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Comparison of the Efficacy of Topical *Arnebia euchroma* Product with Topical Phenytoin on Pressure Ulcer in Patients with Spinal Cord Injury: A Triple-Blind, Randomized Clinical Trial

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Abstract

Background: *Arnebia euchroma (Ae)* in traditional Persian medicine is used for wound treatment. This study assessed the efficacy of *Ae* liniment on pressure ulcer (PU) remedy in patients with Spinal Cord Injury.

Methods: In this triple-blind, randomized clinical trial, grade 2 and 3 wounds were randomly assigned to receive either *Ae* liniment or Phenytoin Cream 1% twice a day for 5 weeks. Recovery was measured by the wound size, exudate, and tissue type by the "Pressure Ulcer Scale for Healing" (PUSH) tool on days 0, 7, 14, 21, 28, and 35. PUSH score between groups was compared with the Mann-Whitney U test, and also within each group by Friedman test.

Results: 74 patients (37 in each group) participated and completed the study. Mean±SD of PUSH Scores at baseline, and 1,2,3,4,5 week after the treatment in *Ae* group were 9.73±2.65, 9.92±3.08, 8.24±3.86, 7±4.08, 5.22±4.3, 3.41±3.85 and in Phenytoin group were 10.05±1.85, 9.97±1.9, 9.59±2.08, 9.22±2.09, 8.54±2.72, 7.57±3.26. PUSH Score decrease in the *Ae* group was 70.33 ± 32.25% , and in group 2 was 27.67± 26.8% ($P < 0.001$), which indicates that in comparison of the PUSH Score decrease between the two groups, this reduction was significantly higher in the *Ae* group. During the study, complete wound healing was observed in 16 patients (43.2%) in the *Ae* group and in the Phenytoin group in 3 wounds (8.1%) ($P = 0.010$). No side effects were reported in either group.

Conclusions: PU healing was significantly better in the *Ae* group than phenytoin cream. It may be considered as a potential option in the treatment of PU in patients with Spinal Cord Injury.

Keywords: *Arnebia euchroma*, Pressure ulcer, Persian medicine, Herbal medicine, Wound healing

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Introduction

A pressure ulcer (bed sore or decubitus ulcer) is a localized area of tissue necrosis that progresses. When soft tissue is under pressure by bone and outside, high pressure causes capillary collapse and prevents nutrients from reaching the tissue (1). The bed sore`s incidence varies between 4% -38% in intensive care units (2), that affects the quality

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↑What is "already known" in this topic:
Arnebia euchroma (*Ae*) has a healing effect on wounds and burns. This plant has been studied for its properties in enhancing wound healing, promoting re-epithelialization, increasing fibroblasts, collagen production, and improving vascularization.
Its prominent components (shikonin and alkannin) have anti-inflammatory and antimicrobial activity. The efficacy of *Ae* product for wound healing in pressure ulcers is not entirely clear.

→What this article adds:
This is the first study to evaluate the therapeutic results of *Ae* on pressure ulcers. Results reveal the superiority of *Ae* product over phenytoin for wound healing in patients.

of life in patients with spinal cord injury (SCI) (3). Pressure ulcer is the third most costly disease after cancer and cardiovascular disease (4). Treatment approaches include pressure relief, wound hydration, nutritional, metabolic, vascular, and circulatory status, and, if necessary, debridement and surgery (5). Generally, topical treatments include dressings, ointments, and creams such as silver sulfadiazine, neomycin, and phenytoin (6). Wound healing processes include: Rapid response, Inflammatory response, proliferation, migration and contraction-recovery (7). Medic herbs have a big act on sore healing procedures (8). Arnebia euchroma (Royle) I.M. Johnst, which belongs to the Boraginaceae family (9), and is known as "Heveh choaeh" in traditional Persian medicine and It is ancestrally applied for wound healing (10). Its famed ingredients (shikonin and alkanin) have extensive medicinal effects such as anti-inflammatory and antimicrobial (11-13), Its root is beneficial in skin disease, dermatitis, wounds, and burns (14). Based on studies, this plant can prosper in re-epithelization, an increase of fibroblasts, collagen production, and vascularization (15). There are several animal studies showing the beneficial effects of this plant on wound healing (16, 17). Therefore, the researchers decided to investigate this plant on bed sore recovery. The aim of this study was a comparison between Ae liniment and phenytoin cream 1% on bed sore.

Methods

Preparation of Arnebia euchroma product

After buying the dried roots of the Ae plant from the local market of Tehran, it was identified by Professor Gholamreza Amin under the voucher number PMP-1238 and it was kept in the herbarium of the Faculty of Pharmacy of Tehran University of Medical Sciences. Ae liniment was produced from roots (100 grams) and olive (Olea europea) oil (1kg), with a weight ratio of 1:10 (18). After crushing the dried roots of Ae, they were heated in olive oil at 60-80 °Celsius for 10 hrs. Then they were filtered and filled in containers.

Study design

This randomized, parallel-group, triple-blind trial was conducted to evaluate the effect of topical Ae liniment on pressure ulcers in patients who were referred to Ahwaz Welfare Services Clinic from Feb. 2020 to Oct. 2020. Inclusion criteria for the study included Spinal cord injury patients with bed sore; Age 15-75 years; Persistence in the study; Having one wound (Grade 2 or 3); wound diameter <15 cm;

The exclusion criteria were: Incidence of any complication, dissatisfaction, and need for emergency surgery to treat wounds.

Patients who had pressure ulcers and met the inclusion criteria were included in the study. After completing the demographic and medical information questionnaire for each person, the degree of the wound was defined by the researcher in everyone (based on the NPUAP pressure ulcer staging protocol table). Subjects with grade 2 and 3 ulcers were randomly divided into two groups: the intervention group used Arnebia Euchroma topically, and the control group used 1% phenytoin cream on pressure ulcers twice a day for 5 weeks. Both groups were taught how to care for the wound (change position every 1 hour, to help the patient move to reduce friction and shearing, using a wheelchair air mattress, using wavy mattresses on the bed, washing with normal saline). Patients were examined at 7-day intervals and the rate of ulcer recovery was assessed according to the PUSH.

Sample size

Considering the alpha error as 0.05, the study power as 80%, and the effect size of 0.7 for the PUSH score according to the results of a pilot study on 10 patients in each group, the sample size was considered as 40 cases in every set considering 20% attrition (32+8).

Randomization method

The stratified randomization method was used for random allocation. At first, patients were separated into two squads of grades 2 and 3. After that, randomization was performed in each group using the block randomization method. For this reason, the "random allocation software" (version: 2) was used, and random block sizes were selected to prepare a list for 80 patients and 2 groups.

The sealed envelopes were used for allocation concealment; the participants' numbers were written on the external part of the envelopes, and the group's name had been written in them.

Blinding

Medicines of both classes were prepared and filled in the same package. The person (physician) who recorded the patient's follow-up conditions and the analyzer also did not know the type of medication the patient was taking and was blind.

Statistical Analysis

The data was analyzed with SPSS software (Version 17.0). Mean and standard deviation were used for quantitative descriptions, and frequency percentage was used for qualitative changes. The PUSH score was compared between groups with the Mann-Whitney U test and also in each group with the Friedman test. The chi-square test was used for qualitative comparisons between groups. P less than 0.05 was considered significant.

Outcome measurements

The pressure Ulcer Scale for Healing (PUSH) tool was used in this study and the PUSH Score was considered as the primary outcome. The tool was developed by the National Pressure Ulcer Advisory Panel to monitor the change in pressure ulcer status over time (19). This tool has three factors:

Wound surface (0-10);

For measuring wound surface area, the maximum length and maximum width are measured by a centimeter ruler. These two measurements are multiplied together to get an estimate of the surface area in square centimeters

Exudate amount (0-3);

The amount of exudate: the amount of exudate (drainage)

available after removing the dressing and before applying medicine is determined.

No, little, moderate, or severe exuda.

Tissue type (0-4).

Type of tissue: There is necrotic tissue (score 4). There is some sludge and no necrotic tissue (score 3). A clean wound with granulated tissue (score 2), a superficial wound that becomes re-epithelialized (score 1). When the wound is closed (score 0).

4- Necrosis: The tissue that is firmly attached to the wound bed or the edges of the wound is black, brown, or tan in color and may be softer or harder than the surrounding skin.

3- Sludge: The tissue that sticks to the wound bed in the form of strings or thick masses or is mucous, is yellow or white in color.

2- Granulation: pink or fleshy red texture with a shiny, moist and grainy appearance.

1- Epithelial tissue: in superficial wounds, it is a new pink or shiny tissue (skin) that grows from the edges or in the form of islands on the surface of the wound.

0 - closed / reappeared: wound completely covered with epithelium (new skin).

The scores of the three factors, including wound surface (0-10), the amount of drainage (0-3) and types of tissues (0-4) added together to provide an overall score (0 -17). A lower score means that the wound has healed more (19, 20). Its validity and reliability have been confirmed in several studies (20, 21).

Follow-ups were performed at weekly intervals (from first to fifth week), except in special and urgent cases such as complications or problems or questions for the patient that required a visit and follow-up before one week. At least 5 follow-up sessions were performed for each patient. The number of daily dressings of the patient was checked at each follow-up of the chart. They were asked about possible complications as the secondary outcome and the wound was examined and recorded according to the size, amount of discharge and its change, etc. according to the PUSH tool.

The percentage of the total Push score decrease was obtained from this formula:

(First Push score _ Push score of the last session)×100÷first Push score).

Results

A total of 110 patients (disabled people) with bed sores were evaluated (Figure 1). Figure 1 is the CONSORT flowchart, which shows the number of falls and its reason in two groups. 36 patients excluded :three people due to 4th-degree infectious wounds, three people due to 1st-degree wounds, four people due to wounds size larger than 15 cm, 6 people due to the impossibility of follow-up during the next two months, 10 people reluctant to participate in the study, 10 people due to age below or above the inclusion criteria). Finally, 74 patients (37 in each group) participated and completed the study (somebody had more than one wound, but just one wound was selected from each patient).

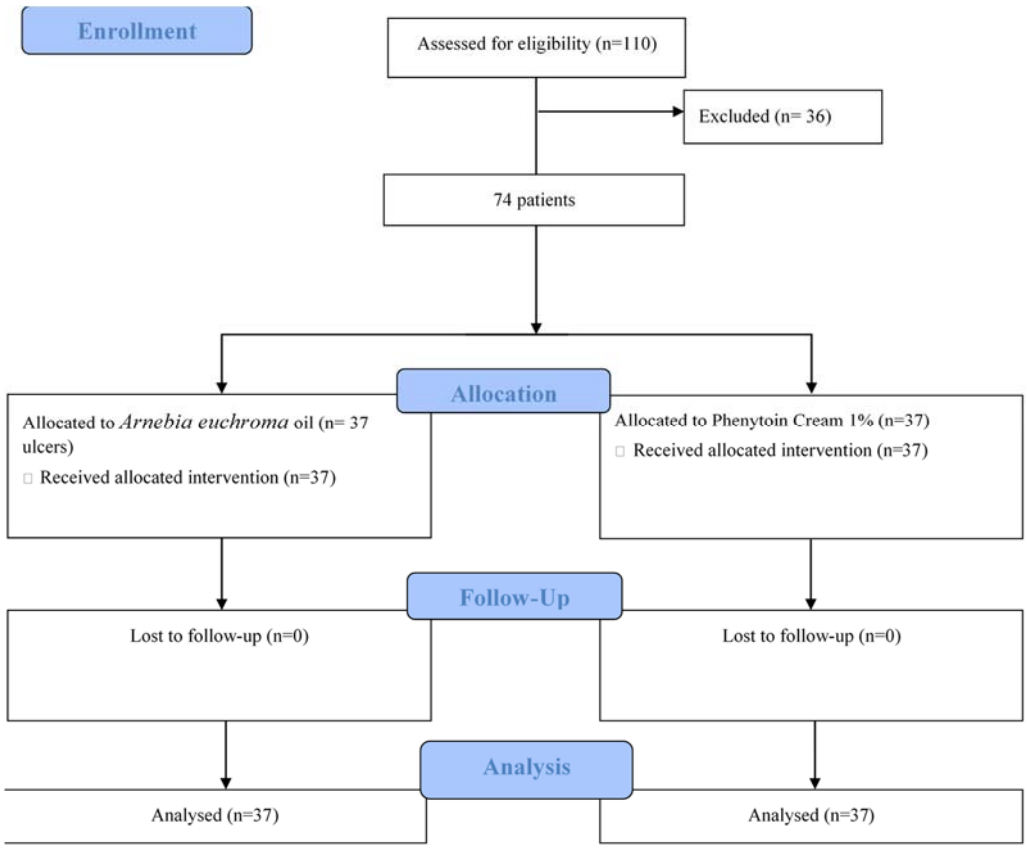

Figure 1. CONSORT flow diagram of the study

The calculated sample size was 32 plus 8 attrition in each group = 40. As we did not have any attrition, the study stopped when 37 patients completed the interventions in each group.

33 ulcers (44.6%) were grade 2, and 41 (55.4%) were grade 3. During the 5-week study period, none of the patients dropped out.

The frequency of age, sex, and the frequency of grade of ulcers are presented in Table 1.

There was no significant difference in wound grade (P = 1.000), and location between groups (P = 0.180).

Changes in wound size in both groups during the study can be seen in Table 2, and Table 3 presents the PUSH score in each group during the study. Both groups showed a significant decrease in total PUSH score at the end of the study, but the percentage of this decrease in the Ae group was notably bigger than the phenytoin group ($P < 0.001$) (Figure 2).

In both groups, at weeks 4 and 5, all wounds were without discharge.

At the end of the 5th week, 16 (43.2%) ulcers in the Ae group and 3(8.1%) ulcers in the phenytoin group experienced a complete recovery (P = 0.010). No side effects were reported in either group.

Table 1. Demographic and Basement characteristics of the participants

Variable f	Arnebia euchroma Group1	Phenytoin Cream 1% Group2	*P* value
Age (year) mean± SD	32.78 ±13.34	37.27±13.37	0.153*
Sex n (%)	Male: 24 (64.9) Female: 13 (35.1)	Male: 25 (67.6) Female: 12 (32.4)	1.000**
Grade of the ulcer n (%)	Stage 2: 16 (43.2%) Stage 3: 21 (56.8%)	Stage 2: 17 (45.9%) Stage 3: 20 (54.1%)	1.000**

SD:standard deviation,*: t-test,**: fisher's exact test.

Table 2. Comparison effect of Arnebia euchroma Liniment and Phenytoin Cream 1% for wound size (area) in patients with pressure ulcer

Time(week)	Arnebia euchroma Group	Phenytoin Cream 1% Group	*P* value□
0	15.81 ±17.31	11.19±8.86	
1	14.35 ±15.54	11.12±8.86	
2	11.87 ±13.82	10.81±8.71	
3	8.56±11.05	9.89±8.41	
4	5.47±9.55	8.54±7.98	
5	3.48 ±8.31	6.99±7.18	
P□□	0.001<	0.001<	
Area decrease			
Area decrease%	85.93±25.23	45.29±29.85	0.001<

□Mann-Whitney U test, □□Friedman test

Table 3. Comparison effect of Arnebia euchroma Liniment and Phenytoin Cream 1% on total Push score change in patients with pressure ulcer

Time (week)	Arnebia euchroma group Mean ± SD	Phenytoin Cream 1% group Mean ± SD	*P* value□
0	9.73±2.65	10.05±1.85	
1	9.92±3.08	9.97±1.9	
2	8.24±3.86	9.59±2.08	
3	7±4.08	9.22±2.09	
4	5.22±4.3	8.54±2.72	
5	3.41±3.85	7.57±3.26	
P□□value	<0.001	<0.001	
Push decrease%	70.33±32.25	27.67±26.8	<0.001

□Mann-Whitney U test, □□Friedman test

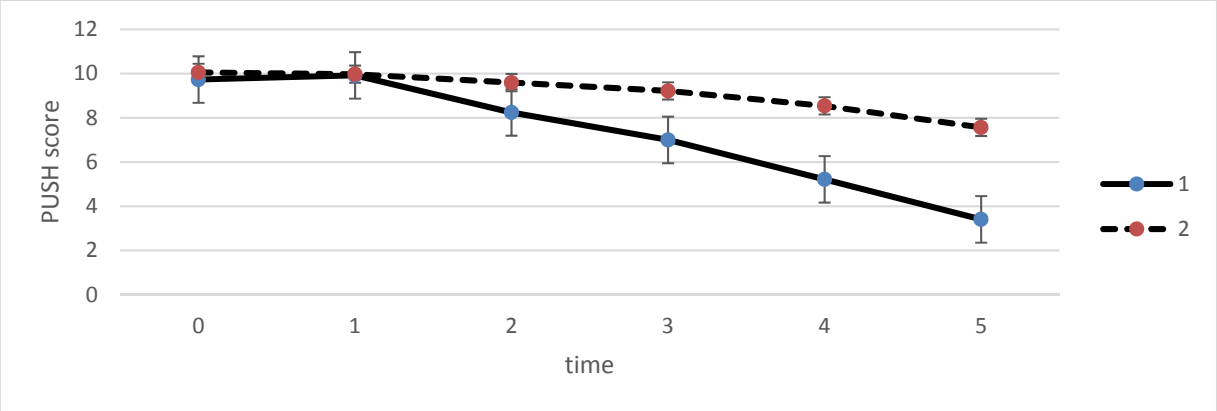

Figure 2. Comparison effect of Arnebia euchroma Linment =group1, and Phenytoin Cream 1% =group2 on total Push score in patients with pressure ulcer

Discussion

This present study showed Ae liniment significantly improved pressure ulcers compared to phenytoin. There are several studies about the effectiveness of this plant on various types of wounds (15, 22-25). However, no clinical research has been found on the efficacy of Ae on pressure ulcers. In a perusal, the therapeutic efficacy of Ae extract compared to alpha ointment on wound healing in rats was inspected. It showed that Ae and alpha ointment mainly recovered re-epithelialization, proliferation of fibroblast and collagen production and acted as anti-inflammator. This study proved that the sap of Ae is an efficient remedy compared to alpha ointment (26). In another study in 50 rats, the result of Ae on burns was investigated, and the results of this study indicated the effectiveness of this plant on burn wounds (27). In an experimental study, it was shown that topical Ae has therapeutic efficacy on after-laser ulcers (23). In addition, in a clinical study on 45 people with second-degree burns, the therapeutic effects of Ae were compared with silver sulfadiazine cream. The outcomes of this research revealed that the wound healing time and the intensity of pain and burning in the Ae group were less than in the silver group (24). This plant has wound healing properties, antibiotics, antivirus, anti-inflammatory, antipyretic antithrombotic, antiproliferative, cytotoxic and anti-cancer (9, 28). According to studies, this plant inhibits the growth of gram-positive and negative bacteria and has a very good antioxidant activity (29, 30). As a result, Ae with antioxidant and antimicrobial and wound healing activities is likely to have been more successful in reducing pressure ulcers than phenytoin.

In the comparison chart, the changes in total PUSH score criteria in two groups show a slight increase in the number of push (group 1) at the end of the first week, which is due to increased secretion in the wound due to the therapeutic effect of Ae drug. An increase in the total score of the benchmark may mistakenly suggest a wound deterioration in the form of a graph.

It is recommended to pay attention to this important point in using herbal medicines with similar properties. In some patients who used Ae product, the increase in wound secretion started after two or three days, and the secretion stopped until the second week. The event of increased secretion did not occur in some of the wounds of the Ae group.

Another point is that in the case of large wounds that are much larger than 24 cm^2, follow-up on treatment is not accurate using only the PUSH criterion. Because according to the study of wounds with these characteristics in this study showed that even despite reducing the size of the wound to more than half, the standard push number has not changed and has remained constant. Until the push number in the area section is below the upper limit, the total number will not indicate a degree of wound healing, and part of the wound healing and reduction will remain hidden and not measured, but in wounds with size and dimensions. Smaller ones with a small area do not have this problem and using the PUSH criterion is practical.

Conclusion

This study demonstrated that Arnebia e. Liniment, which has been used for many years in many regions, is an effective medicine for pressure ulcer healing. Compared with phenytoin in patients with spinal cord lesions, it has good therapeutic effects on pressure ulcers.

Authors' Contributions

Sakineh Erabi: conceptualization, validation,investigation, project administration, and writing the original draft. Ali Ghobadi: Methodology, preparation of drugs, writing/reviewing, and editing. Fataneh Hashem-Dabaghian: methodology, formal analysis, and validation. Mostafa Dahmardehei: methodology corporation in study design; Hoorieh Mohammadi Kenari: conceptualization, methodology,validation, writing, reviewing and editing, supervision, and project administration.

Ethical Considerations

This clinical trial was approved by the Ethics Committee of Iran University of Medical Sciences IR.IUMS.REC.1398.560 (date of approval 2019-08-31). It was also registered in Iran's clinical trials registry with the number IRCT20190907044714N1.

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Conflict of Interests

The authors declare that they have no competing interests.

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