Determining the Effect of Plantago Major L and Rosa Damascene Herbal Ointment for Bedsore Healing

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Abstract

Background:

Bedsore is damage or loss of skin integrity due to prolonged pressure which there are several ways to treat and prevent them. The aim of current study was to determine the effect of *Plantago major* L and *Rosa damascene* herbal ointment for bed sore healing in hospitalized patients.

Methods:

This was a clinical trial study that was accomplished with 100 patients who were divided into control (50 patients) and intervention (50 patients) groups. The control group had received routine treatment (dressing with Comfeel) but the intervention group only had received herbal ointment and then both groups were compared with each other through Push tool.

Results:

The mean and standard deviation of recovery time in the Comfeel group was 27.40 ± 12.467 and in the herbal ointment group was 21.57 ± 12.695 . In the pre intervention evaluation, the mean and standard deviation of the Push score in the herbal ointment group was $323/44 \pm 0/10$ while in the last evaluation in the same group it was $160/16 \pm 0/0$. But in Comfeel group, in the pre-intervention evaluation, the mean and standard deviation of the Push score was $10/0 \pm 68/317$, while in the last evaluation it was $364/60 \pm 0/0$. The highest frequency of bed sores in the study units was in the sacral region (49%) and the lowest frequency was in the sole of the foot with 1%.

Conclusion:

The results showed that *Plantago major* L and *Rosa damascene* herbal ointment was effective in accelerating the recovery time and wound healing.

Trial registration: IRCT.ir, IRCT20100130003227N13. Registered 24-05-2019

Introduction

Bed sore is severe localized injury on the skin and underlying tissue usually over a bony prominence site as a result of long-term pressure, or pressure in combination with shear or friction (1). This disorder is a most common complication for bedridden patients hospitalized in chronic and acute care services and causes major problems on health of patients, their relatives and caregivers. Loss of sensory immobility and perception are the main risk factors for initiating the bed sore, because patients may not be aware of the discomfort and do not change their position to relieve the pressure or pressure in combination with friction (2). Bedsore is so painful for patients and could reduce their ability to take part in physical and social activities which finally will affect on patient's sanity (3).

This disorder is a heavy burden on the shoulders of health system, so that leads to major impact on quality of life, health status, and health care costs (4). The average cost of medical-treatment for a patient who has bed sore grade 4 in a hospital is increased several folds. In Iran, the percentage of bedsore have been computed up to 44% in ICU (intensive care units) (3, 5).

In the current economic situation and due to the high cost of routine bed sore treatment, governments are proposed a new strategy to control the cost of treatment and the effects of bed sores as a serious problem for patients, and it was that in health care facility the prevention of production bedsore to be considered as a priority (6, 7). Moreover, different medical treatment methods such as anti-biotic therapy and infection control using local antiseptics, nutritional intervention by including protein rich diet, and stimulus of blood-circulation, dressing with honey, the use of electrical stimulation, laser therapy, high-pressure oxygen and medicinal plants are used for bed sore medication (8, 9).

Due to the lack of side effects, availability and reasonable price, the use of medicinal plants in treatment of any diseases and disorder in the world are increasing, so that according to the report of World Health Organization (WHO) 80% of the world's population uses medicinal plants for treatment (10, 11). Many medicinal plants have wound healing ability and used in treatment of different wounds. Among the most important plants used in the treatment of wounds are the *Plantago major* L and *Rosa damascene* (12, 13). *Plantago major* L and *Rosa damascene* contains secondary metabolites such as phenolic compounds, flavonoids, alkaloids, terpenoids, vitamin C, minerals, waxes, amino acids and tannins, that can be used in the treatment of skin, respiratory system, gastrointestinal tract, circulatory system diseases, infections and treatment of wounds (12, 13, 14, 15, 16).

Due to the high prevalence of bed sores and its complications in Iran, as well as due to the traditional use and high effectiveness of *Plantago major* L and *Rosa damascene* in the treatment of wounds, we regulated these hypotheses:

- 1) The *Plantago major* L and *Rosa damascene* herbal ointment is effective for bed sore healing.
- 2) The *Plantago major* L and *Rosa damascene* herbal ointment is effective in accelerating the bed sore healing.

Materials And Methods

The current study confirmed by ethics committee in the researches of Khomein University of Medical Sciences and also registered in Iranian Registry of Clinical Trials center entitled NO. IRCT 20100130003227N13 on 24-05-2019. This clinical trial study was performed on patients with bed sores (Grade 2 and 3) in Khomein City of Iran. Based on previous studies, the sample size was calculated as a total of 100 patients and were divided into two groups of control (N: 50) and intervention (N: 50). In the intervention group, patients received the dressing with *plantago major* L and *Rosa damascene* herbal ointment and in the

control group, patients just received the routine care (dressing with comfeel). None of the patients in this study died or gave up (Figure 1). The complete details of the patients are given in Table 1.

Inclusion And Exclusion Criteria

The inclusion criteria in this study were: age over 18 years, the same usage of antibiotics in control and intervention groups, no history of previous bedsore, lack of peripheral vascular disease, no history of sensitivity to *Plantago major* L and *Rosa damascene*, no chronic and debilitating diseases and no history of quadriplegia or paraplegia. The exclusion criteria were: The incidence of any skin problems or sensitivity (swelling, rash, redness, ulcers, and hives), reluctance to cooperate and death of patients, sepsis or septic shock, bone involvement, patients undergoing chemotherapy or radiotherapy, pregnancy, breastfeeding and end-stage.

Before any intervention, the purpose and method of study were explained to the patients and written consent was obtained from them. The control group patients, had received conventional care including changing their body position every 2 hours and dressing with comfeel. The intervention group, besides changing of body position every 2 hours, they had received standard and premium formula of herbal ointment which was a combination of 1.5 grams of brewed *Plantago major* L, 1 gram of brewed *Rosa damascene* and 50 grams of honey. This herbal ointment was used according to the characteristics and needs of patient's wounds.

Data Collection

The data were collected for all patients: gender, age, drugs side effects, the long of hospitalizing period and information associated to the incidence of bedsore and BRADEN scale which includes sensory perception, moisture, activity, mobility, nutrition, friction and shear was used to eliminate confounding factors. The mobility and grade of bedsores which has been emerged, by a checklist as below completely immobile grade 1, very limited grade 2, slightly limited grade3 and no limitations grade4 and also grades of bedsore were considered by using the European Pressure Ulcer Advisory Panel (EPUAP) grading system (17, 18). To measure and compare the healing of wounds, the PUSH tool was used which evaluate exudate amount, tissue type and width.

All processes of intervention, recording and observation were performed by two trained people to control the influencing factors.

Statistical Analysis

Collected data has been analyzed by using software SPSS version 20 by Chi-square, Exact Fisher's and T-test. P value less than 0.05 were considered as a significant difference in this study.

Results

According to the results, the mean age of the study units was 68.63 ± 1.529 and this mean was 70.64 ± 2.018 in the Comfeel group and 66.62 ± 2.282 in the herbal ointment group. In relation to qualitative variables such as gender, in the study units, men had the highest frequency in terms of gender (69 men and 31 women).

The highest frequency of bed sores in the study units was in the sacral region (49%) and the lowest frequency was in the sole of the foot with 1%. The frequency of existing the types of the bed sores has also been reported in Table (1).

Table 1
Frequency of wound site and bed sore grades

Variable	Variable Mode	Relative frequency of variables in Comfeel group	Relative frequency of variables in Herbal oint group	Relative frequency of variables in total
Wound site	Heel	2	2	4
	Sacral	28	21	49
	Spinal cord appendages	2	1	3
	iliac	3	3	6
	Gluteus	12	12	24
	Between shoulders	3	5	8
	femor	0	5	5
	Sole of the foot	0	1	1
Grade	2	30	29	59
	Between 2 & 3	6	6	12
	3	14	15	29

The mean of the pre intervention Braden scoring, the mean of the Push scoring before and during the study were compared in two groups. Kolmogrov Smirnov test, in Table (2) shows that the two groups are Match in terms of variables such as the Braden scale and Push score before the intervention. The average time of patient's affecting by bedsore was after 18.73 ± 5.36 days in the intervention group and after 15.46 ± 7.40 days in the control group. The average time of hospital stays was 30.63 ± 5.93 days in the intervention group and 35.70 ± 7.25 days in the control group.

Table 2
Kolmogrov Smirnov test in Braden scale and Push score before the intervention.

Mean and standard deviation Group	Push score before intervention	Braden score before intervention
Herbal oint	323/44±0/10	475/70±0/15
Comfeel	317/68±0/10	490/88±0/15
Total	226/56±0/10	339/79±0/15
Kolmogrov Smirnov test	The test showed that the two groups were match in terms of push score before the intervention. Z= 5.799 P= 0.000	The test showed that the two groups were match in terms of Braden score before the intervention. Z= 3.233 P= 0.000

According to the Table (3), in the pre intervention evaluation, the mean and standard deviation of the Push score in the herbal ointment group was 323/44±0/10 while in the last evaluation in the same group it was 160/16±0/0. But in Comfeel group, in the pre-intervention evaluation, the mean and standard deviation of the Push score was 10/0±68/317, while in the last evaluation it was 364/60±0/0.

Also, in evaluating wound depth, mean and standard deviation before intervention in herbal ointment group was 077/37±0/0, which in the last evaluation had reached 000/00±0/0. But in Comfeel group, in the pre-intervention evaluation, the mean and standard deviation of wound depth was 069/32±0/0, while in the last evaluation it was 016/016±0/0. Wound extent was also assessed in two groups. The mean and standard deviation before the intervention in the herbal ointment group arrived from 252/74±0/6 to 100/10±0/0 after the intervention. In Comfeel group, it increased from 258/06±0/7 before the intervention to 244/38±0/0 after the intervention.

Table 3
Comparison of mean and standard deviation of Push tool score, wound depth and extent

mean and standard deviation of the variable Group	Push tool score before intervention	Push tool score after intervention (30 days)	Push tool score after intervention (more than 30 days)	Wound depth before intervention (centimeter)	Wound depth after intervention (centimeter) 30days	Wound depth after intervention days (centimeter) 30more than	Wound size before intervention(square centimeters)	(30 days)Wound size after intervention(square centimeters)
Comfeel	317/68±0/10	472/98±0/1	364/60±0/0	069/32±0/0	028/068±0/0	016/016±0/0	258/06±0/7	314/24±0/1
Herbal ointment	323/44±0/10	288/68±0/0	160/16±0/0	077/37±0/0	010/010±0/0	000/00±0/0	252/74±0/6	181/44±0/0
Total	226/56±0/10	283/33±0/1	199/38±0/0	0514/345±0/0	0152/039±0/0	008/008±0/0	180/90±0/6	185/84±0/0

There was no significant difference between the two groups regarding wound discharge (P: 0.14).

In this study, according to the statistical analysis, a significant difference was observed between the healing time of pressure ulcers between the two groups. Such a way that the mean and standard deviation of recovery time in the Comfeel group was 27.40 ± 12.467 and in the herbal ointment group was 21.57 ± 12.695 (Table 4). Other findings of this study include less pain in patients and the disappearance of unpleasant odors in some wounds completely within 48 hours in the herbal ointment group.

Table 4
Mean and standard deviation of recovery time in both groups.

	group	N	Mean±S.D	p
Date	Comfeel	50	27.40±12.467	0.025
	Herbal	50	21.57±12.695	

Discussion

Honey has abundant beneficial effects to the human health. The antimicrobial activity against the pathogens connected with invasive wound infections including methicillin-resistant *Staphylococcus aureus* (MRSA) was linked either to the production of hydrogen-peroxide by glucose oxidase enzyme or non-peroxide antimicrobial activity which could be connected to the presence of polyphenols and flavonoids, low pH value, osmotic effect of sugar, carbohydrate and its break-down Maillard products, aromatic acids, 10-HAD defensin-1 protein, 1,2-dicarbonyl compound methylglyoxal and bacillomycin F antibiotic like polypeptide (19, 20, 21, 22).

The authors concluded that reducing the wound pH value could decrease protease activity, increase fibroblast synthesis, increase oxygen release that all together promote wound healing. Alam et al. summed up lucrative effects of honey for the treatment of diabetic associated wounds that were mostly connected to its strong antioxidant and antimicrobial activity, low pH value, hydrogen peroxide activity which stimulates both fibroblast proliferation and angiogenesis, debridement of slough and necrotic tissue through autolytic debridement induced by honey proteases, minimizing wound odor either through its antimicrobial activity against anaerobic bacteria causing malodor or by converting glucose into lactic acid by lactic bacteria which replaced malodor of the by-products of amino acids metabolism, minimizing scar formation and by inflammation control (23). Natural honey was also found efficient in preventing and decreasing the oral mucositis in radiotherapy treated patients (24).

In a study performed by Amini and his colleagues, methanol and aqueous extracts of *Plantago major* leaves had a stimulating effect on the healing of burn wounds in a mouse model (25). In another study Zubari et al. showed that the aqueous extract of mixture of *Plantago major* and *Aloe vera* stimulated the wound for faster healing in the mouse model (26) and it was shown that leaf extract of *Plantago major* increase cell proliferation in vitro, which play an important role in wound healing process (27).

Many studies have examined and emphasized the antioxidant properties of *Rosa damascene* (28, 29). Haj Hashemi et al. showed the anti-inflammatory and analgesic activity of *Rosa damascene* extract in animal model (30) and also, Abu Ali Sina mentioned the effect of *Rosa damascene* on wound healing and helping to accelerate the granulation process (31).

Also, the mean hospital stays of patients in the control group was longer than the intervention group and it was in accordance with the study of Dhikhil & et al. The recent study findings showed that the most common location of bedsore was in sacrum which was in accordance with the study of Leijon & et al. and Lupiañez-Perez & et al (32, 33) and the study of Aljezawi and et al. showed that the most common place for pressure ulcers was on the buttocks which was not the same as our findings (34).

Conclusion

Due to the therapeutic effects of the compounds in this herbal ointment and also the importance of bedsores and due to the economic situation of the people and the unavailability of new dressings for all people, this herbal ointment can be used as an effective and cheap alternative herbal medicine along with other treatments. Further studies with larger sample sizes are required to validate our findings.

Limitations

The subjects in this study were people over 18, and we couldn't study the effect of this drug in people under 18. Therefore, its effect on this age group can be investigated in future studies.

Declarations

Ethics approval and consent to participate: All the ethical considerations based on the international ethical protocols were considered by authors and the work was approved by ethics committee of the Khomein of medical sciences university (Approval code: IR.KHOMEIN.REC.1397.003). This study has also been registered in the Iranian Registry of Clinical Trials (IRCT20100130003227N13).

Consent for publication

Not applicable.

Availability of data and materials:

Please contact corresponding author (M.T) for data requests.

Competing interests:

The authors declare that they have no competing interests.

Funding:

Not applicable.

Authors' contributions:

MT and AS proposed the original concept. MT and AS designed the intervention and collected data. MT and AL prepared the herbal tea. MT, MB, MA, AA, DA and HM equally participated in the data analysis. All authors contributed to writing the manuscript.

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Figures

Figure 1

Patients flow across the study