

A Comparative Study of Novel Lipocolloid Silver Dressing with Conventional Dressing for Wagner Grade I And Ii Diabetic Ulcer

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ABSTRACT

Diabetic ulcer patients accounts for a good majority of cases attending the hospital and getting admitted, many methods are in use for the management of such cases other than conventional dressing. The present study is undertaken to compare the efficacy of a novel lipocolloid silver dressing (Technology Lipido-Colloid-Ag) with conventional dressing for Wagner Grade I and II ulcer in terms of progression of granulation tissue as percentage of total ulcer surface area, number of sitting for debridement. In the study its seen lipocolloid silver dressings showed better reduction in the amount of slough covering the wound surface, granulation appeared better in ulcers treated with lipocolloid silver dressings than conventional dressings and patients managed with lipocolloid silver dressing required lesser number of debridement than conventional dressing group. The mean duration of hospital stay was less among those patients in lipocolloid group than conventional group and the number of dressings required for wound healing is less for lipocolloid silver dressings than conventional dressing . It was seen that lipocolloid silver dressings provide better wound healing by reducing the amount of slough and increasing the granulation formation.

KEY WORDS : Wagner's, Lipocolloid, Slough

INTRODUCTION

Diabetes has been described as an “iceberg” disease. According to the world health organization, at least 171 million people worldwide have diabetes mellitis¹. The figure is likely to double by 2030. India has the highest number of diabetic patients and has been considered as the “diabetic capital of the world.” Diabetic foot ulcer occurs in about 20% of all patients with diabetes and precedes 85% of all lower limb amputations². Leg amputation risk are 40 times higher among persons with diabetes than with non-diabetics³. Healing depends on many factors such as glycemic control, vascularity of the tissue, bacterial load, location of the wound, nutritional status of the patient. Treatment of diabetic leg ulcer has been varied and non specific since no regime has been completely effective. Treatment has been aimed at providing optimal condition required for natural wound healing, including halting or reversing underlying conditions causing ulcer, controlling infections including debridement, local and systemic antibiotics, and many other topical agents which promotes wound healing.

Early recognition and proper therapy of diabetic foot lesion may save the foot and leg. There continues to be great interest and research put into the treatment and prevention of diabetic foot. Usually, normal

saline and betadine solution are used in the management of diabetic foot ulcers. Now-a-days Silver dressings are being utilised for diabetic foot management.

Here we are studying the role as a effective drug in management of diabetic foot ulcers. On contact with wound exudate, the TLC-Ag (Technology Lipido-Colloid-Ag) matrix forms a gel leading to a moist environment favorable to wound healing. UrgoClean Ag is an advanced wound care dressing made of cohesive poly-absorbent fibres impregnated with a silver lipocolloid matrix (Technology Lipido-Colloid-Ag healing matrix [TLC-Ag]). The poly-absorbent fibres are effective with desloughing properties as shown in a randomised controlled trial (RCT) (Meaume et al, 2014) where the poly-absorbent fibres showed similar efficacy and safety when compared with Hydrofiber, but presented better desloughing properties in the management of ulcers. In most commercially available silver containing dressings, the silver is impregnated into the dressing's absorbent component (e.g. fibrous material such as hydrofibres, or polyurethane foam). UrgoClean Ag differs as the silver sulphate is incorporated in lipocolloid layer that is in contact with the wound (Desroche et al, 2016). Ag⁺ ions confer to antimicrobial activity that may help to reduce local bacterial load; it has a broad spectrum of antimicrobial activity covering Gram-negative, Gram-positive bacteria and certain yeasts. It is particularly effective against *Staphylococcus aureus*, *Streptococcus pyogenes*, MRSA and *Pseudomonas aeruginosa* (pyocyanic bacillus) which are most frequently responsible for locally infected wounds.

After 24 hours, UrgoClean Ag reduced the biofilm population by more than 99.99% (4.6 log reduction), which was maintained for seven days (up to 4 log reductions) (Dalac et al, 2016). At the same time, the poly-absorbent fibres absorb exudate and form a gel. These poly-absorbent fibres bind to the slough residues, absorbing and draining it to aid elimination (autolytic debridement). By removing exudate, slough and bacteria it keeps the wound clean from all materials that may favour the proliferation of bacteria and the formation of biofilm, while allowing a better action of Ag⁺ ions in the wound bed.

In addition, the product can be removed in one piece due to the resistance to traction of the poly-absorbent fibres and lastly, the formed gel does not stick to the wound, which allows an easy removal of the dressing with little or no damage to healing tissues, leading to no or minor pain.

AIMS AND OBJECTIVES

To compare the following between lipocolloid pad impregnated with silver dressings and conventional dressings: progression of granulation tissue as percentage of total ulcer surface area and the number of sitting for debridement and the average duration of hospital stay

METHODOLOGY

Study design: Observational Study

Study duration: 1 year period from August 2021 – August 2022).

Study setting: Tertiary care centre, Government Medical College Kozhikode.

Study population: Diabetic patients with WAGNER GRADE I and II ulcers of lower limb extremities attending OPD /IP at department of General surgery, Government medical college Kozhikode

Inclusion criteria

1. Diabetic patients in the age group of 13-75 years admitted in general surgery ward Or attending OPD with complaints of diabetic foot ulcer
2. Wagner's Grade I and II Lesions with ulcer size less than 7 cms in its largest dimension.

Exclusion criteria

1. Wagner's 3, 4 and 5 lesions
2. All causes of foot ulcer, which can be attributed to other coexisting disease like paraplegia, varicose vein etc.
3. Patient with known hypersensitivity to colloidal silver.

Sample size

$$n = (Z\alpha + Z\beta)^2 \cdot pq / d^2$$

$$P = 63.1$$

$$q = 100 - 63.1 = 36.9$$

$$d = 20\%$$

$$n = 92$$

Methods of Data Collection:

All the cases of diabetic foot either admitted or attending Out Patient Department of General surgery with diabetic foot over a period of one year with Wagner Grade 1 and 2 were enrolled in this study. Patients with foot ulcer and patients with known diabetes mellitus were included in the study. In addition to detailed history thorough clinical examination included assessment of foot ulcer according to Meggitt Wagner Grading, examination of peripheral pulses, examination of peripheral nerves for sensory, motor or autonomic loss and systemic complications of diabetes mellitus if any.

Evaluation of role of colloidal silver dressing

Patients will be divided into two groups: Conventional dressing group and silver colloidal dressing group. Conventional dressings group will be managed with debridement and topical antimicrobial agents and saline dressings. Lipocolloidal silver dressing group will be managed with debridement and application of lipocolloidal silver dressing. Conventional dressing is changed every 12 or 24 hours. Lipocolloid silver dressing changed after 24-48 hrs to 3 - 5 days depending on wound condition. Patients were managed and followed up every week for 6 weeks interval and progress was assessed.

Initial wound assessment

Ulcer examination was done in all these patients and wound assessed of its characteristics and photographed. Ulcer assessed at the beginning of the study and at the end of the study and the dressing was changed every Second or third day or early if mandated

Outcome measures -

1. Changes in the percentage of slough to the total ulcer surface area.
2. Progression of granulation tissue as percentage of total ulcer surface area.
3. Number of sittings for debridement
4. Average duration of hospital stay
5. Total number of dressings required.

- Overall wound response was evaluated on baseline ,weekly for 6 weeks

-The visual scores for the percentage of wound covered with slough are

1. 76-100% of wound covered by slough
2. 51-75 of wound covered by slough
3. 26-50% of wound covered by slough

4. 11-25% of wound covered by slough
5. 0-10% of wound covered by slough
6. No slough covering the ulcer.

-The visual scores for the percentage of wound filled by granulation tissues are

- 1) No granulation tissue covering the ulcer.
- 2) Pink/dull <25% wound filled.
- 3) Bright beefy 25-74% wound filled.
- 4) Bright beefy red 75-100% wound filled.

Ethical Concerns:

The study protocol submitted to Institutional Ethics Committee, Government Medical College, Kozhikode for approval. After explaining the details regarding the study, an informed consent will be obtained from the participants. Confidentiality of the data will be maintained

RESULTS

The mean age of the study patients were 58.97 ± 12.74 years with a minimum age of 25 and a maximum age of 75 years. Majority among them belonged to older adulthood age category in both conventional and lipocolloid silver group. Among 184 study patients, 138 (75%) were males and 46 (25%) were females. That is, Male: female ratio = 3:1. Among both conventional (males= 71.7%) & lipocolloid silver group (males=78.3%), majority were males. Among 184 patients, 66 (35.9%) were alcoholics and 70 (38%) were smokers. Among conventional group, 40.20% were smokers and 34.8% were alcoholics. Whereas in lipocolloid silver group majority were alcoholic(37%) and 35.9% were smokers. The distribution of co-morbidities among the study patients is – 94 (51.1%) had hypertension, 76 (41.3%) had coronary artery disease, 83 (45.1%) had chronic kidney disease and 94 (51.5%) had dyslipidemia. Among the study participants, 42 (22.8%) had HBA1C <7.5, 88 (47.8%) had HBA1C 7.5-10.5 and 54 (29.30%) had HBA1C >10.5. Pus culture swabs were sent from all study participants on day 0. The organisms isolated are Staphylococcus from 21 patients, Streptococcus from 31 patients, E Coli from 26 patients, Klebsiella from 28 patients, Pseudomonas from 20 patients, Acinetobacter from 22 patients, MBG from 18 patients and MRSA from 18 patients. Out of 184 patients, 162 (88%) were OP cases and 22 (12%) were IP cases. Mean duration of stay for IP cases was 10.31 ± 3.34 days, with minimum stay of 5 days and maximum stay of 16days.

Among 22 IP cases, 12 patients stayed for less than 10 days and 10 patients stayed for more than or equal to 10 days . Among conventional group majority of them had a hospital stay of more than or equal to 10 days when compared to the lipocolloid silver group, where no patient was admitted for more than or equal to 10 days. On applying student t test- mean duration of hospital stay was less among those patients in lipocolloid silver group when compared to conventional group and was found statistically significant (Table 1)

TABLE 1 : MEAN DURATION OF HOSPITAL STAY CONVENTIONAL V/S LIPOCOLLOID SILVER GROUP

Group	Duration of hospital stay			P value
	N	Mean	Standard deviation	
Lipocolloid silver	11	7.54	1.75	0.000
Conventional	11	13.09	1.86	

Among 184 patients, 41.80% had less than 15 number of dressings, 16.80% had 15- 30 number of dressings and 41.30% had more than 30 number of dressings. In conventional group, majority (81.50%) did more than 30 dressings, whereas in lipocolloid silver group majority (82.60%) did only less than 15 (Table 2).

TABLE 2: NUMBER OF DRESSINGS LIPOCOLLOID SILVER V/S CONVENTIONAL

Group	No of dressings required			P value
	<15 nos.	15- 30 nos.	>30 nos.	
Lipocolloid silver	76 (82.6%)	15 (16.3%)	1 (1.1%)	0.000
Conventional	1 (1.1%)	16 (17.4%)	75 (51.5%)	

Majority of the patients who had >30 number of dressings were more among the conventional group. On applying chi square test, no of dressings was significantly associated with the type of dressing done. Among conventional group, 44.60% did 5- 10 no. of debridement, whereas in lipocolloid group majority did only <5 no. of debridement (Table 3)

TABLE 3: NUMBER OF DEBRIDEMENT

Group	No of debridement			P value
	<5 no.	5 – 10 no.	>10 no.	
Lipocolloid silver	43 (46.7%)	37 (40.2%)	12 (13%)	0.000
Conventional	17 (18.5%)	41 (44.6%)	34 (37%)	

The study comprised of a total of 184 patients. 92 patients received conventional and 92 received lipocolloid silver dressings for the healing of ulcer. Both groups had considerable amount of slough at the time of recruitment which has been compared which was statistically significant ($p=0.027$). 47 patients had 76-100% of area covered with necrotic tissue in lipocolloid silver group and 64 patients in conventional group. 40 patients had 51-75% of area covered with slough in lipocolloid silver group and 23 patients in conventional group. 5 patients had 26-50% of the area covered with necrotic tissue in both lipocolloid silver and conventional group. Both the groups had considerable amount of necrotic tissue at the time of recruitment which has been compared ($p= 0.027$)

TABLE 4: PRESENCE OF SLOUGH

Slough	Lipocolloid silver group	Conventional group	p value
1 (76-100%)	47 (42.3%)	64 (57.7%)	0.027
2 (51-75%)	40 (63.5%)	23 (36.5)	
3 (26-50%)	5 (50%)	5 (50%)	
TOTAL	92	92	

TABLE 5: SLOUGH COVERING WOUND SURFACE AFTER 6 WEEKS

Necrotic tissue	Lipocolloid silver group	Conventional group	p value
4 (11-25%)	11 (25.6%)	32 (74.4%)	0.000
5 (0-10%)	44 (48.9%)	46 (51.5%)	
6 (No slough covering ulcer)	37 (72.5%)	14 (27.5%)	
TOTAL	92	92	

Both groups were compared, which showed significant reduction of necrotic tissue in lipocolloid group at the end of the study (Table 5).

TABLE 6 : PRESENCE OF GRANULATION TISSUE

Visual score	Lipocolloid silver group	Conventional group	p value
1 (No granulation tissue)	55 (46.6%)	63 (53.4%)	0.219
2 (<25%)	37 (56.1%)	29 (43.9%)	
TOTAL	92	92	

TABLE 7. GRANULATION TISSUE FILLING THE WOUND AFTER 6 WEEKS

Visual score	Lipocolloid silver group	Conventional group	p value
2 (<25%)	15 (29.4%)	36 (70.6%)	0.000
3 (25-74%)	70 (61.9%)	43 (38.1%)	
4 (75-100%)	7 (35%)	13 (65%)	
TOTAL	92	92	

Both

groups were compared which showed significant granulation tissue covering the wound in lipocolloid silver group than the conventional group at the end of the study. (p=0.000).(Table 6 and Table 7)



Figure 1 : Lipocolloid silver dressing Day 0



Figure 2 : Lipocolloid silver dressing 6W



Figure 3 : Lipocolloid silver dressing at Day 0 Figure 4 : Lipocolloid silver dressing at 6W



Figure 5 : Lipocolloid silver dressing at Day 0 Figure 6 : Lipocolloid silver dressing at 6W

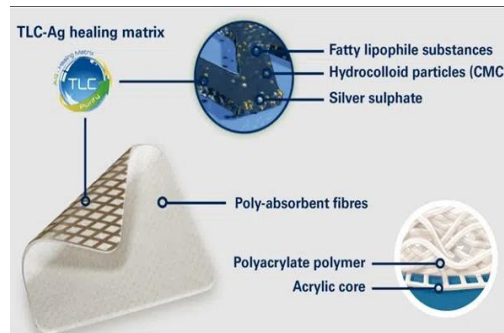


Figure 7 :Lipocolloid Silver Dressing

DISCUSSION

Wound dressings have evolved from providing physical protection to the raw surface, absorbing exudates and controlling local infections by local medications to the level of providing adequate environment promoting wound healing. This has been achieved by modern wound dressing agents which promote granulation tissue formation. Microorganisms within a biofilm grow in a protected microenvironment largely through production of a biofilm matrix composed of extracellular polysaccharides, proteins and nucleic acids (Davey and O’Toole 2000). The fact that biofilm-based infections are rarely resolved, even in individuals who have a competent innate and adaptive immune response, highlights the high degree of resistance exhibited by biofilms (Stewart and Costerton 2001). Various agents have been tried upon to initiate early response in wound healing. UrgoClean Ag is an advanced wound care dressing made of cohesive poly-absorbent fibres impregnated with a silver lipido-colloid matrix (Technology Lipido-Coloid-Ag healing matrix [TLC-Ag]). The value of TLC-Ag healing matrix has also been recognised in its effectiveness in the management of wounds presenting with a risk of infection as demonstrated in two RCTs (Harding et al, 2012; Lazareth et al, 2012).

UrgoClean Ag not only addresses the high microbial burden that can delay or prevent wound healing (Dalac et al, 2016), but is also effective against biofilms that prolong and prevent healing, cause chronic inflammation, increase the risk of infection and are often tolerant to antimicrobials (Desroche et al, 2016; Percival, 2017).

In this study on 184 patients, 92 patients received conventional saline and antimicrobial dressings and 92 patients received lipocolloid silver dressings. The mean age of the study patients were 58.97 ± 12.74 years with a minimum age of 25 and a maximum age of 75 years. Majority among them belonged to older adulthood age category in both conventional and lipocolloid group showing that diabetic foot ulcers being common in the elderly age group. This is in accordance with two studies conducted by Tseng CH¹⁰ which described a mean age of 62 for diabetic foot and another study by Lin C et al¹¹ whose study over a period of eight years showed a mean age of 65.33 ± 12.84 for diabetes foot and related complications to peak. Male Sex distribution was more in comparison to female sex. Among 184 study participants, 138 (75%) were males and 46 (25%) were females. That is, Male: female ratio = 3:1. This is accordance with the higher incidence of diabetic foot related complications in relation to females. A similar observation was made in a study conducted in 248 patients by Dinh et al. The results of this study indicate that women have a lower risk than men for foot ulceration. This lower risk appears to be the result of less severe neuropathy, increased joint mobility, and lower foot pressures.¹² Among 184 patients, 66 (35.9%) were alcoholics and 70 (38%) were smokers. Among conventional group, 40.20%

were smokers and 34.8% were alcoholics. Whereas in lipocolloid silver group majority wear alcoholics(37%) and 35.9% were smokers. Xia et al states that smoking has extensive effects on all stages of diabetic foot ulcerations, both the onset and healing processes. Smoking can worsen diabetic peripheral sensory, autonomic and motor neuropathy, which lead to foot ulcerations. Microvascular alterations, such as impaired vasodilation with increased vasoconstriction leading to tissue hypoxia can interfere with the healing process. Smoking also has negative impacts on wound healing in almost all phases through very complex mechanisms. Bikramjit et al in a study of 89 diabetic patients admitted with diabetic foot the proportion of smokers and chronic alcoholics were 42 (53.14%) and 32 (40.51%) respectively. They stated that diabetic patients who were smokers and/or chronic alcoholic underwent more amputations with longer hospital stay than others who had no addiction. The prognosis was worse in the subgroup of patients who were both smoker and chronic alcoholic¹³.

Among conventional group majority of them had a hospital stay of more than or equal to 10 days when compared to the lipocolloid silver group, where no participant was admitted for more than or equal to 10 days. On applying student t test- mean duration of hospital stay was less among those participants in lipocolloid silver group when compared to conventional group and was found statistically significant. In conventional group, majority (81.50%) did more than 30 dressings, whereas in lipocolloid silver group majority (82.60%) did only less than 15. The study comprised of a total of 184 patients. 92 patients received conventional and 92 received lipocolloid silver dressings for the healing of ulcer. Both groups had considerable amount of necrotic tissue at the time of recruitment which has been compared which was statistically significant ($p=0.027$). Both groups were compared, at the end of 6 weeks in view of necrotic tissue which showed significant reduction of necrotic tissue in lipocolloid silver group at the end of the study ($p=0.000$). Both groups were compared for granulation tissue filling the wound after 6 weeks. 15 patients had pink dull granulation tissue <25% filling the wound, 70 patients had bright beefy red granulation tissue 25-74% filling the wound and 7 patients had bright beefy red granulation tissue 75-100% granulation tissue filling the wound in the lipocolloid silver group after 6 weeks. 36 patients had pink dull granulation tissue <25% filling the wound, 43 patients had bright beefy red granulation tissue 25-74% filling the wound and 13 patients had bright beefy red granulation tissue 75-100% granulation tissue filling the wound in the conventional group after 6 weeks.

Both groups were compared which showed significant granulation tissue covering the wound in lipocolloid silver group than the conventional group at the end of the study. ($p=0.000$)

CONCLUSION

With the use of lipocolloid silver dressings in comparison with the conventional saline dressing for the treatment of diabetic ulcers of the lower limb, the following conclusions were derived. Lipocolloid silver dressings showed faster and better ulcer healing compared to conventional saline dressing. Lipocolloid silver dressings showed faster and better reduction in the amount of necrotic tissue or slough covering the wound surface. Granulation and epithelialization appeared to occur early and better in ulcers treated with lipocolloid silver dressings than with conventional saline dressings. Patients managed with lipocolloid silver dressing required lesser number of sitting for debridement when compared to conventional saline dressing group. Mean duration of hospital stay was less among those patients managed with lipocolloid dressing when compared to conventional saline dressing group. The Number of dressings required for wound healing is less for lipocolloid silver dressings when compared to conventional Saline dressing.

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