

The Effect of *Plantago major* Hydroalcoholic Extract on the Healing of Diabetic Foot and Pressure Ulcers: A Randomized Open-Label Controlled Clinical Trial

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Abstract

Aims: Diabetic foot ulcer (DFU) and pressure ulcer (PU) both are common types of ulcers worldwide. The wound healing effect of *Plantago major* leaves has been shown in a few animal studies. This study aimed to evaluate the clinical efficacy of *P. major* hydroalcoholic extract on DFU and PU healing. **Methods:** In this clinical trial, patients with DFU or PU who met the inclusion criteria were randomly assigned to drug (*P. major*) or control groups. For patients in the drug group, *Plantago* extract 10% topical gel was applied on the wound once daily concurrent with dressing and routine wound care for two weeks, while for the control group, an appropriate novel dressing was used along with routine wound care for the same duration. The percentage of wound size reduction at the end of the seventh and 14th days of intervention was recorded and compared between the groups. **Results:** Fifty and 44 patients in drug and control groups, respectively, completed the interventions. *Plantago* extract gel significantly resulted in more reduction in the wound size compared to control at the end of the first ($64.90 \pm 29.75\%$ vs. $33.11 \pm 26.55\%$; $P < 0.001$) and second week ($86.85 \pm 24.34\%$ vs. $52.87 \pm 32.41\%$; $P < 0.001$). Furthermore, the number of patients with complete wound healing in the drug group ($n = 32$, 64%) was significantly more than the control group ($n = 9$, 20.45%; OR: 3.129, 95% CI: 1.685-5.809, $P < 0.001$).

Conclusion: The use of 10% topical gel of *P. major* leaf extract results in the acceleration of DFU and PU healing.

Key points: Application of *P. major* topical gel results in the acceleration of diabetic foot ulcer and pressure ulcer healing.

- *P. major* extract helps reducing the wound's erythema.
- *P. major* leaf extract assists decreasing the wound size.
- The number of patients completing wound healing process is higher among whom undergoing *P. major* dressing.

Keywords

plantago major, healing, diabetic foot ulcer, pressure ulcer, clinical trial

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