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AN OPEN LABEL SINGLE ARM CLINICAL STUDY TO EVALUATE THE EFFICACY OF RAW PAPAYA CRUSH DRESSING IN WOUND BED PREPARATION OF ZAKHME BISTARI (BED SORE / PRESSURE ULCER)

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ABSTRACT

Zakhme Bistari (bed sore/pressure ulcer) is a chronic wound commonly associated with prolonged pressure, immobility and impaired tissue perfusion. Effective wound-bed preparation requires removal of slough and devitalized tissue, control of microbial burden, maintenance of moisture balance and promotion of healthy granulation and epithelialization. Raw papaya (Carica papaya Linn.) contains proteolytic enzymes, particularly papain and chymopapain, which provide a rationale for its use as a biological debridement agent. An open-label, single-arm clinical study was conducted among patients with Zakhme Bistari selected from the OPD and IPD of the Department of Ilmul Jarahat. Forty patients were enrolled considering possible dropouts, of whom 30 were included for statistical analysis. Convenience sampling was used and the study duration was 45 days. Patients were assessed using subjective parameters including slough/exudate, dead skin, wound length and width, and inflammation. Objective assessment included detailed history, general physical examination and the Pressure Ulcer Scale for Healing (PUSH). The PUSH score was calculated based on wound surface area, exudate amount and wound tissue type. Among the 30 patients analyzed, 18 (60%) were male and 12 (40%) were female. Slough was absent in 40.0% of patients initially and increased to 83.3% by Visit 6; the improvement was statistically highly significant at Visits 5 and 6 ($p=0.001$). Mean wound size decreased progressively from 8.59 ± 6.30 cm² at baseline to 0.78 ± 0.61 cm² at Visit 6, corresponding to a mean reduction of 91.44%; the reduction was statistically significant from Visit 1 onward ($p=0.009$ at Visit 1 and $p=0.001$ at subsequent visits). The study findings indicate that raw papaya dressing may be beneficial for wound-bed preparation and healing of Zakhme Bistari, particularly in reducing slough and wound size and supporting progression toward healthy granulation and epithelialization. Its potential advantages include simplicity, accessibility and low cost. However, the findings should be interpreted cautiously because the study was open-label, single-arm, had a limited sample size and used convenience sampling. Larger controlled and multicentric studies are recommended to establish its efficacy, safety and comparative effectiveness.

KEYWORDS: Zakhme Bistari; Pressure Ulcer; Bed Sore; Carica papaya; Raw Papaya Dressing; Papain; Chymopapain; Wound Bed Preparation; Debridement; Unani Medicine.

I. INTRODUCTION OF ZAKHME BISTARI (BED SORE / PRESSURE ULCER)

Pressure ulcers, also known as bed sores or decubitus ulcers, are localized injuries to the skin and underlying tissues caused mainly by prolonged pressure, friction, and shear, particularly over bony prominences. They are a major healthcare concern among bedridden, elderly, critically ill, and immobilized patients. Prolonged pressure compromises capillary blood flow, resulting in ischemia, hypoxia, cellular damage, and tissue necrosis. Common sites include the sacrum, heels, greater trochanters, malleoli, and occiput. Several factors increase the risk of pressure ulcers, including immobility, advanced age, malnutrition, neurological disorders, incontinence, poor circulation, diabetes mellitus, and prolonged hospitalization. Pressure ulcers contribute significantly to pain, infection, delayed healing, psychological distress, prolonged hospital stays, increased healthcare costs, and reduced quality of life. Clinically, pressure ulcers are classified according to the depth and severity of tissue damage, ranging from Grade I, characterized by non-blanchable erythema of intact skin, to Grade IV, involving extensive tissue destruction with possible exposure of muscle, tendon, or bone. Severe ulcers may result in complications such as infection, osteomyelitis, septicemia, and delayed wound healing. Effective management requires proper wound-bed preparation, including removal of necrotic tissue and control of bacterial load and exudate. Debridement may be performed using surgical, mechanical, autolytic, biological, or enzymatic methods. Conventional management also includes pressure redistribution, regular repositioning, nutritional support, wound cleansing, appropriate dressings, infection control, and surgical reconstruction when necessary. Despite advances in wound care, prolonged healing, recurrence, infection, and high treatment costs remain challenges. Therefore, there is growing interest in safe, affordable, accessible, and effective treatment alternatives, including therapies derived from traditional systems of medicine.[1-3]

Unani medicine provides a traditional framework for understanding and managing wounds, known as **Zakhm**. A bed sore or pressure ulcer is described as Zakhm-e-Bistari**,** associated with prolonged recumbency and continuous pressure, leading to tissue damage, redness, and ulcer formation. Traditional Unani management emphasizes prevention through frequent repositioning, maintenance of cleanliness and hygiene, and appropriate local applications**.**

In Unani philosophy, chronic wounds may be associated with the accumulation of **Madda (morbid matter)** and weakening of Quwwat-e-Mudabbira-e-Badan**,** the body's natural regulatory and healing power. Wound management therefore focuses on removing unhealthy or necrotic tissue, controlling inflammation, cleansing the wound, and promoting healthy granulation and tissue repair. Topical agents possessing Mujaffif (drying), Jali (cleansing), and Mohallil-e-Awram (anti-inflammatory) properties are traditionally considered useful in wound care. Overall, the Unani approach to **Zakhm-e-Bistari** combines preventive measures, local wound care, and restoration of the body's healing capacity. These traditional principles may provide a basis for investigating accessible and cost-effective Unani interventions for pressure-ulcer management.[111-19]

II. Papaya in the treatment of of Zakhme Bistari (bed sore / pressure ulcer)

Papaya (Carica papaya Linn.), known as **Papita** in Unani medicine, is an important medicinal plant recognized for its diverse therapeutic properties. It is described as having a third-degree temperament (Mizaj) of Haar Yabis (Hot and Dry)**.** Its traditional pharmacological properties include Mujaffif (drying), Jali (cleansing/detergent), Mohallil-e-Awram (anti-inflammatory), Tiryaq-e-Samoom (antidotal), Mukharrij-e-Balgham (expectorant), and Habis-ud-Dam (anti-hemorrhagic) activities.

These properties suggest that papaya may have considerable potential in **wound management**, particularly through cleansing the wound, reducing inflammation and excessive moisture, controlling bleeding, and supporting the healing process. Therefore, Carica papaya may be considered a promising traditional therapeutic agent for the management of **Zakhm (wounds) and Zakhm-e-Bistari (bed sores)**.[5-7]

Scientific studies have identified several biologically active constituents in **papaya (Carica papaya Linn.)**, including papain, chymopapain, carpaine, fibrin, and lycopene. Among these, papain and chymopapain are important proteolytic enzymes that can facilitate the breakdown and removal of necrotic or devitalized tissue while helping preserve viable tissue. This enzymatic debridement assists in wound cleansing and preparation of the wound bed, thereby supporting tissue repair.

Papaya has also demonstrated potential anti-inflammatory, antimicrobial, antioxidant, and wound-healing properties**.** Green papaya and papain-containing preparations have been investigated for their ability to reduce slough and microbial contamination, promote granulation tissue formation, and support re-epithelialization. Papaya-based preparations have been studied in the management of burns, diabetic foot ulcers, infected wounds, and chronic wounds**.** Overall, the proteolytic and other biological activities of papaya may contribute to effective wound-bed preparation, removal of devitalized tissue, reduction of inflammation and microbial burden, and promotion of tissue regeneration, providing a scientific basis for further investigation of papaya in the management of pressure ulcers.[14-17]

From the **Unani perspective**, the de-sloughing action of papaya can be correlated with the removal of **Wizr (slough)**, which is considered an impediment to normal

wound healing. Classical Unani scholars, including **Ibn-ul-Quff**, emphasized the importance of removing unhealthy tissue and morbid substances to facilitate restoration of normal tissue structure. The debriding activity of papaya may therefore be conceptually aligned with traditional Unani principles of wound management by helping remove devitalized tissue and supporting healthy granulation.

Raw papaya dressing may offer several practical advantages over conventional debridement methods. It is potentially inexpensive, readily available, simple to prepare, non-invasive, & generally well tolerated**.** Its accessibility may be particularly valuable in resource-limited healthcare settings where advanced wound-care facilities are not readily available. Thus, raw papaya dressing represents a potentially useful traditional approach for wound-bed preparation & management of pressure ulcers, its clinical efficacy and safety should be established through well-designed clinical studies.[15-19]

The present dissertation on Zakhm-e-Bistari (pressure ulcers/bed sores) highlights the continuing clinical burden of pressure ulcers and the need for safe, affordable, accessible, and effective wound-care approaches. The study explored the role of raw papaya (**Carica papaya** Linn.) dressing as a traditional Unani-based approach for wound-bed preparation, particularly for the removal of slough and devitalized tissue and promotion of healthy granulation.

The findings of the study, supported by the principles of **Unani medicine** and available modern scientific evidence, suggest that papaya dressing may facilitate de-sloughing, reduction of unhealthy tissue, improvement in wound condition, and progression toward healthy granulation and healing**.** Its proteolytic enzymes, particularly papain and chymopapain, provide a plausible scientific basis for its debridement activity. The approach is also relatively simple, inexpensive, and potentially suitable for resource-limited healthcare settings.

The present study therefore indicates that raw papaya dressing may be a promising adjunct in the management of pressure ulcers and wound-bed preparation. However, because the study was an open-label, single-arm clinical study with a limited sample size and convenience sampling, the findings should be interpreted cautiously. Larger, controlled, and multicentric clinical trials with standardized papaya preparations and longer follow-up are recommended to establish its efficacy, safety, optimal dosage, and comparative effectiveness against established wound-care modalities.

III. AIM AND OBJECTIVES

To evaluate the efficacy of raw Papaya dressing in healing of **Zakhme bistari** (Bed sore) & provide effective and easy treatment, easily available and economically cost-effective.

IV. Historical Background of Pressure Ulcers

Pressure ulcers are among the oldest documented pathological conditions, with evidence suggesting that pressure-related tissue injury and the consequences of prolonged immobility were recognized as early as ancient civilizations. Findings from Egyptian mummified remains indicate the presence of tissue injuries consistent with prolonged pressure. In classical Greek medicine, **Hippocrates (Buqrat)** and other physicians recognized ulcerative lesions in bedridden patients and emphasized hygiene, pressure relief, appropriate positioning, nutrition, and favorable environmental conditions.

During the **Greco-Arab and Unani periods**, the understanding of chronic wounds developed further under the broader concept of **Zakhm**. Unani scholars associated delayed wound healing with the accumulation of harmful substances, humoral imbalance, and impaired natural healing capacity. Important physicians contributed significantly to wound-care concepts: **Galen (Jalinoos)** emphasized humoral balance and tissue healing; **Ibn Sina (Avicenna)** described wound assessment, cleanliness, nutrition, contamination prevention, and appropriate dressings; and **Ibn al-Quff** emphasized cleansing wounds and removing unhealthy tissue, concepts that closely resemble modern wound-bed preparation and debridement.

During the **Renaissance**, clinical observations increasingly established the relationship between prolonged immobility, continuous pressure, and ulcer formation, particularly over bony prominences. In the **19th century**, the ischemic theory became prominent, proposing that sustained external pressure compresses blood vessels, reduces tissue perfusion and oxygenation, and ultimately causes tissue necrosis.

During the **20th century**, research demonstrated that pressure-ulcer development is more complex than ischemia alone. Modern understanding incorporates multiple mechanisms, including sustained pressure, shear stress, friction, reperfusion injury, and cellular deformation**.** These mechanisms may interact to produce both superficial and deep tissue injury. As scientific knowledge progressed, standardized pressure-ulcer staging and classification **systems** were developed to improve diagnosis, communication, treatment planning, and monitoring. Contemporary management has subsequently evolved into **a** multidisciplinary and preventive approach**,** involving physicians, nurses, surgeons, rehabilitation professionals, nutritionists, and wound-care specialists.

Overall, the historical development of pressure-ulcer management reflects a transition from traditional observations and basic pressure-relief measures to a scientifically informed, evidence-based approach emphasizing early risk assessment, pressure redistribution, repositioning, nutritional optimization, skin surveillance, wound-bed preparation, and

comprehensive multidisciplinary care**.** This evolution also demonstrates how several principles described in classical Unani medicine, particularly wound cleansing, removal of unhealthy tissue, and maintenance of favorable conditions for healing, have conceptual parallels with modern wound-care practices.[20-23]

V. Epidemiology and Prevalence

Table No. 01: Global Prevalence.[24-25]

Healthcare Setting	Major Risk Factors	Clinical Importance / Preventive Measures
Acute Care Hospitals	Prolonged bed rest, restricted mobility, postoperative recovery, use of medical devices, and severity of illness	Hospital-acquired pressure ulcers are important indicators of quality of care. Regular risk assessment, repositioning, skin monitoring, pressure redistribution, and multidisciplinary preventive care are essential.
Intensive Care Units (ICUs)	Prolonged immobilization, mechanical ventilation, sedation, hemodynamic instability, reduced tissue oxygenation, and medical devices	Critically ill patients are at particularly high risk. Continuous skin assessment, early preventive interventions, pressure-relieving surfaces, nutritional support, and frequent repositioning are important.
Rehabilitation Centers	Temporary or permanent mobility limitations following major surgery, trauma, stroke, neurological disorders, or spinal cord injury	Reduced mobility can result in prolonged pressure exposure. Individualized repositioning, mobility training, pressure redistribution, skin surveillance, and rehabilitation are required.
Long-Term Care Facilities	Advanced age, multiple comorbidities, cognitive impairment, dependence in activities of daily living, and chronic immobility	Prevention should be incorporated into routine long-term care through regular risk assessment, repositioning, nutritional optimization, skin care, and caregiver education.
Home-Based Care	Inadequate repositioning, limited caregiver support, delayed recognition of skin changes, chronic disability, and limited access to specialized wound-care services	Elderly and chronically disabled patients require caregiver education, regular skin inspection, appropriate positioning, pressure-relieving devices, nutritional support, and timely referral when wounds develop.

Table No. 02: Global prevalence of Hospital-acquired pressure ulcers Hospital-acquired pressure ulcers remain one of the most frequent preventable complications among immobilized patients.[25]

Setting	Approximate Prevalence
Acute hospitals	5–15%
ICU patients	15–40%
Long-term care	10–25%
Neurological rehabilitation	up to 30%

VI. Indian Prevalence and High-Risk Population Groups

Table No. 03: Indian Prevalence and High-Risk Population Groups.[27]

Parameter / Population Group	Description / Risk Factors	Clinical Significance
Indian prevalence	Studies from India indicate a prevalence of approximately **8–18%** among hospitalized high-risk populations, with potentially higher rates in intensive care settings.	Highlights the significant burden of pressure ulcers in Indian healthcare settings.
Elderly people	Reduced skin elasticity, decreased subcutaneous tissue, impaired microcirculation, delayed wound healing, chronic diseases, malnutrition, prolonged bed rest, and functional dependency.	One of the most vulnerable groups for pressure-related tissue injury.
Patients with paraplegia	Severe mobility restriction and reduced or absent sensation below the level of spinal injury; inability to reposition independently.	Prolonged pressure over bony prominences can occur without the patient recognizing discomfort.
Unconscious patients	Loss of pain perception, inability to move spontaneously, prolonged immobilization, dependence on caregivers, and use of medical devices.	Very high risk because protective movement and sensory responses are absent.
Post-operative patients	Prolonged immobility during and after surgery, anesthesia, reduced circulation, postoperative pain, restricted	Increased risk of pressure injury during hospitalization and

	movement, and delayed recovery.	postoperative recovery.
Patients with long-term neurological disorders	Muscle weakness, impaired sensation, restricted mobility, functional dependency, and reduced ability to reposition independently.	Chronic neurological impairment substantially increases pressure-ulcer risk.

VII. ETIOLOGY AND RISK FACTORS

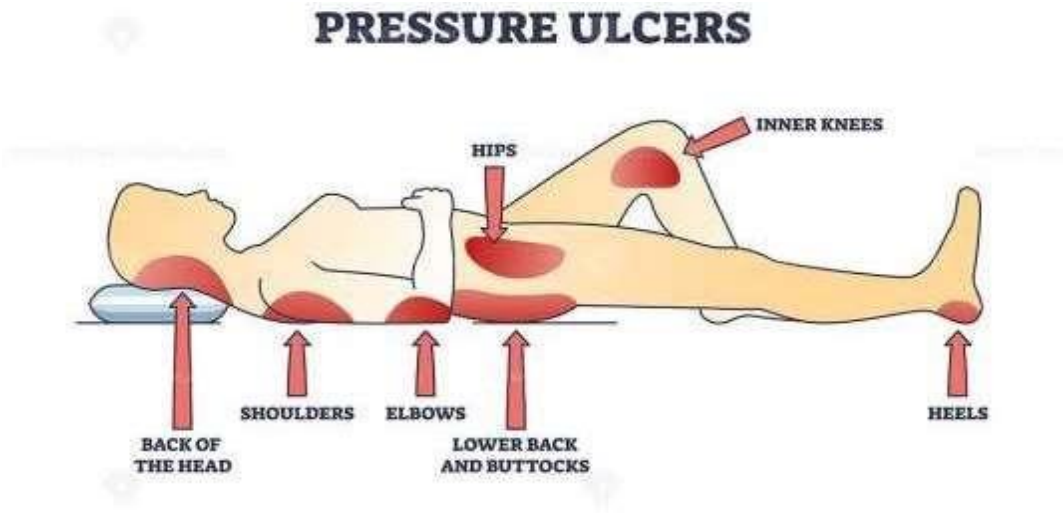
Table No. 04: Etiology And Risk Factors.[28]

Intrinsic Factor	Effect / Mechanism	Contribution to Pressure Ulcer Formation
Age	Aging causes reduced dermal thickness, decreased collagen synthesis, reduced elasticity, and diminished regenerative capacity.	Makes the skin more fragile and less tolerant of prolonged pressure.
Poor Nutrition	Protein deficiency and inadequate nutritional intake impair tissue repair.	Causes delayed epithelialization, reduced angiogenesis, impaired collagen formation, and delayed wound healing.
Vascular Disease	Peripheral vascular disease and impaired circulation reduce blood flow to tissues.	Decreases oxygen and nutrient delivery, increasing tissue ischemia and necrosis.
Diabetes Mellitus	Hyperglycemia causes vascular impairment, neuropathy, and reduced wound-healing capacity.	Delays tissue repair and increases susceptibility to pressure-related injury and infection.
Neurological Disorders	Neurological disease may cause sensory loss, paralysis, muscle weakness, and impaired mobility.	Patients may not recognize painful pressure or be able to reposition themselves adequately.
Reduced Mobility	Inability to change position independently leads to prolonged pressure over bony prominences.	Increases duration and intensity of tissue loading and consequently increases ulcer risk.
Sensory Impairment	Reduced sensation diminishes awareness of pain or discomfort caused by prolonged pressure.	Delays protective repositioning and allows tissue damage to progress.

VIII. Pathophysiology and Mechanism of Bed sore

Table no. 05 Pathophysiology and Mechanism.[29-30]

Pathophysiological Mechanism	Major Process	Result / Effect
Ischemia theory	Prolonged external pressure compresses capillaries and reduces microcirculation.	Decreased oxygen and nutrient supply → tissue hypoxia → cellular damage and necrosis.
Hypoxia and ATP depletion	Reduced blood flow decreases oxygen availability and aerobic metabolism.	Reduced ATP production, impaired cellular function, membrane transport abnormalities, and cellular injury.
Acidosis	Oxygen deficiency causes a shift from aerobic to anaerobic metabolism with lactic acid accumulation.	Reduced tissue pH and worsening cellular dysfunction.
Ischemia–reperfusion injury	Restoration of blood flow after prolonged ischemia generates oxidative and inflammatory responses.	Reactive oxygen species (ROS), endothelial injury, inflammation, microvascular dysfunction, and secondary tissue destruction.
Cell deformation theory	Excessive mechanical stress directly deforms cells and disrupts their structure and function.	Membrane disruption, cytoskeletal collapse, mitochondrial dysfunction, and apoptosis.
Lymphatic obstruction	Pressure compresses lymphatic vessels and reduces lymphatic drainage.	Edema, accumulation of metabolic waste and inflammatory products, and delayed healing.
Tissue necrosis	Prolonged mechanical loading causes persistent ischemia, inflammation, and irreversible cellular injury.	Progressive tissue death and formation of pressure ulcers.
Inflammation	Damaged and dead cells release inflammatory mediators that attract immune cells.	Increased vascular permeability, edema, persistent inflammation, and additional tissue damage.



IX. Clinical feature and Complication

Table No. 06: Clinical feature and Complication.[33]

Stages	Clinical Features	Major Complications
Early stage	Non-blanchable erythema, local warmth, edema and pain/tenderness	Progression to tissue damage
Intermediate stage	Skin breakdown, exudation, slough and partial/full-thickness tissue loss	Local infection, cellulitis, delayed healing
Advanced stage	Deep tissue destruction, necrosis, extensive ulceration and possible sinus formation	Abscess, osteomyelitis, septicemia, delayed rehabilitation and increased mortality

X. CONCEPT OF ZAKHM (WOUND) IN UNANI MEDICINE

In traditional **Unani** medicine, the idea of wound care plays a significant role. Under **Ilmul Jarahat** (Science of Surgery), **Unani** academics talked about wounds and saw wound healing as a combination of the body's natural healing ability (**Tabiyat**) and a doctor's logical therapeutic intervention (**Tabib**). **Zakhm** refers to the interruption of tissue continuity (**Inqita-e-Ittisal**) caused by either internal or external factors in classical writings.[34] According to **Unani** medicine, **Tabiyat Mudabbira-e-Badan** (medicatrix naturae) governs healing as a natural biological occurrence. The doctor's job is to promote the body's natural healing process and remove barriers to healing. "When continuity of tissues is interrupted and **Tabiyat** remains capable of restoration, healing occurs through natural reconstruction." This principle resembles modern concepts of tissue repair and regeneration.

XI. CLASSIFICATION OF ZAKHM IN UNANI MEDICINE[35-36]

Table No. 07: classification of Wound (Zakham)

Classification	Meaning	Characteristics
Zakhm-e-Hadith	Acute wound	Fresh wound with preserved healing potential; pain, inflammation and rapid repair
Zakhm-e-Muzmin	Chronic wound	Persistent wound with delayed healing, unhealthy discharge and slough formation; pressure ulcers are closely related to this category
Zakhm-e-Mutaffin	Putrefactive/degenerative wound	Ulcers associated with unhealthy secretions and tissue degeneration
Qurooh	Ulcers	Chronic defects characterized by tissue loss and delayed repair

Table No. 08: Wound Bed Preparation and Debridement.

Topic	Summary
Wound Bed Preparation	A systematic approach to optimize the wound environment, remove barriers to healing, control infection, maintain moisture balance, promote tissue repair and closure.
TIME Principle	**T – Tissue:** removal of necrotic/non-viable tissue. I – Infection/Inflammation: control of microbial burden and excessive inflammation. M – Moisture**:** maintenance of an optimal moist environment. E – Edge: promotion of epithelial migration and advancement of wound edges.
Main Objectives	Removal of necrotic tissue, reduction of microbial burden, maintenance of moisture balance, stimulation of healthy granulation tissue, and promotion of epithelialization.
Slough	Yellow, white or grey material containing fibrin, inflammatory cells, microorganisms and

	devitalized tissue; delays granulation and epithelialization and therefore requires removal.
Necrotic Tissue	Results from ischemia and tissue death due to prolonged pressure; delays healing, increases infection risk and interferes with wound assessment.
Bacterial Biofilm	Organized bacterial colonies within an extracellular matrix that contribute to persistent inflammation and delayed healing; requires wound cleansing and repeated debridement.
Inflammatory Exudate	Excessive wound exudate can contribute to local tissue damage and delayed healing; appropriate wound cleansing and moisture management are important.
Debridement	Essential component of WBP involving removal of necrotic tissue, slough, microorganisms and other debris to improve the wound bed, reduce microbial burden and promote granulation and epithelialization.
Surgical Debridement	Rapid removal of devitalized tissue using scalpels, scissors or curettes; useful for extensive necrosis or infected wounds but may require anesthesia and specialized personnel.
Mechanical Debridement	Physical removal using irrigation, wet-to-dry dressings, hydrotherapy or monofilament pads; effective but may cause pain and potentially remove healthy tissue.
Autolytic Debridement	Uses the body's natural enzymes and moisture, often supported by hydrogels, hydrocolloids or films; selective and relatively painless but slower.
Enzymatic Debridement	Uses proteolytic enzymes to selectively break down necrotic tissue while preserving viable tissue; less invasive and potentially useful in elderly, comorbid and resource-limited patients.
Raw Papaya as Biological Debridement	Unripe Carica papaya contains papain and chymopapain, which can break down denatured proteins and necrotic tissue while supporting wound-bed cleaning, granulation and epithelialization.
Additional Actions of Papaya	The source describes anti-inflammatory, antioxidant, antibacterial and wound-healing properties associated with constituents such as flavonoids, carotenoids, vitamins, alkaloids and phenolic compounds.

XII. Evidence review of Unani remedies in pressure ulcer management with special reference to papaya (carica papaya linn.), Honey and Leech therapy

Table No. 09: Papaya (carica papaya linn).

Aspect	Summary
Botanical identity	Carica papaya Linn., belonging to the family **Caricaceae**.
Traditional wound use	Fresh latex, unripe fruit and other preparations have traditionally been used for burns, traumatic wounds, infected ulcers and chronic wounds.
Wound cleansing	Proteolytic enzymes help break down devitalized tissue and slough, producing a natural **enzymatic debridement** effect and facilitating wound-bed cleaning.
Digestive disorders	Traditionally used as a digestive aid for dyspepsia, indigestion, constipation, stomach discomfort and poor appetite; papain and chymopapain support protein digestion.
Inflammatory conditions	Traditionally used for joint pain, soft-tissue edema, trauma, arthritis and localized inflammation. Its antioxidant and phytochemical constituents are associated with these effects.
Skin disorders	Used traditionally for eczema, acne, ringworm, psoriasis, fungal infections, burns and insect bites. Its antibacterial, antioxidant and exfoliating properties may support removal of damaged tissue and skin regeneration.
Ulcer management	Unripe papaya, latex and fruit pulp have traditionally been used for **pressure ulcers, diabetic foot ulcers, venous ulcers, traumatic wounds and burns**.
Wound-healing actions	The source describes papaya as supporting **slough removal, reduction of microbial burden and inflammation, granulation tissue formation and epithelialization**.

XIII. Papaya in Unani Medicine

Despite not being one of the traditional Greco-Arab medicinal plants, papaya has developed into a significant therapeutic agent in modern **Unani** medicine due to its demonstrated effectiveness in treating chronic wounds. **Tanqiya-e-Quruh** (cleaning of the ulcer), removal of harmful humoral material (**Mawad-e-Fasida**), regulation of inflammation, and encouragement of healthy tissue regeneration (**Indimal-e-Quruh**) are all necessary for effective ulcer treatment in **Unani** medicine. By promoting the enzymatic clearance of necrotic tissue, lowering microbial contamination, enhancing granulation tissue development, and quickening epithelialization, papaya successfully supports these ideas. Therefore, the current concepts of wound bed preparation and biological debridement strongly align with the old **Unani** idea of ulcer cleansing.

Table No. 10: Comparative Summary of Unani Remedies.

Parameter	Papaya	Honey	Leech Therapy
Debridement	Excellent	Mild	Minimal
Antimicrobial	Moderate	Strong	Mild
Granulation	Good	Good	Moderate
Cost	Low	Moderate	Moderate
Ease of Use	High	High	Limited

XIV. MATERIALS AND METHODS

Table No. 11: Material, Method and Parameters.

Parameter	Summary
Study Setting	Patients were selected from the OPD and IPD of the Department of Ilmul Jarahat.
Ethical Consent	Informed consent was obtained from patients before commencement of the study.
Study Design	Open-label clinical study.
Sample Size	**40 patients** were enrolled, considering possible dropouts; **30 patients** were included for statistical analysis.
Sampling Technique	Convenience sampling.
Study Duration	**45 days**.
Inclusion Criteria	Diagnosed cases of **Zakhme Bistari (bed sore)** based on history, clinical presentation and general physical examination; patients of any age and either gender; mentally fit patients able to provide written consent.
Exclusion Criteria	Patients sensitive to papaya; patients with specified systemic conditions such as uncontrolled diabetes mellitus, malignant ulcer, anemia, acute fever, convulsions and hematological disorders including AIDS/hepatitis; patients unwilling to follow the study protocol; mentally retarded patients.
Withdrawal Criteria	Development of an adverse effect/allergy; failure to follow the prescribed treatment schedule or attend follow-up for dressing.
Subjective Parameters	Slough/exudate, dead skin, wound length and width, and inflammation.
Objective Parameters	Detailed history, general physical examination and **PUSH Scale** assessment.

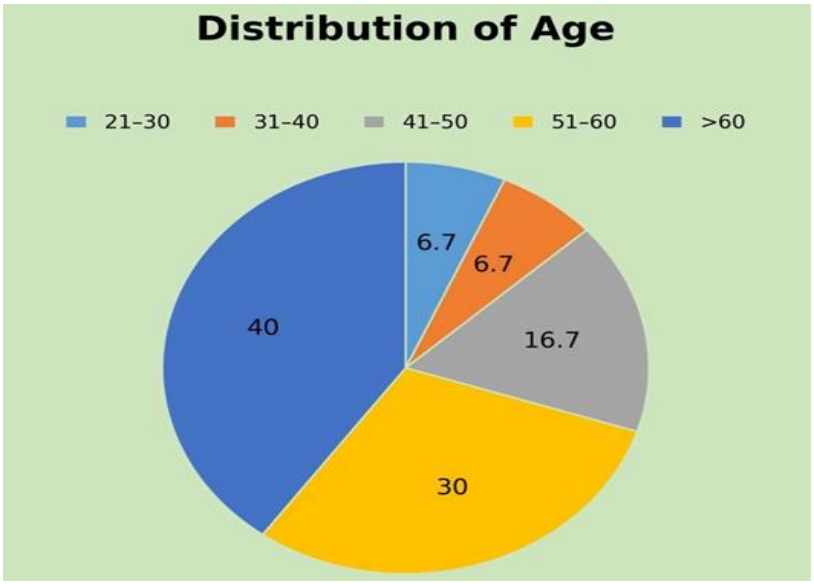
Table No. 12: Push Scale.

LENGTH X WIDTH (in cm2)	**0** **0**	**1** **<0.3**	**2** **0.3-0.6**	**3** **0.7-1.0**	**4** **1.1-2.0**	**5** **2.1-3.0**	**Sub-score**
		6 3.1-4.0	7 4.1-8.0	8 8.1-12.0	9 12.1-24.0	10 >24.0	
EXUDATE AMOUNT	0 None	1 Light	2 Moderate	3 Heavy			Sub-score
TISSUE TYPE	0 Closed	1 Epithelial Tissue	2 Granulation Tissue	3 Slough	4 Necrotic Tissue		Sub-score
TOTAL SCORE							

XV. OBSERVATIONS AND RESULTS

Table no. 13: Age distribution of cases studied (n=30).

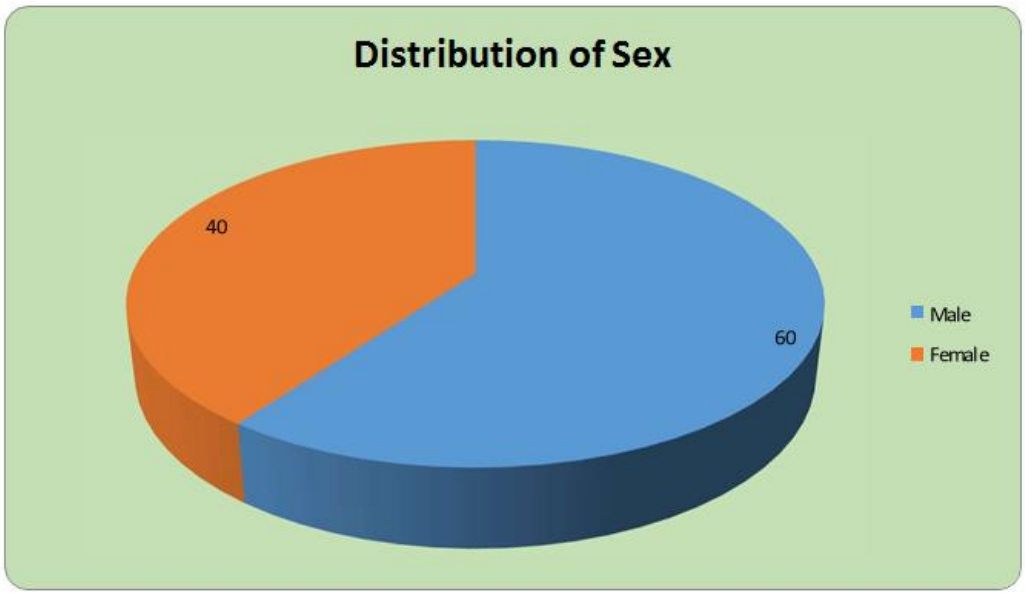
Age Group (years)	No. of cases	% of cases
30–39	3	10.0
40–49	4	13.3
50–59	9	30.0
60–69	12	40.0
70–79	2	6.7
Total	30	100.0



Graph 2: Age distribution of cases studied (n=30).

Table No. 14: The sex distribution of cases studied (n=30).

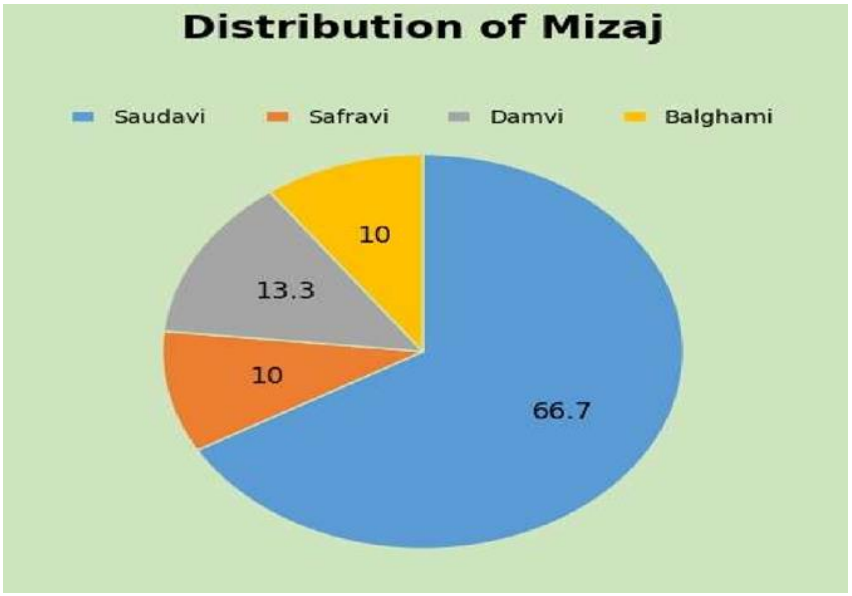
Sex	No. of cases	% of cases
Male	18	60.0
Female	12	40.0
Total	**30**	**100.0**



Graph 3) The sex distribution of cases studied (n=30).

Table No. 15: Distribution of type of mizaj (temperament) of cases studied (n=30).

Type of Mizaj	No. of cases	% of cases
Saudavi	20	66.7
Safravi	3	10.0
Damvi	4	13.3
Balgami	3	10.0
Total	**30**	**100.0**



Graph 4): Distribution of type of mizaj (temperament) of cases studied (n=30).

Table No. 16 (a) The distribution of improvement in Slough (n=30).

Day 0 (n=30)			Visit 1 (n=30)		Visit 2 (n=30)		Visit 3 (n=30)		Visit 4 (n=30)		Visit 5 (n=30)		Visit 6 (n=30)	
Slough	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Absent	1	40.0	12	40.0	12	40.0	12	40.0	14	46.7	23	76.7	25	83.3
	2													
Present	1	60.0	18	60.0	18	60.0	18	60.0	16	53.3	7	23.3	5	16.7
	8													
Total	3	100.	30	100.	30	100.	30	100.	30	100.	30	100.0	30	100.
	0	0		0		0		0		0				0
Values are n (% of cases).														

Table No. 16 (b): The statistical comparison of improvement in Slough (n=30).

Comparisons (Pair-wise)	P-value	Significance
Day 0 v Visit 1	0.999^{NS}	Non-Significant
Day 0 v Visit 2	0.999^{NS}	Non-Significant
Day 0 v Visit 3	0.999^{NS}	Non-Significant
Day 0 v Visit 4	0.157^{NS}	Non-Significant
Day 0 v Visit 5	0.001^{***}	Highly Significant
Day 0 v Visit 6	0.001^{***}	Highly Significant
P-values by Wilcoxon's signed rank test. P-value<0.05 is considered to be statistically significant. ***P-value<0.001, NS – Statistically non-significant.		

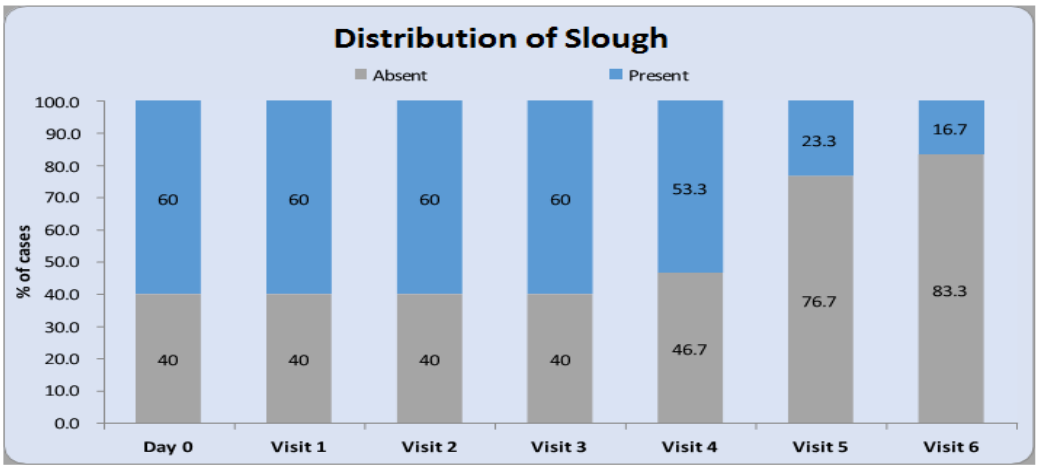
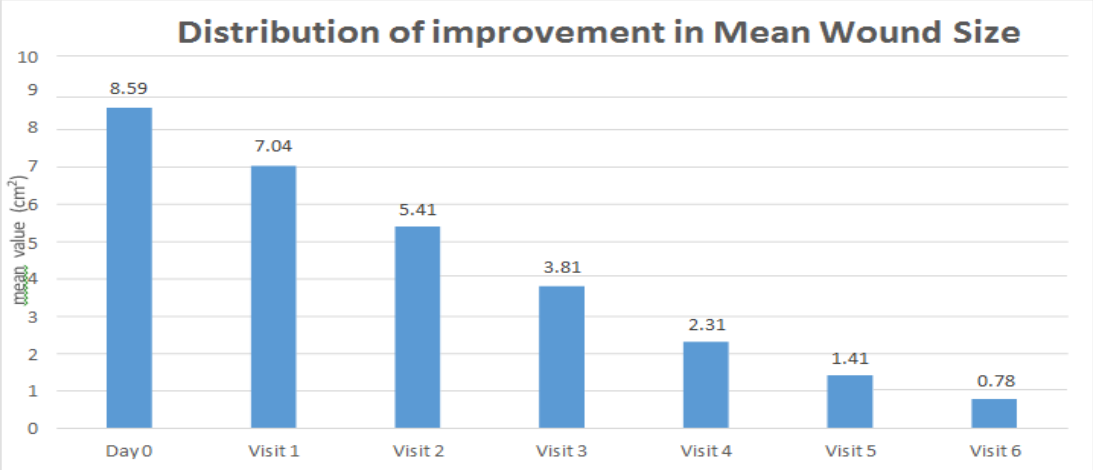


Table No. 17 (a) Distribution of improvement in Mean Wound Size (n=30).

Wound Size (cm^2)	Day 0 (n=30)	Visit 1 (n=30)	Visit 2 (n=30)	Visit 3 (n=30)	Visit 4 (n=30)	Visit 5 (n=30)	Visit 6 (n=30)
Mean	8.59	7.04	5.41	3.81	2.31	1.41	0.78
SD	6.30	5.13	3.85	3.00	1.49	1.08	0.61
Mean % change	0%	19.18%	37.21%	56.67%	74.12%	84.19%	91.44%
Values are Means and SD.							

Table No. 17: (b) The statistical comparison of improvement in Wound Size (n=30).

Comparisons (Pair-wise)	P-value	Significance
Day 0 v Visit 1	0.009^{**}	Moderately Significant
Day 0 v Visit 2	0.001^{***}	Highly Significant
Day 0 v Visit 3	0.001^{***}	Highly Significant
Day 0 v Visit 4	0.001^{***}	Highly Significant
Day 0 v Visit 5	0.001^{***}	Highly Significant
Day 0 v Visit 6	0.001^{***}	Highly Significant
P-values by Repeated analysis of variance (RMANOVA) with Bonferroni's correction for multiple comparisons. P-value<0.05 is considered to be statistically significant. **P-value<0.01, ***P-value<0.001.		



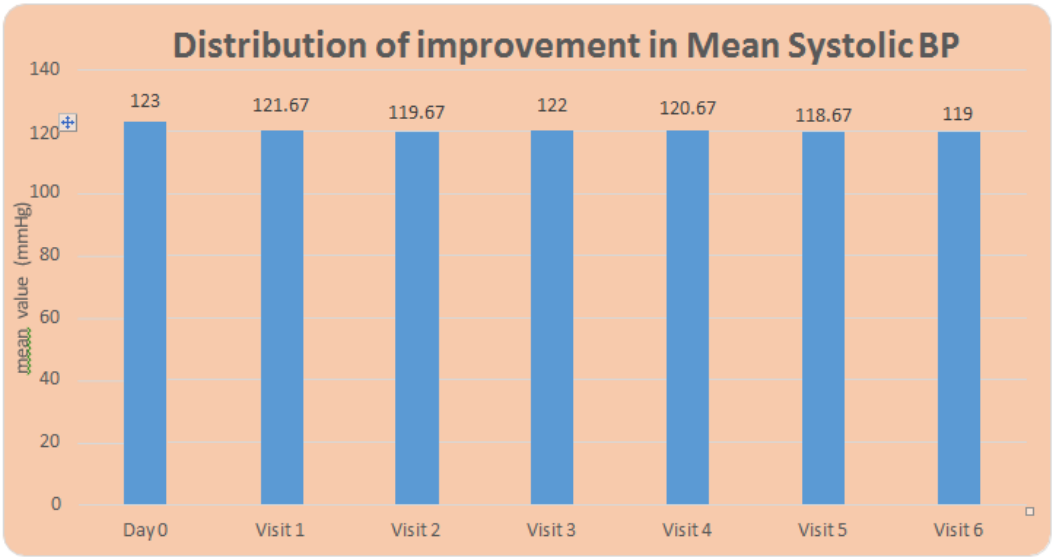
Graph 6) Distribution of improvement in Mean Wound Size (n=30).

Table No. 18 (a) Distribution of improvement in Mean Systolic BP (n=30).

Systolic BP (mmHg)	Day 0 (n=30)	Visit 1 (n=30)	Visit 2 (n=30)	Visit 3 (n=30)	Visit 4 (n=30)	Visit 5 (n=30)	Visit 6 (n=30)
Mean	123.00	121.67	119.67	122.00	120.67	118.67	119.00
SD	7.49	6.48	6.69	9.96	10.48	8.60	8.03
Mean % change	0%	1.12%	2.64%	1.03%	1.82%	2.98%	3.11%
Values are Means and SD.							

Table no. 18 (b) The statistical comparison of improvement in Systolic BP (n=30).

Comparisons (Pair-wise)	P-value	Significance
Day 0 v Visit 1	0.784^{NS}	Non-Significant
Day 0 v Visit 2	0.409^{NS}	Non-Significant
Day 0 v Visit 3	0.542^{NS}	Non-Significant
Day 0 v Visit 4	0.401^{NS}	Non-Significant
Day 0 v Visit 5	0.382^{NS}	Non-Significant
Day 0 v Visit 6	0.308^{NS}	Non-Significant
P-values by Repeated analysis of variance (RMANOVA) with Bonferroni's correction for multiple comparisons. P-value<0.05 is considered to be statistically significant. NS – Statistically non-significant.		



Graph 7) Distribution of improvement in Mean Systolic BP (n=30).

DISCUSSION

Pressure ulcers, described in the present study as **Zakhme Bistari**, are chronic wounds resulting primarily from prolonged pressure, immobility and impaired tissue perfusion. Persistent pressure over bony prominences compromises microcirculation and produces tissue hypoxia, cellular injury, necrosis and subsequent ulceration. Effective management therefore requires removal of devitalized tissue, control of slough and exudate, maintenance of an appropriate wound environment and promotion of tissue repair. The present study was undertaken to evaluate the efficacy of raw papaya (Carica papaya Linn.) crush dressing in wound-bed preparation and healing of Zakhme Bistari.

From the Unani perspective, pressure ulcer may be correlated with **Zakhm-e-Muzmin**, a chronic wound characterized by delayed healing, unhealthy discharge and slough formation. Unani wound management emphasizes cleansing of the wound, removal of unhealthy tissue, regulation of inflammation and restoration of the body's natural healing capacity. The concept of Tanqiya-e-Quruh and removal of Mawad-e-Fasida has conceptual similarity with modern wound-bed preparation and debridement. Thus, the use of papaya as a cleansing and debriding agent can be considered compatible with these principles.

The study enrolled 40 patients, of whom 30 were included for statistical analysis. The study was conducted as an open-label, single-arm clinical study over 45 days using convenience sampling. Patients were evaluated through subjective parameters such as slough, exudate, dead skin, wound dimensions and inflammation, while objective assessment included history, general physical examination and the Pressure Ulcer Scale for Healing (PUSH)**.** The PUSH assessment incorporated wound surface area, exudate amount and tissue type, allowing serial assessment of wound progression.

A. Demographic characteristics

In the present study, the largest proportion of participants belonged to the **21–30-year and 31–40-year age groups**, each comprising 30% of the study population. Participants aged 41–50 years constituted 23.4%, while 13.3% were aged 51–60 years and only 3.3% were above 60 years. Thus, although pressure ulcers are commonly associated with elderly and debilitated individuals, the present study population included a substantial proportion of younger and middle-aged patients.

Regarding sex distribution, 18 patients (60%) were male and 12 (40%) were female**.** The higher proportion of males in the present study represents the characteristics of the enrolled sample and should not be interpreted as evidence of a higher biological susceptibility among males. With respect to Unani temperament (Mizaj), Safravi temperament was predominant**,** accounting for 66.6% of participants, followed by Damvi temperament at 20%, while Saudavi and Balgami temperaments each constituted 6.7%. This distribution is an observation of the present study population and may provide a basis for further investigation into the possible relationship between Mizaj and chronic wound characteristics. However, the present study was not designed to establish a causal association between Mizaj and pressure-ulcer development or healing.

B. Effect of raw papaya dressing on slough

One of the important objectives of wound-bed preparation is the removal of slough and devitalized tissue, because the presence of slough can interfere with granulation and epithelialization and may contribute to persistence of the wound. The present study demonstrated a progressive improvement in slough status during treatment. At baseline, slough was absent in **12 patients (40%)** and present in **18 patients (60%)**. The proportion without slough remained unchanged through Visit 3, increased to 46.7% at Visit 4, and subsequently

increased markedly to **76.7% at Visit 5 and 83.3% at Visit 6**.

Statistical analysis demonstrated that the difference between Day 0 and Visits 1, 2 and 3 was not statistically significant, while the difference at Visit 4 approached improvement but remained non-significant (p=0.157). In contrast, the changes at **Visit 5 and Visit 6 were highly statistically significant (p=0.001)**. This delayed but marked improvement may indicate that repeated application and continued wound-bed preparation were associated with progressive removal of slough over the treatment period.

The observed improvement is biologically plausible because raw papaya contains **papain and chymopapain**, proteolytic enzymes capable of breaking down denatured proteins and devitalized tissue. The dissertation describes these enzymes as providing a rationale for biological/enzymatic debridement and wound-bed cleansing.

From the Unani perspective, this de-sloughing effect may be correlated with the removal of **Wizr (slough)** and unhealthy tissue. Classical Unani surgical principles emphasize cleansing of wounds and removal of unhealthy tissue to facilitate restoration of normal tissue. Therefore, the observed reduction in slough is consistent with both the proposed scientific mechanism of papaya and the traditional concept of wound cleansing.

C. Effect on wound size

Reduction in wound area was the most prominent quantitative finding of the present study. The mean wound size decreased progressively from **8.59 ± 6.30 cm² at baseline** to 7.04 ± 5.13 cm² at Visit 1, 5.41 ± 3.85 cm² at Visit 2, 3.81 ± 3.00 cm² at Visit 3, 2.31 ± 1.49 cm² at Visit 4, 1.41 ± 1.08 cm² at Visit 5 and **0.78 ± 0.61 cm² at Visit 6**. This represented a progressive mean percentage reduction of **19.18%, 37.21%, 56.67%, 74.12%, 84.19% and 91.44%**, respectively. Statistical analysis showed that the reduction in wound size was **moderately significant at Visit 1 (p=0.009)** and became highly significant from Visit 2 through Visit 6 (p=0.001)**.** The progressive reduction in wound dimensions suggests improvement in the overall wound condition during the treatment period.

The progressive reduction in wound area may be explained, at least in part, by effective removal of slough and devitalized tissue, which facilitates development of a more favorable wound bed. The dissertation describes wound-bed preparation as a systematic process aimed at removing barriers to healing, controlling infection and inflammation, maintaining moisture balance and promoting granulation and epithelialization.

Papain and chymopapain present in unripe papaya provide a plausible mechanism for this observation through proteolytic breakdown of devitalized tissue. In addition, the dissertation describes papaya as possessing potential anti-inflammatory, antioxidant, antibacterial and wound-healing activities. These effects may collectively contribute to improvement in the wound environment. However, because the present study did not include a control group, the observed reduction in wound size cannot be attributed exclusively to papaya dressing.

D. Interpretation in relation to wound-bed preparation

The findings of the present study are particularly relevant to the Tissue component of the TIME principle**,** in which removal of non-viable tissue is a fundamental component of wound-bed preparation. The progressive disappearance of slough and reduction in wound area observed in this study suggest improvement in the wound bed during the treatment period. The dissertation describes enzymatic debridement as a relatively selective method of breaking down necrotic tissue while preserving viable tissue, and raw papaya is proposed as a biological source of proteolytic enzymes.

The study also provides a conceptual bridge between Unani and contemporary wound-care principles. In Unani medicine, wound cleansing and removal of unhealthy tissue are important components of Tanqiya-e-Quruh, while modern wound management emphasizes debridement, control of microbial burden, moisture balance and stimulation of healthy tissue formation. The present intervention therefore represents an attempt to apply a traditionally oriented treatment within a clinically assessable wound-care framework.

E. Effect on systolic blood pressure

Systolic blood pressure was also monitored during the study. The mean systolic blood pressure decreased from **123.00 ± 7.49 mmHg at baseline** to 119.00 ± 8.03 mmHg at Visit 6. The maximum mean percentage change was 3.11%. However, none of the comparisons from baseline to subsequent visits was statistically significant; the reported p-values ranged from 0.308 to 0.784.

Therefore, the observed small variations in systolic blood pressure appear to represent normal variation during the study rather than a demonstrated treatment effect. Importantly, the absence of statistically significant changes suggests that raw papaya dressing did not produce a measurable effect on systolic blood pressure in the study population.

CONCLUSION

The present open-label, single-arm clinical study was undertaken to evaluate the efficacy of raw Papaya (Carica papaya Linn.) crush dressing in wound-bed preparation of Zakhme Bistari (bed sore/pressure ulcer)**.** The study included 40 enrolled patients, of whom 30 were available for statistical analysis, and patients were followed for a period of 45 days. Assessment was carried out using clinical parameters and the Pressure Ulcer

Scale for Healing (PUSH). The study demonstrated a progressive improvement in slough and wound size following raw papaya dressing. Slough was absent in 40.0% of patients at baseline and increased to **83.3% at Visit 6**. The improvement in slough became highly statistically significant at Visit 5 and Visit 6 (p=0.001).A marked reduction in mean wound size was also observed, from **8.59 ± 6.30 cm² at baseline to 0.78 ± 0.61 cm² at Visit 6**, representing a **91.44% mean reduction**. The improvement was statistically significant from Visit 1 (p=0.009) and highly significant from Visit 2 through Visit 6 (p=0.001). The findings suggest that raw papaya dressing may be beneficial in wound-bed preparation, particularly in the removal of slough and reduction of wound dimensions. The possible therapeutic effect may be related to the proteolytic enzymes **papain and chymopapain** present in raw papaya, which provide a plausible basis for enzymatic/biological debridement and wound cleansing. The intervention also corresponds conceptually with Unani principles of Tanqiya-e-Quruh and removal of unhealthy tissue. The study further indicates that raw papaya dressing has potential practical advantages because of its simplicity, accessibility and potentially low cost, making it a promising option for further evaluation, particularly in settings where advanced wound-care facilities may be limited. However, the findings should be interpreted cautiously because of the open-label, single-arm design, limited sample size and convenience sampling**,** and because there was no control or comparator group. Therefore, the present study provides preliminary evidence rather than definitive proof of efficacy. In conclusion, raw papaya crush dressing appears to be a promising, simple and economical approach for wound-bed preparation in Zakhme Bistari, with notable improvement in slough clearance and reduction in wound size. Larger randomized controlled and multicentric studies using standardized papaya preparations, appropriate comparator treatments, longer follow-up and systematic safety assessment are recommended to establish its efficacy, safety and comparative effectiveness.

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