

## ORIGINAL RESEARCH

# Assessment of role of silver colloidal gel with povidone iodine ointment in patients with diabetic foot

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### ABSTRACT

**Background:** The increasing prevalence of diabetes has resulted in concomitant illness. The present study was conducted to assess silver colloidal gel with povidone iodine ointment in patients with diabetic foot. **Materials & Methods:** 60 patients with diabetic foot ulcer at department of surgery, Shri Guru Ram Rai Institute of Medical and health Science and associated Shri Mahant Indresh Hospital were divided into 2 groups. Group I: Povidone iodine ointment dressing and group II: Silver colloidal gel dressing. **Results:** The mean age of the studied patients of group A (Silver colloidal gel) was  $52.8 \pm 12.7$  years whereas that of group B (povidone iodine ointment)  $54.3 \pm 10.7$  years with majority of the studied patients were above 46 years. The majority of the studied patients were having spontaneous mode of onset i.e., 66.7% and 73.3% respectively for group A and B whereas trauma was in 33.3% and 26.7% for Group A and B respectively but the difference was statistically insignificant ( $p > 0.05$ ). The wound size was significantly lower at 4th and 6th week in group A than group B ( $p < 0.05$ ). The wound healing status at sixth week and it was found that amputate was in 3.3% in group A than 6.7% in group B. Grafting was required in 10.0% and 33.3% in group A and B respectively. 56.7% were healed in group A than only 26.7% in group B but the difference was statistically insignificant ( $p > 0.05$ ). The floor status as on 6th week and found that healed/grafting/flap/amputate/ primary suturing was in 76.7% in group A than 66.7% in group B. The tissue was pale in 20.0% of the group B patients than 0.0% in groups A. Pink tissue were in 23.3% in group A and 13.3% in group B and the difference was statistically significant ( $p = 0.029$ ). The tested swab positive cases with type of organism and found that the majority of the patients were affected by E. coli followed by S. Aureus on both the groups and Klebsiella and Proteus mirabilis in group B but the difference was statistically insignificant ( $p > 0.05$ ). The comparison between outcomes of povidone iodine dressing group and silver dressing group in terms of surface area reduction of wounds and it was found that final area was significantly lower in group A than group B ( $p = 0.039$ ). Percentage reduction in ulcer area was also significantly lower in silver gel group than group B ( $p < 0.001$ ). **Conclusion:** Silver colloidal gel dressing is preferred over povidone iodine ointment in diabetic foot ulcers.

**Key words:** Diabetic foot ulcers, povidone iodine, Silver colloidal gel

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### INTRODUCTION

The increasing prevalence of diabetes has resulted in concomitant illness. The critical effects of hyperglycemia include micro-vascular complications (nephropathy, neuropathy and retinopathy) and macro-vascular complications (coronary artery disease, stroke and peripheral arterial disease). Diabetes is a leading cause of non-traumatic lower extremity amputation, which is often preceded by a non-healing ulcer. The lifetime risk of foot ulceration in people with diabetes is 15.0%-20.0%. More than 15.0% of foot ulcers result in amputation of the foot or limb. Several other population-based studies indicate a 0.5%-3.0% annual

collective incidence of diabetic foot ulcers. The prevalence of foot ulcers reported varies from 2.0% to 10.0%. Approximately 45.0%-60.0% of all diabetic foot ulcerations are purely neuropathic, whereas 45.0% have both neuropathic and ischemic components. It has been estimated that around 15.0%-27.0% patients with diabetes require lower limb amputations predominantly (50.0%) due to infection.<sup>1</sup> Diabetic foot ulcers are a consequence of many factors including loss of protective sensation due to peripheral neuropathy where the feet become numb and the injury goes unnoticed. Also, arterial insufficiency complicates the neuropathic ulcer which leads to poor

wound healing. Foot deformity and calluses can result in high plantar pressure, which results in additional risk. Mechanical stress at the wound site is hypothesized to affect wound healing. Many other factors contribute to the risk of foot ulceration and its subsequent infection in patients with diabetes. Uncontrolled hyperglycemia, duration of diabetes, trauma, improper footwear, callus, history of prior ulcers/amputations, older age, blindness/impaired vision, chronic renal disease and poor nutrition have also been demonstrated to play a role in the pathogenesis and progression of diabetic foot ulceration. Infection further deteriorates the diabetic foot resulting in a non-healing chronic wound. Recently, vitamin D deficiency was proposed as a risk factor for diabetic foot infection.<sup>2</sup>

Wound dressings are an important aspect of diabetic foot ulcer treatment. Dressings should, relieve symptoms, protect wounds, and promote healing. There is no single dressing that can meet all the needs of a diabetic patient with an infected foot ulcer. Various germicides have been tried from time to time for wound dressing in diabetic ulcers. These include povidone-iodine, silver ions, hydrogen peroxide, benzalkonium chloride, pilohexanide etc.<sup>3</sup>

Silver has antiseptic, antimicrobial, anti-inflammatory properties and is a broad-spectrum antibiotic. Silver is biologically active when it is in soluble form i.e., as Ag<sup>+</sup> or Ag<sup>0</sup> clusters. Ag<sup>+</sup> is the ionic form present in silver nitrate, silver sulfadiazine, or other ionic silver compounds. Ag<sup>0</sup> is the uncharged form of metallic silver present in nanocrystalline silver.<sup>4</sup> Free silver cations have a potent antimicrobial effect which destroys microorganisms immediately by blocking the cellular respiration and disrupting the function of bacterial cell membranes.<sup>5</sup> This occurs when silver cations bind to tissue proteins, causing structural changes in the bacterial cell membranes which in turn cause cell death. Silver cations also bind and denature the bacterial DNA and RNA, thus inhibiting cell replication.<sup>6</sup> The present study was conducted to assess silver colloidal gel with povidone iodine ointment in patients with diabetic foot.

## MATERIALS & METHODS

The present prospective, observational, randomized study was conducted over 60 patients with diabetic foot ulcer at department of surgery, Shri Guru Ram Rai Institute of Medical and health Science and associated Shri Mahant Indiresch Hospital.

A detailed history with special reference on days of presentation and mode was taken. A complete physical, Local and systemic Examination was done. Lab evaluations (CBC, RBS, FBS, Urine Examination) were performed and Chest X-ray Foot, Hb1ac followed by USG colour Doppler were also carried out. Patients were reviewed till the day of discharge, were followed and antibiotics was changed

as per sensitivity pattern of organism grown in the culture. Subsequently, the patients were allocated to one of the following two groups on the basis of their management: Group I: Povidone iodine ointment dressing and group II: Silver colloidal gel dressing.

The dressing the wound was examined daily for the amount of discharge, the colour of discharge, the smell of the discharge, the nature of edge, the appearance of granulation tissue, oedema and redness. When slough was present, it was excised. None of the patients had excessive discharge which would have required dressing more than once in a day. The method of dressing was same for all the patients. The surrounding area wound was cleaned with saline commencing from the edge of the wound to distal area. The wound was cleaned with saline solution. All the discharge or the pus was wiped out. If there was any loose slough, it was excised. Then the wound was covered with Colloidal gel.

In traumatic and contaminated wounds, the wound was cleaned thoroughly and debridement was done. The amount of silver colloidal gel used in each wound was decided from the size of wound, the depth of the wound and the amount of the discharge. It differed in each patient and at times in the same patient. After complete debridement, the wounds of 30 selected patients in our study were dressed with dilute povidone-iodine initially till infection (purulent discharge) cleared.

A similar number of patients selected from almost similar types (total 30 cases) and almost similar size of wound were dressed with silver colloidal Gel after initial complete debridement till second surgery or wound healed and they were compared with control (Povidone-iodine + saline) dressing in form of, clearance of local infection, rate of healing, time of second surgery, total hospital stay and duration of treatment. During the daily examination of the wound, reduction in discharge/pain/oedema, nature of granulation tissue, and condition of the wound were noted. On commencing the study, the non-healing nature of wound was decided by history and thorough clinical examination. Culture and sensitivity were done and antibiotics were given as per culture and sensitivity report, in both cases (Silver Colloidal gel as well as control group). During daily the examination of the wound, an attempt was made to look for any side effects like, pain, irritation, burning, itching and dermatitis.

The healing of the wound was followed up, to note whether the healing was with granulation or by scarring. The amount of scar tissue was also noted to be within the limits or was excessive. Presence of tenderness in the scar tissue was also noted. The part of the body on which the wound was present was examined for any loss of function. Data thus obtained were subjected to statistical analysis. P value < 0.05 was considered significant.

## RESULTS

**Table I: Distribution of patients**

Age in years	Group A (n=30)	Group B (n=30)	p-value
≤30	1 (3.3%)	2 (6.7%)	0.919
31-45	7 (23.4%)	8 (26.6%)	
46-60	10 (33.3%)	9 (30.0%)	
>60	12 (40.0%)	11 (36.7%)	
<b>Mean Age</b>	52.8±12.7	54.3±10.7	0.622

Table I shows that the mean age of the studied patients of group A (Silver colloidal gel) was 52.8±12.7 years whereas that of group B (povidone iodine ointment) 54.3±10.7 years with majority of the studied patients were above 46 years and the difference was statistically insignificant between the groups (p>0.05).

**Table II: Distribution of the studied patients on the basis of mode of onset**

Mode of onset	Group A (n=30)	Group B (n=30)	P-value
Spontaneous	20 (66.7%)	22 (73.3%)	0.573
Trauma	10 (33.3%)	8 (26.7%)	

Table II shows that the majority of the studied patients were having spontaneous mode of onset i.e., 66.7% and 73.3% respectively for group A and B whereas trauma was in 33.3% and 26.7% for Group A and B respectively but the difference was statistically insignificant (p>0.05).

**Table III: Comparison of wound size at different interval of time**

Wound size in cms at different time period	Group A (n=30)	Group B (n=30)	P-value
Initial	6.9±4.3	8.2±5.2	0.295
2 <sup>nd</sup> week	5.19±3.8	6.8±4.6	0.144
4 <sup>th</sup> week	2.6±2.1	4.0±2.4	0.019
6 <sup>th</sup> week	1.1±1.0	2.9±1.2	0.001
<b>Difference (initial – 6<sup>th</sup> week)</b>	5.8±0.9	5.3±0.9	0.035

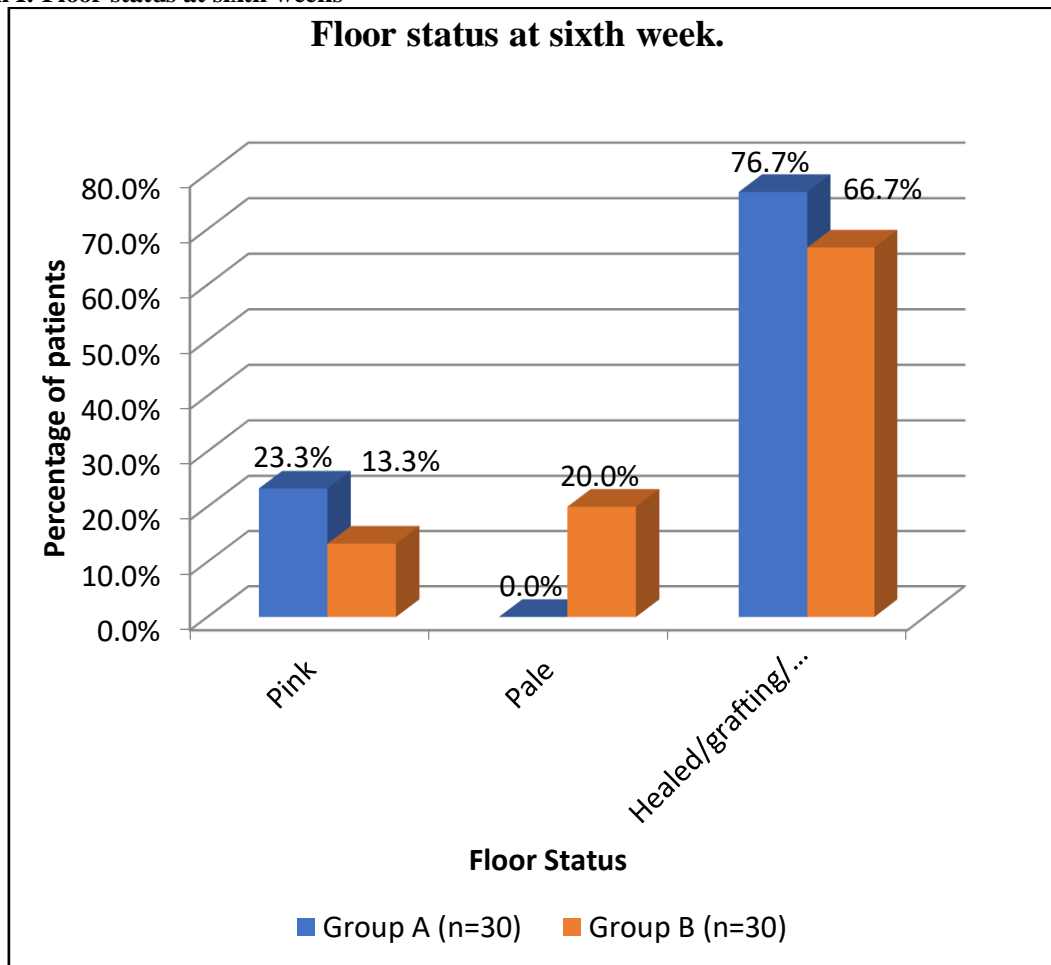
Table III shows that the wound size was significantly lower at 4th and 6th week in group A than group B (p<0.05).

**Table IV: Wound healing status at sixth week**

Status of wound at 6 <sup>th</sup> week	Group A (n=30)	Group B (n=30)	P-value
Amputate	1 (3.3%)	2 (6.7%)	0.078
Grafting	3 (10.0%)	10 (33.3%)	
Healed	17 (56.7%)	8 (26.7%)	
Flap	1 (3.3%)	0 (0.0%)	
Primary Suturing	1 (3.3%)	0 (0.0%)	
Not healed	7 (23.4%)	10 (33.3%)	

Table IV shows that the wound healing status at sixth week and it was found that amputate was in 3.3% in group A than 6.7% in group B. Grafting was required in 10.0% and 33.3% in group A and B respectively. 56.7% were healed in group A than only 26.7% in group B but the difference was statistically insignificant (p>0.05).

**Graph I: Floor status at sixth weeks**

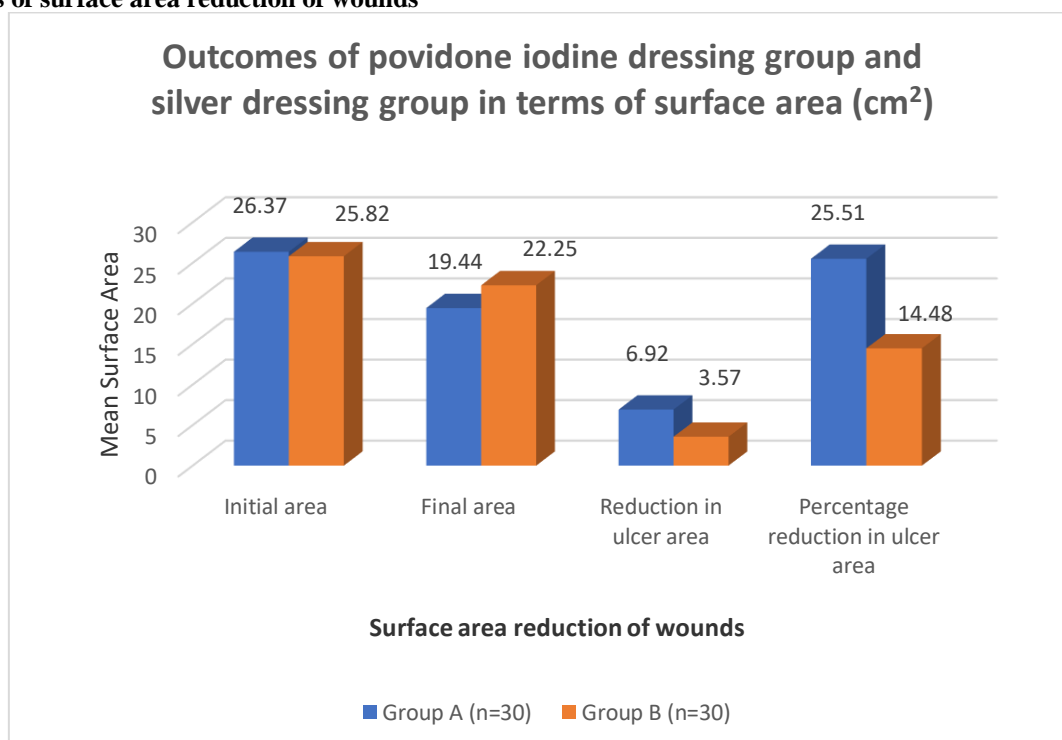


The floor status as on 6th week and found that healed/grafting/ flap/amputate/ primary suturing was in 76.7% in group A than 66.7% in group B. The tissue was pale in 20.0% of the group B patients than 0.0% in groups A. Pink tissue were in 23.3% in group A and 13.3% in group B and the difference was statistically significant (p=0.029).

**Table V: Swab positive cases with type of organism**

Organism	Group A (n=30)	Group B (n=30)	P-value
Acinetobacter	0 (0.0%)	1 (3.3%)	0.209
Citrobacter	2 (6.7%)	1 (3.3%)	
E. Coli	7 (23.3%)	4 (13.3%)	
Klebsiella	2 (6.7%)	5 (16.7%)	
No growth	5 (16.7%)	7 (23.3%)	
Proteus mirabilis	0 (0.0%)	4 (13.3%)	
Pseudomonas	4 (13.3%)	1 (3.3%)	
S. Aureus	5 (16.6%)	5 (16.8%)	
Pus culture	5 (16.7%)	2 (6.7%)	

Table V shows that the tested swab positive cases with type of organism and found that the majority of the patients were affected by E. coli followed by S. Aureus on both the groups and Klebsiella and Proteus mirabilis in group B but the difference was statistically insignificant (p>0.05).

**Graph II: Comparison between outcomes of povidone iodine dressing group and silver dressing group in terms of surface area reduction of wounds**

Graph II shows the comparison between outcomes of povidone iodine dressing group and silver dressing group in terms of surface area reduction of wounds and it was found that final area was significantly lower in group A than group B ( $p=0.039$ ). Percentage reduction in ulcer area was also significantly lower in silver gel group than group B ( $p<0.001$ ).

## DISCUSSION

Diabetes is considered the new emerging epidemic of the world. Neuropathy and peripheral vascular disease are the complications of diabetes that predispose to foot ulceration in diabetics. Infection is commonly seen in DFU.<sup>7</sup> Besides adequate wound debridement and antibiotic therapy, dressing plays an important role in the healing of DFU. Usage of topical antimicrobial or topical antiseptic agents is still considered as an option in infected ulcers.<sup>8</sup> The present study was conducted to assess silver colloidal gel with povidone iodine ointment in patients with diabetic foot.

We found that the mean age of the studied patients of group A (Silver colloidal gel) was  $52.8\pm 12.7$  years whereas that of group B (povidone iodine ointment)  $54.3\pm 10.7$  years with majority of the studied patients were above 46 years. The majority of the studied patients were having spontaneous mode of onset i.e., 66.7% and 73.3% respectively for group A and B whereas trauma was in 33.3% and 26.7% for Group A and B respectively but the difference was statistically insignificant ( $p>0.05$ ).

Holmes C et al<sup>9</sup> in their study 26 papers were discussed, and included 13 randomized designs, twelve prospective cohorts, and one retrospective

cohort, representing 2386 patients with diabetic foot ulcers. They included complete epithelialization, 58% of collagen-treated wounds completely healed (weighted mean 67%). Only 23% of studies reported control group healing with 29% healing (weighted mean 11%) described for controls. Authors concluded that collagen-based wound dressings can be an effective tool in the healing of diabetic foot wounds. It showed an overall increase in healing rates. It also suggested that future works focus on biofilms and extracellular regulation, and include high risk patients. We found that the wound size was significantly lower at 4th and 6th week in group A than group B ( $p<0.05$ ). The wound healing status at sixth week and it was found that amputate was in 3.3% in group A than 6.7% in group B. Grafting was required in 10.0% and 33.3% in group A and B respectively. 56.7% were healed in group A than only 26.7% in group B but the difference was statistically insignificant ( $p>0.05$ ). Hanumanthappa MB et al<sup>10</sup> included 200 cases out of which 100 cases were in test group. The percentage of granulation tissue increased significantly from 20% to 80% in 3 weeks' time. Granulation tissue was healthy & highly vascular in the majority of the cases. No adverse effects were observed. They concluded that widespread availability, negligible cost, ease of use, absence of adverse effects and facilitated wound healing make amniotic membrane dressing superior to conventional dressing in the management of varicose ulcers.

The floor status as on 6th week and found that healed/grafting/ flap/amputate/ primary suturing was in 76.7% in group A than 66.7% in group B. The

tissue was pale in 20.0% of the group B patients than 0.0% in groups A. Pink tissue were in 23.3% in group A and 13.3% in group B and the difference was statistically significant ( $p=0.029$ ). We observed that the majority of the patients were affected by *E. coli* followed by *S. Aureus* on both the groups and *Klebsiella* and *Proteus mirabilis* in group B but the difference was statistically insignificant ( $p>0.05$ ). We found that final area was significantly lower in group A than group B ( $p=0.039$ ). Percentage reduction in ulcer area was also significantly lower in silver gel group than group B ( $p<0.001$ ). Imran M et al<sup>11</sup> involved 136 wounds (75.97%) out of 179 were completely healed with honey dressing and 97 (57.39%) out of 169 with saline dressing. The median wound healing time was 18.00 (6 - 120) days in group A and 29.00 (7 - 120) days in group B.

### CONCLUSION

Authors found that silver colloidal gel is safe and effective in wound management and gives better efficacy and faster response as compared to traditional povidone iodine ointment and other topical antiseptics. The result of this study therefore appears to show more favourable results for silver colloidal gel group than for conventional povidone iodine ointment dressing. Hence silver colloidal gel dressing is preferred over povidone iodine ointment in diabetic foot ulcers.

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