Comparative Study Between Collagenase And Hydrogel Dressing In Management Of Chronic Wounds At A Tertiary Health Centre.

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Abstract

Background: Chronic wound is when there is no complete healing after 6 weeks or poor response to a treatment change. Although any wound has the potential to become chronic, medical conditions commonly associated with chronic/non-healing wounds are diabetes mellitus, chronic venous congestion, arterial insufficiency and pressure sores. We are compared efficacy of collagenase (enzymatic debridement) and hydrogel dressing (autolytic debridement in management of chronic wounds at a tertiary health centre.

Material and Methods: This prospective, comparative study, with in-patients more than 18 years admitted in Shri B.M Patil Medical College and Hospital, Vijayapura, Karnataka, India. Patients were randomised by lottery method, Group A-20 patients treated with collagenase dressings & Group B-20 patients treated with hydrogel dressings.

Results: Total 40 patients were taken for the study. Age & gender distribution (Table 1) statistically not significant. Most patients were from 41-70 years age group, male to female ratio was approximately 2:1 in both groups. It was noted that complete responder, partial responder, non-complete responder & non-responder patients in group A were 65%, 20%, 10% & 5%. While in group B complete responder, partial responder, non-complete responder & non-responder patients were 50%, 15%, 25% & 10%. Difference between complete responder (completely healed) & non-complete responder (less than 50% reduction from the baseline area) was statistically significant in group A & group B

Conclusion: Both hydrogel & collagenase are good options in management of chronic wounds. Experience was better with collagenase, larger studies are required for future guidelines.

***Keywords*:** chronic wound; debridement, collagenase dressing, hydrogel dressing

Introduction

A wound is defined as an interruption within the continuity of the epithelial lining of the skin or mucosa resulting from physical or thermal damage. Wound may be acute or chronic. Chronic wound can be considered when there is no complete healing after 6 weeks or if there is poor response to a treatment change.[1]

Although any wound has the potential to become chronic, certain medical conditions are commonly associated with chronic/non-healing wounds such as diabetes mellitus, chronic venous congestion, arterial insufficiency and pressure sores. Some rare causes include rheumatoid arthritis, sickle cell anemia, hemolytic anemia, leukemia, Marjolin's ulcer etc.[2].Furthermore malnutrition and immunodeficiency may complicate wound healing.

Debridement is essential for successful wound management and plays an increasingly critical role in all phases of the TIME framework for managing difficult-to-heal and chronic wounds.[3] Debridement, infection control, edema removal, and surgical correction of underlying defect are basic aspects, as with compromised acute wounds, include.[4] Surgical/Sharp, Autolytic (use of moisture-donating or moisture-retentive dressings such as hydrogels, hydrocolloids or transparent films), Biologic (using sterile maggots), Mechanical (e.g. wet-to-dry dressings, therapeutic irrigation and ultrasound therapy) & Enzymatic (e.g. collagenase ointment) are types of debridement.[5] Many times, one or more types of debridement needed in management in chronic wounds. In present study, we compared efficacy of collagenase and hydrogel dressing after surgical debridement in management of chronic wounds at a tertiary health centre.

Material and methods

This prospective, comparative study was conducted in the department of surgery, Shri B.M Patil medical college & hospital, Vijayapura , Karnataka, India . Patients admitted from Surgical OPD or casualty department, with chronic wound were considered for study. Study was conducted over a period of 1 year (March 2019 to February 2020). Institutional ethical committee approval was taken.

Inclusion Criteria

Patients more than 18 years with a chronic wound, willing to participate in study & follow up.

Exclusion Criteria

Patients suffering from a condition that has interfered with wound healing (e.g. carcinoma, vasculitis, connective tissue disease or an immune system disorder), with corticosteroids, immunosuppressive agents, radiation therapy and chemotherapy, known hypersensitivity to any of the dressing components.

A detailed history, clinical examination and relevant investigations were performed altogether patients. Procedure was explained to patients in local language & written informed consent from patients was taken for participation in present study. Patients were randomised into the two groups by lottery method.

- Group A composed of 20 patients treated with collagenase dressings.
- Group B composed of 20 patients treated with hydrogel dressings

Wounds of all the patients included within the study underwent sharp surgical debridement initially and through subsequent dressing change to get rid of necrotic tissue and slough. After debridement in the emergency operation theatre, dressing was applied over the wounds as per study group (hydrogel or collagenase) under all aseptic conditions. Antibiotic coverage, sepsis & diabetes management was done according to standard guidelines. Follow up & treatment was given for 8 consecutive weeks until wound healed, which ever occurred first. On admission approximate wound area measured. On admission wound photographs were taken & initial photographs were compared with follow-up photos.

At the end of study period of 8 weeks, the patients were categorized subjectively as follows:

1. Complete responder – complete healing
2. Partial responder – 50% or greater reduction from baseline area
3. Non-complete responder – less than 50% reduction from the baseline area
4. Non-responder – no reduction in wound area or increase in area over baseline 4

Data was collected & analysed. Categorical variables were analysed by using the Pearson's Chi-square/Fishers exact test. Two groups were compared using Student's t-test. Results were expressed as n (%). p-Values of <0.05 were considered to be statistically significant.

Results

Total 40 patients were considered for present study. Group A composed of 20 patients treated with collagenase dressings & Group B composed of 20 patients treated with hydrogel dressings. Age & gender distribution is shown in Table 1. Statistically age & gender distribution between two groups was not significant. Most patients was from 41-70 years age group. Male to female ratio was approximately 2:1 in both groups.

Table 1- Age & gender

Characteristic	Group A (%)	Group B (%)	Total (%)
Age group (years)			
19-30	1 (3%)	1 (3%)	2 (5%)
31-40	3 (8%)	3 (18%)	6 (15%)
41-50	4 (10%)	6 (15%)	10 (25%)
51-60	5 (13%)	4 (10%)	9 (23%)
61-70	5 (13%)	4 (10%)	9 (23%)
>70	2 (3%)	2 (3%)	4 (10%)
Gender			
Male	13 (33%)	14 (35%)	27 (68%)
Female	7 (18%)	6 (15%)	13 (33%)

In present study duration of wound in both groups was not statistically significant. Most wounds had duration of 6 weeks-6 months (60%).

Table 2-Duration of chronic wound

Duration of urticaria	Group A (%)	Group B (%)	Total (%)
6 weeks-6 months	11 (28%)	13 (33%)	24 (60%)
6 months-1 year	6 (15%)	5 (13%)	11 (28%)
≥1 year	3 (8%)	2 (5%)	5 (13%)

On history & examination, cause for chronic wound was decided. Cause wise distribution between two groups was not significant statistically. Idiopathic was most common cause (38 %), followed by diabetes mellitus (23%), chronic venous congestion (15%), arterial insufficiency (13%) & pressure sores (13%).

Table 3- Cause for chronic wound

Major cause	Group A	Group B	Total
diabetes mellitus	5 (13%)	4 (10%)	9 (23%)
chronic venous congestion	3 (8%)	3 (8%)	6 (15%)
arterial insufficiency	2 (5%)	3 (8%)	5 (13%)
pressure sores	3 (8%)	2 (5%)	5 (13%)
Idiopathic	7 (18%)	8 (20%)	15 (38%)
Others	20 (50%)	20 (50%)	40

Serial wound measurements were taken at each follow up. We noted that complete responder , partial responder, non-complete responder & non-responder patients in group A were 65%, 20%, 10% & 5%. While in group B complete responder , partial responder, non-complete responder & non-responder patients were 50%, 15%, 25% & 10%. Difference between complete responder (completely healed) & non-complete responder (less than 50% reduction from the baseline area) was statistically significant in group A & group B. No serious complication or mortality was noted in present study.

Table-4: Response to treatment

	First week		Second week		Fourth week		Sixth week		Eighth week	
	A	B	A	B	A	B	A	B	A	B
Complete responder	0	0	0	0	3 (15%)	1 (5%)	5 (25%)	3 (15%)	13 (65%)	10 (50%)
Partial responder	0	0	1 (5%)	2 (10%)	4 (20%)	5 (25%)	11 (55%)	9 (45%)	4 (20%)	3 (15%)
Non-complete responder	1 (5%)	2 (10%)	3 (15%)	2 (10%)	5 (25%)	5 (25%)	3 (15%)	4 (20%)	2 (10%)	5 (25%)
Non-responder	19 (95%)	18 (90%)	16 (80%)	16 (80%)	8 (40%)	9 (45%)	3 (15%)	4 (20%)	1 (5%)	2 (10%)

Discussion

Wound healing is the result of interactions among cytokines, growth factors, blood and the extracellular matrix. These are affected by various local and systemic factors. Local factors which includes hypothermia, pain, infection, radiation and tissue oxygen tension directly influence the characteristics of the wound whereas systemic factors are the overall health or disease state of the individual that affect individual's ability to heal.[6]

Surgical debridement of the wound helps in healing by removing the dead necrotic tissue, particulate matter, or foreign materials, and reducing bacterial load. These devitalized tissues hinder cell migration necessary for healing and predispose to infection, thus necessitating removal. The disadvantage is associated inadvertent viable tissue removal as there is lack of any objective biological/molecular marker to discriminate impaired and nonimpaired tissue to direct the extent of debridement. [7]

Autolytic debridement is achieved with the help of moisture retaining dressings through the endogenous enzymes present in the wound that digest the necrotic slough and allow the dressing to separate. These moisture-retaining dressings include hydrogels, hydrocolloids and transparent films. Hydrogels (A three-dimensional network of hydrophilic polymers) are insoluble hydrophilic materials made from synthetic polymers such as poly (methacrylate) and polyvinyl pyrrolidine. The high-water content of hydrogels (70-90 %) helps granulation tissues and epithelium in a moist environment. Soft elastic property of hydrogels provides easy application and removal after wound is healed without any damage. Temperature of cutaneous wounds is decreased by hydrogels providing soothing and cooling effect. Difficulties of hydrogel dressings are exudates accumulation leads to maceration and bacterial proliferation that produces foul smell in wounds.

Enzymatic debridement involves topical application of exogenous enzymes to the wound bed where they work synergistically with endogenous enzymes to break down the devitalized tissues. These enzymatic agents include collagenase, varidase, papain (from papaya) and bromelain (from pineapple). Enzymatic debridement can be used alone or in conjunction with other debridement methods, such as sharp or surgical debridement.[8] Maintenance debridement with enzymes (collagenase) is frequently used between clinic visits to gently remove slough or to enzymatically debride thick crusts (especially in neuroischemic wounds).[9]

We compared hydrogel & collagenase in dressings of chronic wounds. We noted a statistically significant difference between complete responder (completely healed) & non-complete responder (less than 50% reduction from the baseline area) in group A & group B. Collagenase group had more rate of complete healing while non-complete healing & non-responder were more in hydrogel group. Similar findings are noted in other studies. [10-13]

In a systemic review, Ramundo et al. demonstrated a higher efficacy in debridement of necrotic tissue with collagenase products compared to inactive preparation in decubitus ulcers and leg ulcers of various causes in placebo-controlled studies.[10] Milne CT et al.,[11] noted that in maintenance debridement by either collagenase or hydrogel can be used to complete wound closure when used in conjunction with a validated predictive wound-healing tool that closely monitors therapy. This study showed statistical significance in favour of collagenase when evaluating closure rates from the onset of the pressure ulcer. In other study collagenase group experienced greater reduction of non-viable tissue and faster reduction in overall wound size.[12]

A review noted that the evidence about the effectiveness of collagenase and other debriding enzymes was inconclusive due to differences in the enzymes studied and in outcomes measured (five studies, strength of evidence: insufficient).[14]

Conclusion

Both hydrogel & collagenase are good options in management of chronic wounds. Though we noted better experience with collagenase, larger studies are required for future guidelines. In management of chronic wounds maintenance debridement with collagenase should be considered.

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