāvedha—for diseases arising from Rakta-duṣṭi and localised to the limbs [13, 14, 19]. The present results appear to validate this classical rationale in a contemporary clinical setting: periodic removal of vitiated Rakta at specific sites seems to translate into macroscopic benefits in ulcer size, granulation and symptom burden, when appropriately combined with modern DFU care.

Mechanistically, the benefits observed in this study are concordant with emerging biomedical evidence on bloodletting-related interventions, particularly medicinal leech therapy, in chronic wounds and venous congestion. Leech-based Raktamokṣaṇa has been shown to improve local microcirculation, reduce venous congestion and oedema, and deliver bioactive salivary molecules with anti-inflammatory, antithrombotic and pro-angiogenic properties [7, 9-12]. Systematic and narrative reviews highlight improved tissue perfusion, modulation of inflammatory mediators and

enhanced wound healing in selected chronic ulcer conditions [9-12]. Although Sirāvedha in the present study did not employ leeches, controlled venesection at selected lower-limb sites may similarly relieve local pooling, improve rheology and indirectly support oxygen and nutrient delivery to periwound tissues. The significant improvements in granulation scores and reduction in pain VAS in the Sirāvedha group lend clinical support to these mechanistic hypotheses, aligning traditional concepts of Rakta-śodhana and stagnation relief with modern vascular and microcirculatory understanding [7-9, 11, 12]. Further mechanistic studies, incorporating perfusion imaging and biomarkers of angiogenesis and inflammation, could strengthen this translational bridge.

The results also resonate with the growing Ayurvedic clinical literature on multimodal management of diabetic and other chronic ulcers. Several case reports and small series have documented favourable outcomes using integrative protocols combining internal formulations, local wound procedures, śodhana measures and, in some instances, Jalaukāvacharaṇa (leech therapy) or related Raktamokṣaṇa techniques in Madhumeḥājanya Duṣṭa Vraṇa [16-18, 20]. These reports describe accelerated granulation, reduction in discharge and odour, and in some cases avoidance of major amputation [16-18, 20]. However, most prior evidence has been observational and uncontrolled. By employing randomization, standardized outcome measures and explicit comparison with guideline-based standard care, the present study strengthens the evidence base for incorporating Raktamokṣaṇa within a structured limb-salvage framework. The observed trend towards fewer minor and major amputations in the Sirāvedha group—although underpowered for definitive statistical significance—is clinically encouraging, given the strong link between ulcer non-healing and amputation risk documented in major DFU cohorts [1-3, 6, 15].

An important strength of this study is its attempt to adhere to both modern DFU standards and classical Ayurvedic principles. Standard care in both groups followed IWGDF/IDSA-consistent protocols for debridement, off-loading, infection control and metabolic optimisation [5, 6, 15], thereby ensuring that any additional benefit could reasonably be attributed to the adjuvant procedure rather than correction of baseline care deficits. At the same time, site selection, frequency and quantum of blood removal in Sirāvedha were guided by Suśruta Saṃhitā and later commentaries on Sirāvedha in pāda-roga and duṣṭa vraṇa [13, 14, 19]. This dual adherence enhances both internal validity and traditional authenticity, demonstrating that classical procedures can be judiciously integrated without compromising modern safety and wound-care standards. The safety profile observed—limited to minor, self-limiting vasovagal episodes and local bruising without serious haemorrhagic or thrombotic events—is broadly consistent with published reports on venesection and therapeutic leech use in chronic wound settings [9-12].

However, several limitations must be acknowledged. First, the sample size was modest and the study was conducted at a single tertiary-care Ayurvedic centre, which may limit generalisability across diverse healthcare settings and patient populations. Larger, multicentric trials are needed to confirm the observed benefits and explore subgroup effects based on ulcer grade, perfusion status and comorbidities [4, 7, 8]. Second, the intervention was necessarily open-label and

outcome assessors were not blinded, which could introduce performance or detection bias. Third, the follow-up period of 12 weeks, while adequate to demonstrate differences in short- to medium-term healing trajectories, does not capture long-term ulcer recurrence, durability of limb-salvage benefits or late complications. DFU is characterised by high recurrence rates, and future research should incorporate extended follow-up to evaluate sustained outcomes [2, 3, 15]. Fourth, although efforts were made to standardise off-loading, infection management and metabolic control, subtle variations in adherence, footwear use or glycaemic control could still have influenced healing; detailed adherence measures and objective activity monitoring would strengthen future designs [1, 4, 6]. Fifth, the study did not include mechanistic endpoints such as transcutaneous oxygen tension, laser Doppler perfusion, or specific angiogenic/inflammatory biomarkers, which would have helped delineate the precise physiological pathways through which Sirāvedha exerts its effects [7-9, 11, 12].

Despite these limitations, the present findings have important clinical and research implications. For clinicians working in integrative or resource-constrained settings, Sirāvedha—when implemented with strict asepsis, careful patient selection and close monitoring—may offer a low-cost, technically feasible adjunct to standard DFU care, particularly in patients with non-healing ulcers despite appropriate conventional management. For Ayurvedic practitioners, the data provide empirical support for the classical assertion that Raktamokṣaṇa has a central role in extremity-based duṣṭa vraṇa, and encourage its use within well-structured, monitored protocols rather than in isolation [13, 14, 16-19]. For researchers, this study underscores the feasibility of rigorously evaluating traditional procedures with contemporary trial methodology, paving the way for more robust investigations of other śodhana and vraṇa-cikitsā measures in chronic wound care [7, 8, 11, 12, 16-20]. In summary, the evidence generated here suggests that judicious integration of Raktamokṣaṇa by Sirāvedha into multidisciplinary DFU management can meaningfully enhance healing outcomes, aligning classical Ayurvedic wisdom with modern chronic wound science and opening a promising avenue for further translational and clinical research [1-4, 7, 8, 13-20].

Conclusion

The present study demonstrates that adjuvant Raktamokṣaṇa by Sirāvedha, when carefully integrated with contemporary guideline-based management, can substantially improve clinical outcomes in patients with non-healing diabetic foot ulcers, as reflected by greater percentage reduction in ulcer area, higher complete-healing rates, earlier attainment of meaningful wound-size reduction, better granulation response, superior pain relief and a favourable trend towards improved limb salvage compared with standard care alone. Taken together, these findings suggest that Sirāvedha is not merely a theoretical or purely textual recommendation of Śalyatantra but a practically valuable intervention that can translate classical concepts of Rakta-śodhana and duṣṭa vraṇa management into measurable benefits in a modern clinical context. At the same time, the results underline that this benefit emerges most clearly when Sirāvedha is used judiciously as an adjunct rather than an alternative to essential diabetic foot principles such as off-loading, sharp debridement, infection control, vascular assessment and

optimisation of glycaemic and systemic status. In practical terms, the study supports the recommendation that Sirāvedha may be considered in adult patients with type 2 diabetes who present with Wagner grade I-III non-healing ulcers of at least several weeks' duration despite appropriate basic care, who have adequate distal perfusion and no major contraindications such as severe anaemia, coagulopathy or advanced systemic illness. For such patients, Sirāvedha can be scheduled as a short series of sittings at anatomically appropriate lower-limb venous sites described for pāda-roga and duṣṭa vṛāṇa, performed under strict aseptic precautions, with careful tailoring of blood volume removed according to age, constitution and haemoglobin level and with standard emergency preparedness. The procedure should be embedded within a multidisciplinary limb-salvage framework involving diabetologists, surgeons, Ayurvedic physicians, nurses and podiatrists, ensuring that decisions about debridement, antibiotics, revascularisation and off-loading remain aligned with prevailing best practice. Institutions that wish to adopt this approach should develop standard operating procedures for Sirāvedha in diabetic foot, provide structured training and credentialing for practitioners, and ensure robust documentation of clinical outcomes and adverse events to maintain safety and quality. At the level of patient counselling, clinicians should explain that Sirāvedha is an adjunct aimed at improving local circulation, reducing congestion and supporting wound healing, and emphasise the continued importance of foot hygiene, pressure redistribution, smoking cessation and strict metabolic control. For future work, the present findings justify larger, multicentric and longer-duration trials that include objective measures of perfusion and tissue biology, as well as comparative evaluations of Sirāvedha with other Raktamokṣaṇa modalities such as Jalaukāvaccharaṇa, so that practical protocols can be refined and tailored to different ulcer profiles and resource settings. Overall, this research supports a balanced, integrative and protocol-driven use of Sirāvedha in selected non-healing diabetic foot cases and encourages clinicians and policymakers to recognise its potential as a cost-effective, culturally rooted and scientifically testable component of comprehensive diabetic foot care.

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