Indian Journal of Unani Medicine
Vol. XVIII, Issue 2, July-December, 2025, Pp. **78-84**
ISSN No.: **0974-6065**

https://doi.org/10.53390/IJUM.2025.18203

MANAGEMENT OF QUROOH-E-ASEERUL-INDIMAAL (*NON-HEALING ULCER*) WITH A UNANI FORMULATIONS: AN OPEN-LABEL PILOT STUDY

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Pilot Study

Received: **06.07.2025** Revised: **18.07.2025** Accepted: **31.07.2025**

ABSTRACT

Background: Non-healing ulcers are a significant clinical challenge, often associated with diabetes, peripheral vascular disease, or chronic infection. Conventional treatments are often expensive and prolonged. Unani medicine offers time-tested remedies that may expedite healing naturally.

Objective: To evaluate the efficacy of topical application of Unani formulation composed of *Kundur (Boswellia serrata), Sibr zard* (*Aloe barbadensis), Amba haldi* (*Curcuma aromatic), Gulnar (Punica granatum Linn), Mur maki (Comiphora myrrh)* and *Mazoo (Quercus infectoria*) and Raw Meshed Papaya (Carica papaya) in managing non-healing ulcers.

Methods: A single-arm open-label clinical study was conducted on 30 patients for 45 days. The Unani formulation was applied topically and healing was assessed using wound surface area reduction, granulation tissue formation, and pain reduction.

Results: 73.3% improvement seen at the end of 45 days of the study ($P < 0.001$).

Conclusion: The studied Unani formulations demonstrated potential as a cost-effective, safe, and efficacious treatment for non-healing ulcers.

No. of Pages: 7 **No. ot Tables: 4** **No. of Figures: 7** **References: 14**

Keywords: Unani medicine, *Qurooh-e-Aseerul-Indimaal*, Non-healing ulcer, *Zaroor*, Unripe Papaya, honey and wound healing.

1. Introduction

Chronic or non-healing ulcers are wounds that fail to proceed through an orderly and timely reparative process. They affect millions globally, especially among diabetics and those with peripheral arterial disease (PAD). Non-healing ulcers increase morbidity and can lead to amputation if left untreated [1]. The Literature of Unani system medicine, describes the *Quruh* (ulcers) and *Qurooh-e-Aseerul-Indimaal* (non-healing ulcer) and recommends numbers of formulations for *Tahleel* (cleansing) and *Taqwiyat-e-Laham* (tissue regeneration) [2]. Non-Healing Ulcer can be treated efficiently with the Unani drugs having *Mundammil-e-Qurooh* (healings drugs), *Mujaffif* (desiccant), *Khatim* (siccative), *Muhallil* (Anti-inflammatory) and *Daaf-e-Taaffun* (antimicrobial) actions [8,9]. This study aims to clinically evaluate the effectiveness of a Unani-based topical formulation in healing chronic ulcers.

2. MATERIALS AND METHODS

2.1 Study Design and Setting:

- A prospective, open-label pilot study

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conducted in the Department of Ilmul Jarahat (Surgery) at HSZH Government (auto.) Unani Medical College & Hospital, Bhopal, MP.

2.2 Inclusion Criteria:

- Age 18–60 years
- Non-healing ulcer for more than 6 weeks

2.3 Exclusion Criteria:

- Ulcers with active gangrene
- Immunocompromised patients
- Pregnant/lactating women
- Not willing to participate.

2.4 Intervention:

Local Treatment:

- Topical application of Test drug comprising of *Kundur (Boswellia serrata), Sibr zard* (*Aloe barbadensis), Amba haldi* (*Curcuma aromatic), Gulnar (Punica granatum Linn), Mur maki (Comiphora myrrh) and Mazoo (Quercus infectoria*) in a form of fine powder called as "zaroor" in USM dialect.
- Dressing of ulcer with Mashed unripe papaya and honey for De-sloughing.
- Wound cleansing with lukewarm *Zarishk* decoction
- Surgical debridement to remove dead and devitalized tissue

Methods of dressing

- The patients were screened on the basis of inclusion and exclusion criteria to obtain the sample Size **(**n=30).
- The Protocol of the study was followed up to 45 days.
- Informed written consent was obtained from every patient before the enrolment in the study.
- Initially the Dressing was done with Mashed unripe papaya and honey for the purpose of De-sloughing once healthy granulation tissue appeared on ulcer floor the dressing changed to second Test drug comprising of *Kundur (Boswellia serrata), Sibr zard* (*Aloe barbadensis), Amba haldi* (*Curcuma aromatic), Gulnar (Punica granatum Linn), Mur maki (Comiphora myrrh) and Mazoo (Quercus infectoria*) in a form of fine powder called as "*Zaroor*" in USM dialect.
- The test drug was dusted over the wound and dressings changed on every next day and fresh dressing done subsequently.
- Cleaning of the wound was done with lukewarm *Zarishk* decoction.
- The Debridement of the wound was done as per the need to remove the dead and devitalized tissue.
- Assessment was done on every 15th day of the study i.e. on 0th day, 15th day, 30th day, 45th day of the study.

2.5 Evaluation Parameters:

- Ulcer size reduction (in cm^2)
- Granulation tissue presence
- Duration of epithelialization
- Wagner's grade of ulcer
- Pain score (VAS)

Method of calculation of wound area

- To measure the wound area, tracing paper was placed over the wound to outline its size and shape.
- The tracing was then transferred onto the graph paper, where the longest length and widest breadth of the wound were measured in centimeters.
- The total wound area (in cm^2) was calculated by multiplying the maximum length by the maximum breadth.

Method of calculation of granulation

- Healthy red granulation tissue was considered as a positive healing indicator.
- Its area was determined by multiplying the maximum length and width of the healthy granulation region.
- The percentage of granulation tissue was obtained by dividing the granulated area by the total wound area, then multiplying by 100.

Method of calculation of epithelialisation

- The area of new epithelial growth was determined by subtracting the current wound area from the wound area recorded during the previous assessment.
- The percentage of epithelialization was calculated by dividing the new epithelialized area by the previous wound area and multiplying the result by 100.

Method of calculation of pain

- The pain was calculated at different point of time with help of Pain score (VAS)

2.6 Statistical Analysis:

- Data analyzed using paired t-test; $p < 0.05$ considered significant.

3. Results

RESULT

At the beginning of the study, all 30 patients presented with non-healing ulcers. Within the first 15 days, all patients showed a positive response to the treatment and their ulcers progressed into the healing phase. By the end of day 30, complete healing was observed in 9 patients (30%), while the remaining 21 patients (70%) continued to show signs of healing. By the end of the 45-day, 21 patients (70%) had fully healed ulcers, and the remaining 9 patients (30%) were still in the healing process. Initially, 25 patients (83.3%) had Wagner's grade-II ulcers and 5 patients (16.7%) had grade-I ulcers. After treatment, 21 patients (70%) had improved to grade-0 ulcers, and 9 patients (30%) had grade-I ulcers. This shift corresponded to an 83.3% improvement by day 45 ($P < 0.001$).

The mean ulcer size before treatment was 56.18 ± 91.86 cm^2, which significantly reduced to 9.60 ± 21.10 cm^2 after treatment. Most patients experienced healing between days 25 and 40, with the average healing time recorded as 31.29 ± 9.02 days. The average percentage of healthy granulation tissue at baseline was 35.16 ± 30.11%, which increased to 99.64 ± 1.50% by day 45. Epithelization also showed marked improvement, rising from a baseline of 0.57 ± 3.11% to 86.82 ± 23.40% at the end of the study. Overall, a statistically significant improvement of 73.3% was observed by day 45 ($P < 0.001$).The average duration of symptoms among participants was 22.03 ± 36.86 months.

Table 1: Area of wound (in cm^2) at different point of time.

Area of wound(in cm^2)	Before Treatment	After Treatment	Day '0'	Day '15'	Day '30'	Day '45'	% difference
0	0 0%	21 -70%	0 0%	0 0%	12 -40%	21 -70%	70.00%
Jan-20	13 -43.30%	4 -13.30%	13 -43.30%	21 -70%	11 -36.70%	4 -13.30%	-30.00%
21-40	6 -20%	2 -6.70%	6 -20%	3 -10%	3 -10%	2 -6.70%	-3.30%
41-60	3 -10%	1 -3.30%	3 -10%	2 -6.70%	0 0%	1 -3.30%	-6.70%
61-80	3 -10%	1 -3.30%	3 -10%	1 -3.30%	1 -3.30%	1 -3.30%	-6.70%
81-100	0 0%	1 -3.30%	0 0%	0 0%	1 \(3.3%)	1 -3.30%	3.30%
>100	5 -16.70%	0 0%	5 -16.70%	3 -10%	2 -6.70%	0 0%	-16.70%
Total	30 -100%	30 -100%	30 -100	30 -100	30 -100	30 -100%	-
The value of P<0.001: highly Significant, Paired proportion test used, 70% Improvement							

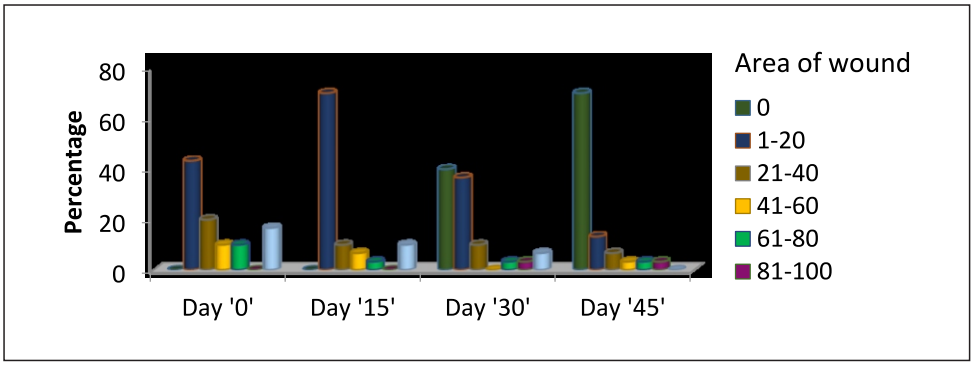

Figure 1: Area of wound (in cm^2) at different point of time.

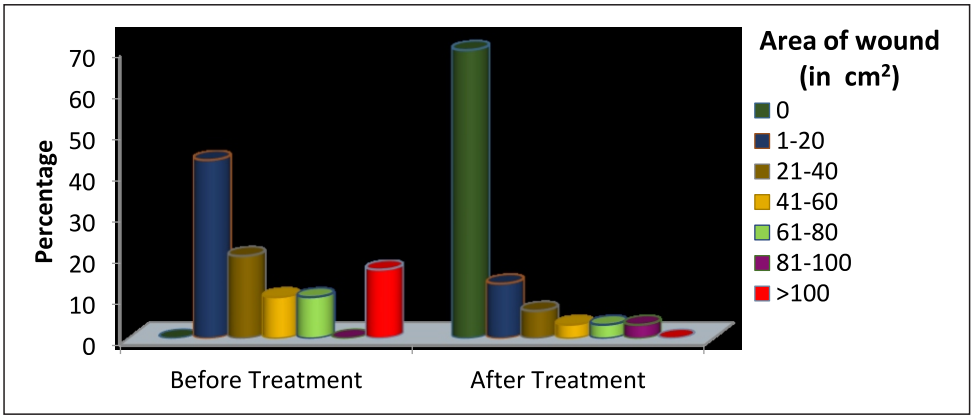

Figure 2: Area of wound.

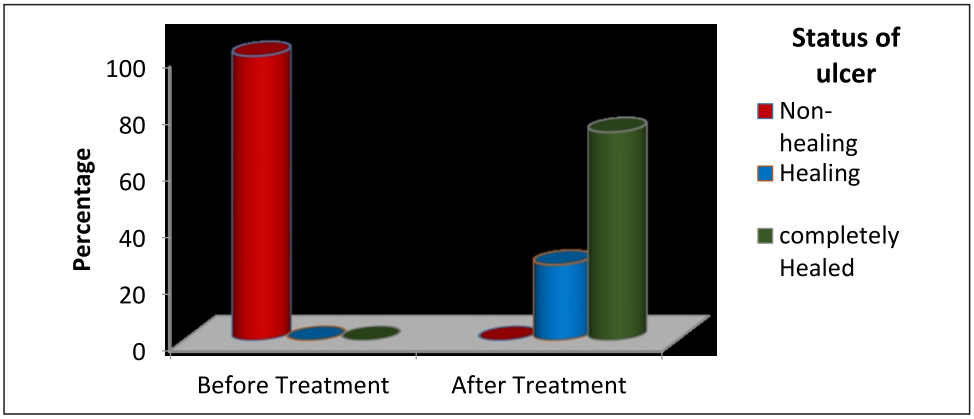

Figure 3: Status of ulcer

Table 2: Mean of healthy Granulations tissue (%) at different point of time.

	Min-Max	Mean ± SD
Before Treatment	0.00-91.25	35.16±30.11
After treatment	92.30-100.00	99.64±1.50
Day 0	0.00-91.25	35.16±30.11
Day 15	25.53-100.00	89.74±17.08
Day 30	42.00-100.00	95.09±12.45
Day 45	92.30-100.00	99.64±1.50

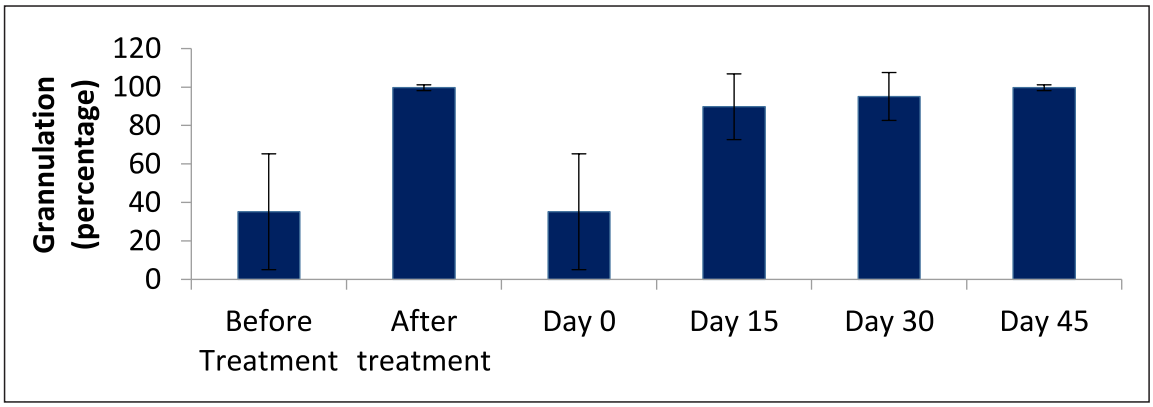

Figure 4: Mean Granulations tissue (percentage) at different point of time.

Table 3: Mean Epithelization (percentage) at different point of time.

Epithelization (percentage)	Min-Max	Mean ± SD
Before Treatment	0.00-17.05	0.57±3.11
After treatment	31.09-100.00	86.82±23.40
Day 0	0.00-17.05	0.57±3.11
Day 15	11.11-80.95	51.63±20.05
Day 30	11.66-100.00	65.11±29.37
Day 45	31.09-100.00	86.82±23.40
The P value < 0.0001: highly significant		

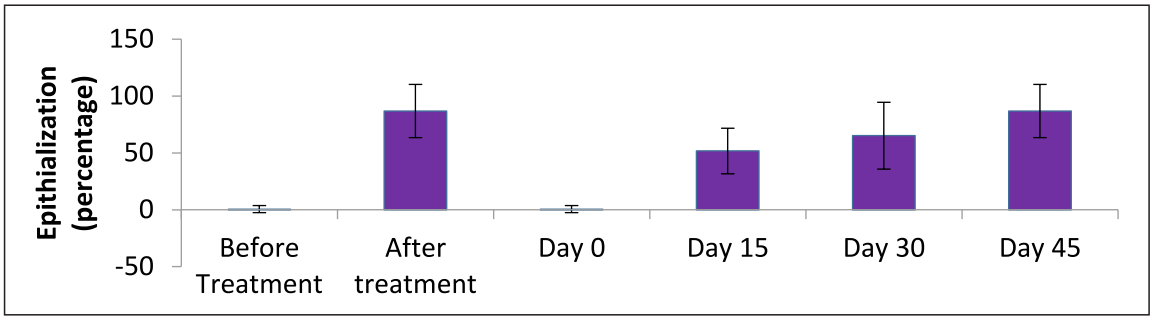

Figure 5: Epithelization.

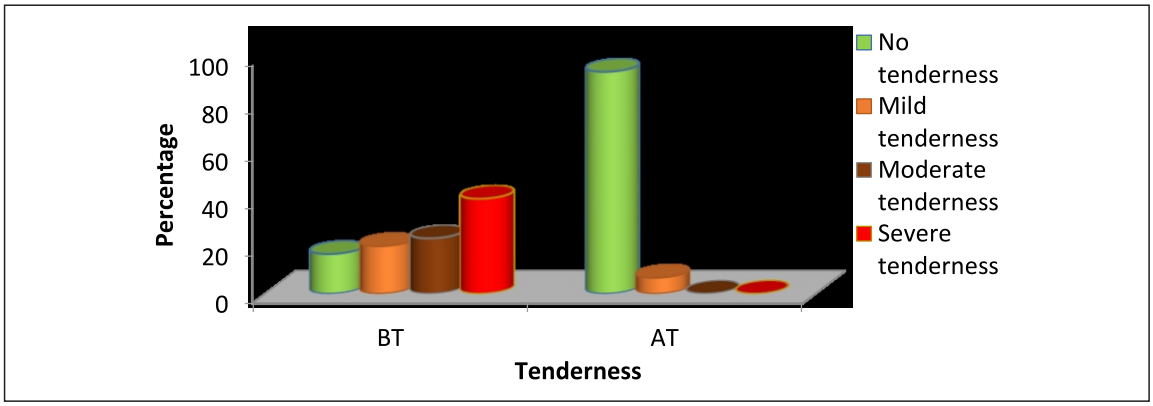

Figure 6: Tenderness Before and after the treatment.

Table 4: Days of relief in pain.

Days of relief in pain	No. of patients	%
<12	12	40.0
12-24	14	46.7
>24	4	13.3
Total	30	100.0

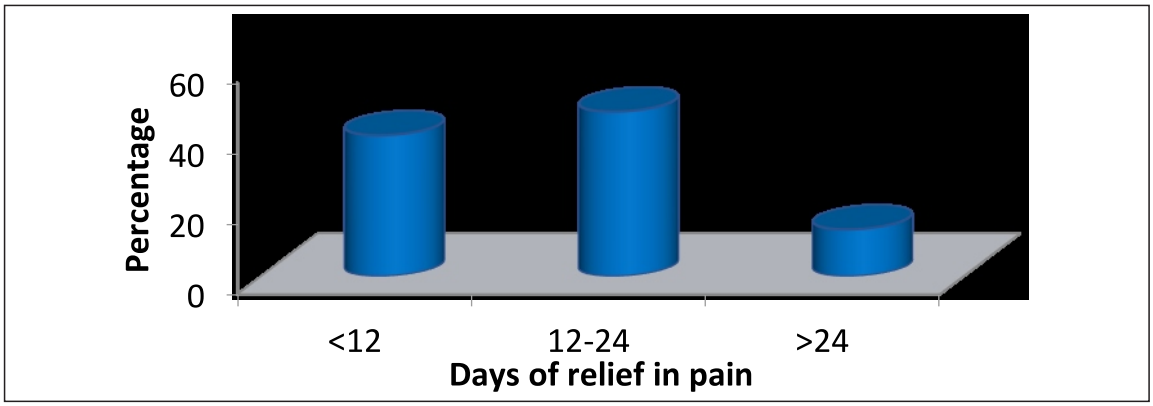

Figure 7: Days of relief in pain.

4. Discussion

The efficacy of the test drugs in this study aligns with Unani principles of *Tanqiya*, *Tahleel*, and *Taqwiyat-i-Mizaj*. [8]. The wound healing effects of this formulation can be attributed to the combined actions of its constituent drugs, which possess properties such as *Muhallil* (anti-inflammatory), *Daf-i-Ta'ffun* (antimicrobial), *Mujaffif* (desiccant), *Mundamil-i-Qurooh* (wound healing), and *Munmbit-i-Leham* (flesh-forming). These therapeutic actions are largely due to the presence of phytoconstituents like curcumin (known for its anti-inflammatory properties), as well as monoterpenoids, sesquiterpenoids, and curcuminoids (which exhibit antimicrobial, antioxidant, and free radical scavenging activities). Additionally, compounds such as heerabolene, eugenol, furanosequiterpenes, monoterpenes, tannins, terpenoids, sterols, and flavonoids contribute to cytoprotective, anti-inflammatory, antioxidant, and tissue healing effects [9,10]. *Carica papaya* contains papain, a proteolytic enzyme that breaks down necrotic tissue without harming viable tissues. It works by cleaving peptide bonds in denatured proteins, making it easier to remove slough and promote a clean wound bed, which is essential for effective healing.[11,12]. Papain, not only clears the wound bed but also stimulates fibroblast activity. Flavonoids, saponins, and alkaloids in papaya that enhance angiogenesis, collagen synthesis, and fibroblast proliferation. [13.14].

Conclusion

The Unani formulation showed promising results in managing non-healing ulcers with no side effects. It may serve as a viable, cost-effective alternative or adjunct to modern wound care therapies.

Limitations

The limitations include small sample size and lack of control group. Further randomized controlled trials are required.

Conflict of interest: There exist no conflict of interest amongst the authors.

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