Research paper

Comparison of a novel herbal skin care ointment with regular ointments to treat skin around the abdominal stoma: A clinical trial study

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ABSTRACT

Introduction: The incidence of gastric ulcers in patients with abdominal stoma is high and affects the quality of patients’ life.

Aim: To evaluate the effect of Adib herbal ointment containing chamomile rose, black nightshade origin versus Comfeel and Conveen ointments on the skin of abdominal stoma.

Material and methods: This is a clinical study in which the volunteers were stoma patients. Study group consisted of 52 qualified subjects, 26 were included in the experimental group and 26 in the control group. A 2-part questionnaire was used for the data collection. The 1st part was demographic information. The 2nd part of the data collection was evaluated according to the pressure ulcer scale for healing (PUSH) tool, which used for examining skin ulcers around the stoma. P ≤ 0.05 was considered as a significant.

Results and discussion: The results of the Mann–Whitney test showed that between the mean score of the total score of the wound before intervention (P = 0.92) and on the 3rd day (P = 0.476), 6th (P = 0.222), 9th (P = 0.11) and 12th (P = 0.418), there was no significant difference between the control and test groups. Also, the Friedman test (intra-group) also showed that between the mean score of the total score of the wound before the intervention and the 3rd, 6th, 9th and 12th days in the control group (P = 0.0001) and in the experimental group (P = 0.0001) There was a significant statistical difference.

Conclusions: Based on the study, Adib herbal ointment could be recommended for the treatment of stoma to the skin as an herbal product as other common treatments.

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1. INTRODUCTION

The skin is the largest and one of the most active organs in the body, covering an area of 2 m².1-3 A discontinuity in the body membrane that blocks the membrane as part of its organ to continue its normal function is called an ulcer. In fact, it is well known that ulcers are the loss of epithelial cells that have spread to the skin, and several factors are involved in the formation process, such as mechanical, chemical, etc.4 The patient’s excretry secretions, such as in ostomy patients, can destroy the skin’s defense barrier and produce several degrees of ulcers, such as dermatitis and even severe scarring.5 Colostomy is an invasive surgery that is performed on the lower gastrointestinal system for a variety of reasons.5 There are more than 100 000 people in the United States and 102 000 in the United Kingdom. According to the Iranian Ostomy Association, the number of stoma in Iran is about 30 000, including 70% colostomy, 20% ileostomy and 10% urostomy.6-7

Patients with stoma are prone to osmotic necrosis, post-stroke, prolapse, stenosis or obstruction and skin irritation.5 Despite extensive advances in the treatment and management of stoma in recent years, the prevalence of skin damage around the ostomy is a constant case.6,8 The care of the skin around the stoma is a growing concern and can be expanded rapidly, the skin surrounding the stoma inflammation can make sticking the ostomy bag difficult, which itself causes damage to the skin. Hence, one of the important nursing interventions in these patients is skin care and maintaining skin integrity. Skin care is one of the tasks of nurses and nurses as a key member of the treatment can offer new solutions in the treatment of this disorder.9 Today, advanced dressings are easy to use on the patient’s body and are easy to remove and make the patient feel good.

Scientists are seeking to produce products that are easy to install, use, and remove. These products are very sensitive and should to have low odor.10 According to the latest researches on the prevention and treatment of ulcers, various methods of protecting strips, glycogen dressings, pectin and gelatin base skin barriers, glycerin hydrogel skin dressings, hydrocolloid powders, chamomile flower extract, and Senegal acacia flower extract are used.11 In addition, according to the experience and observations of the researchers, Comfeel and Conveen commercial ointments are now used to treat these ulcers in the research field. It is worth noting that these ointments are more expensive than low yields, so providing suitable alternatives at a lower cost, taking into account the effectiveness and cost of domestic production is a priority. In recent years, nurses have conducted extensive research on adjuvant therapies that nurses can use, including tactile therapy, herbal therapy, art therapy, and relaxation techniques.12

In many countries, the use of herbs, herbal extracts and other herbal products (such as Acacia senegal, Aloe vera, Eucalyptus, tea, etc.) has a long history and is used to treat ulcers or burns.14-19 Chamomile is one of the herbs considered in traditional medicine due to its various characteristics. Its main ingredients include α-bisabolol, bisabolol oxide, Spiro-water, chamazolin and flavonoids. Bisabolol can effectively reduce inflammation and wound healing, and also has pain relief effects. Flavonoids also have anti-inflammatory and sedative effects. Chamomile is used for skin inflammation, allergic dermatitis, and itchy skin, caused by scratches and surface cuts, and no obvious adverse reactions. Various clinical studies have evaluated the effectiveness of chamomile in wound healing.20,21

Adib herbal ointment with chamomile rose, black nightshade origin, produced by Adib Eksir Company (Teheran, Iran) is licensed by the Iran Ministry of Health and its ingredients play an important role in wound healing. Adib herbal ointment is a newly produced herbal ointment. It contains the active ingredients of multiple plants including nigrum and rose extracts, ascorbic acid, wax, oleic acid (37%-49%) and linoleic acid (37%-47%) (Table 1). Various researches about the herbs used in ointment indicated different properties such as antibacterial properties, for the prevention of ulcerative infection, anti-scar effect, and in-

<table>
<thead>
<tr>
<th>Types of ointment</th>
<th>Main Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adib herbal ointment</td>
<td>Multiple plants including Nigrum and Rose extracts, Ascorbic acid, Wax, Oleic acid (37%-49%), Linoleic acid (37%-47%)</td>
</tr>
<tr>
<td>Comfeel ointment ingredients</td>
<td>Cera Microcrystallina, Glyceryl Olate, Lanolin Alcohol, Cyclomethicone, Magnesium Citrate, Methylparaben, Propylparaben</td>
</tr>
<tr>
<td>Conveen ointment ingredients</td>
<td>Zinc Oxide 12%, Dimethicone 1%, Lanolin Oil, Tocopheryl Acetate (Natural Vitamin E), Cetyl Alcohol, Glycerol Stearate</td>
</tr>
</tbody>
</table>
increased repair speed, anti-inflammatory properties without anti-inflammatory adverse effects and without immunosuppression, reducing 80%–90% of the cost of treatment by not having to admit to the hospital. Burn ointments are offered at different and high prices all over the world, while they do not have the desired effect, while the cost of the Adib herbal burn ointment is much lower than that of existing products.\(^{22}\) Since in most parts of Iran different types of plants are cultivated and their pharmaceutical processing is possible, in the case of identification of their effects accurately, they can be used in the treatment of various diseases. If the therapeutic effects of the herbs are determined, the use of these plants is far better than chemical drugs because chemical drugs have a lot of harmful effects.\(^{23}\)

There are only a few studies in this field. In this regard, this ointment is a natural, inexpensive and affordable ointment, and despite the scientific advances, there is still no definitive treatment for the healing of these ulcers. Considering the fact that this complication has a high prevalence in patients with ostomy and affects the quality of life of these patients, the adoption of an appropriate approach in treatment of this disorder can play a significant role in accelerating its recovery.

2. AIM

The aim of this study is to evaluate the effect of Adib herbal ointment containing chamomile rose, black nightshade origin versus Comfeel and Conveen ointments on the skin of abdominal stoma. The aim of this study was also to compare the effect of Adib, Comfeel and Conveen ointments on the skin surrounding the abdominal stoma. The results of this study could provide a new and suitable method for the recovery and prevention of these ulcers.

3. MATERIAL AND METHODS

3.1. Study design

This is a clinical trial study conducted at the Alzahra Hospital affiliated to the Medical University of Isfahan, Iran, in 2016. In this study, samples were randomly assigned to the experiment (Adib ointment care) and the control group (Comfeel and Conveen ointment care).

3.2. Standard criteria

Inclusion criteria were abdominal stoma, skin irritation around the colostomy, chemotherapy or radiation during the study, non-use of corticosteroids, no active skin diseases (allergic diseases, psoriasis, candidiasis and skin allergies), no diabetes, and no weight loss below 2 kg, colostomy without prolapse or retraction and receiving a 3–10 score through the pressure ulcer scale for healing (PUSH). Exclusion criteria were patients treated with chemotherapy, radiotherapy, corticosteroids and patient death during the study.

3.3. Data collection

In order to collect data, a questionnaire and a tool (PUSH) for the examination of stoma wounds were used. The questionnaire consisted of demographic information and patient’s information, including height, weight, history of the disease, medications, time of colostomy, and potential complications. The data acquisition tool included a PUSH tool for examining skin ulcers around the stoma. The PUSH tool is a commonly used tool developed by the National Pressure Ulcer Advisory Panel (NPUAP), which grades pressure ulcers based on size of wound, wound bed tissue type, and exudate amount.

The PUSH tool, used to assess the wounds, 3 parameters applied to evaluate the wound healing process and the intervention results. The 1st parameter is the wound area, which is measured in terms of the longest length and the largest width in square centimeters. The wound area is 0–10 points depending on the area. The 2nd parameter refers to the amount of exudate present on the wound after removal of the dressing and before application of a topical agent. The 3rd parameter is the appearance of the wound bed, which is defined as the type of tissue present in the region.

The sum of these parameters is scored as a total score of 0–17. A higher value indicates that the ulcer is more severe, and a lower value indicates a better healing. Therefore, the PUSH tool generates PUSH scores using only three variables that describe the ulcer state and healing progression.\(^{24,25}\)

3.4. Ethical consideration

After receiving the permission of the university ethics committee, the subjects were selected who had the criteria for entering the research, and by clarifying the purpose of the study as well as the advantages and disadvantages of the individual methods, the written documents were supplemented by the approval subjects, demographic questionnaire and a special questionnaire on disease information such as place of colostomy, time of colostomy, occurrence of a skin problem around the colostomy.

3.5. Intervention procedure

Eligible study subjects were randomly assigned to both groups using a randomized table. Each random subject was randomly assigned an odd or even number, so sampling continues until the number of subjects is completed. Of the 52 eligible individuals, 26 were in the experimental group and 26 were in the control group.\(^{26,35}\) Both groups of skin ulcers were tested and controlled by the PUSH as a special tool for assessing the skin around the stoma. According to the tool’s guide, the ulcers get scores 3–10. In the routine care, after washing the skin around the colostomy with baby shampoo and normal saline, the skin was gently dried with gauze and then immersed with Comfeel and Conveen ointments. The ointment remained on the skin for 20 minutes, and since the presence of ointment and any fatty substances on the skin interfered with the sticking of the bag, after 20 minutes, the ointment should be washed off the skin and after the drying, a colostomy bag was glued. It is noteworthy that people with ostomy in the area surrounding the stoma suffer from skin ulcers exactly at the adhesive site of the ostomy bag, so their
skin care was done at the time of the exchange of the bag. After the first intervention on days 3 and 6, the wounds in the test group were again disturbed by the PUSH tool.

On the 6th day, the intervention was interrupted, but in the event of a wound, the patient was required to go to the 9th day. Care in the control group was in the following way: during the 1st visit, the ulcers were assessed by the tools, ranked and the routine care was done. In the routine care, after washing the skin around the colostomy with baby shampoo and normal saline, the skin was gently dried with gauze and then immersed with Comfeel and Conveen ointments.

After 20 minutes, Comfeel and Conveen ointments were washed off the skin. The patient’s ulcer was re-examined in the control group on the 9th day after the first visit. The ulcer of the test group was intervened to complete recovery according to the criteria determined by the physician of the health center and ultimately the time it took to recover the ulcer was calculated. It should be noted that the intervention was performed by the researcher in the female patients.

In order to observe the ethical issues, the intervention in the male patients was carried out by a fellow male nurse who had been trained, using a completely similar and standard method. Sampling in the morning shift was performed throughout the week from 8:00 am to 2:00 pm on the 15th day after assuring of the ulcer recovery.

3.6. Statistical method

After collecting the required data, the results were analyzed using SPSS v. 22 software and then studied by descriptive and inferential statistics. The Kolmogorov–Smirnov test was used to assess the normality of the data. All subjects in the two groups were classified and analyzed by statistical tests of the χ², Mann–Whitney and Fridman tests. In the present study, a P ≤ 0.05 was considered to be significant.

4. RESULTS

The mean age of the subjects was 57 years and the age ranged from 46 to 72 years; 81% of the participants were illiterate. The duration of colostomy is from 6 months to 5 years with an average of 2.2 years. Most subjects (86%) underwent colostomy for more than a year. All patients used two-piece bags. The score of condition of the ulcer around the colostomy of 8 subjects (15.38%) was 7, 13 (25%) was 6, 12 (23%) was 5, 12 (23%) was 4 and 7 (13.46%) was 3 (Table 2).

Subjects of the experimental and control groups in terms of quantitative variables (age, body mass index, duration of colostomy, number of weekly baths, average rating of ulcer score, mean rank of ulcer color change scores, rank of recovery days) with independent T-test and Mann–Whitney test and in terms of homogeneous qualitative variables (sex, education level, frequency distribution of patients based on total score of ulcer) with χ² test were homogeneous and a significant difference (P > 0.05) between the above variables was not found. Comparison of the frequency distribution of patients based on the total score of the ulcer in the test and control group before intervention is shown in Table 3.

Comparative results of the mean total number of ulcers before the intervention, 3rd, 6th, 9th and 12th days in the control and test groups are shown in Table 4. The total score

### Table 2. Frequency distribution of ulcer score based on the duration (day) of recovery in the experimental and control group.

<table>
<thead>
<tr>
<th>Ulcer score</th>
<th>Study day</th>
<th>Experimental group</th>
<th>Control group</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>3</td>
<td>3(11.53)</td>
<td>1(3.84)</td>
<td>0(0)</td>
<td>0(0)</td>
</tr>
<tr>
<td>6</td>
<td>1(3.84)</td>
<td>3(11.53)</td>
<td>3(11.53)</td>
<td>0(0)</td>
</tr>
<tr>
<td>9</td>
<td>0(0)</td>
<td>1(3.84)</td>
<td>4(15.38)</td>
<td>4(15.38)</td>
</tr>
<tr>
<td>&lt; 12</td>
<td>0(0)</td>
<td>0(0)</td>
<td>0(0)</td>
<td>2(7.69)</td>
</tr>
<tr>
<td>Total</td>
<td>4(15.38)</td>
<td>5(19.23)</td>
<td>7(26.92)</td>
<td>6(23.07)</td>
</tr>
</tbody>
</table>

Comments: Experimental group – Adib herbal ointment; Control group – Comfeel and Conveen ointments. All numbers are given as (%).

### Table 3. Comparison of frequency distribution of patients based on the total score of ulcer in the experimental and control groups before intervention.

<table>
<thead>
<tr>
<th>Score of ulcer around the colostomy</th>
<th>Experimental group</th>
<th>Control group</th>
<th>Statistical test</th>
<th>χ²</th>
</tr>
</thead>
<tbody>
<tr>
<td>N(%)</td>
<td>Mean</td>
<td>SD</td>
<td>N(%)</td>
<td>Mean</td>
</tr>
<tr>
<td>3</td>
<td>4(15.38)</td>
<td>5(19.23)</td>
<td>0(0)</td>
<td>7(26.92)</td>
</tr>
<tr>
<td>6</td>
<td>7(26.92)</td>
<td>5.03</td>
<td>1.31</td>
<td>5(19.23)</td>
</tr>
<tr>
<td>Total</td>
<td>26(100.00)</td>
<td>26(100.00)</td>
<td>26(100.00)</td>
<td>26(100.00)</td>
</tr>
</tbody>
</table>

Comments: P ≤ 0.05 was considered as a significant.
5. DISCUSSION

The results of this study showed complete healing in the skin around colostomy in all patients on the 15th day of the two groups of experiments (Adib ointment) and the control group (Comfeel or Conveen ointment). In the current study to better evaluate our experiments, we used two control groups. In the present study, there was no significant difference in ulcer healing of colostomy between the experimental group and the control group on any day (pre-intervention, 3rd, 6th, 9th, and 12th days). In other words, Comfeel, Conveen or Adib ointment has a similar effect on the healing process of ulcers. Although all patients with scores of 3, 4, and 5 in the experimental group recovered completely on the 12th day, 2 of the 4 and 5 patients in the control group did not fully recover on the 12th day, which was not statistically significant. In general, it can be said that chamomile is superior to Comfeel or Conveen in the treatment of low-scoring ulcers.

In the study of Ala et al., adults had secondary burns, and the burned area of the body and trunk was 1%–10%. The average recovery time of the Adib skin ointment group and the sulfadiazine ointment was 7.5 and 11.8 days, respectively (P < 0.0001). The mean treatment satisfaction rates for the Adib ointment and sulfadiazine groups were 7.5 and 7.8 days, respectively (P < 0.041). In the sulfadiazine cream group, 1 (3.3%) of patients had wound infection, and 7 (23.3%) of the Adib skin ointment group had ulcers due to ointment. In this study, most patients did not receive this treatment due to lack of knowledge or lack of information about herbal Adib’s ointment; this limitation is consistent with the limitations of this study.

In another study, the treatment of lesions around the stoma caused by chamomile was better than treatment with 1% hydrocortisone ointment. The previously reported results used German chamomile to treat atop dermatitis, skin car-

Table 4. Comparison of the mean score of the total ulcer score at pre-intervention, 3, 6, 9 and 12 days between the two groups of control and experimental.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Experimental group</th>
<th>Control group</th>
<th>Mann-Whitney statistical test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day</td>
<td>Mean rank</td>
<td>Mean rank</td>
<td>P</td>
</tr>
<tr>
<td>Pre-intervention</td>
<td>4.60</td>
<td>4.83</td>
<td>0.925</td>
</tr>
<tr>
<td>3</td>
<td>3.96</td>
<td>3.85</td>
<td>0.476</td>
</tr>
<tr>
<td>6</td>
<td>2.92</td>
<td>2.65</td>
<td>0.222</td>
</tr>
<tr>
<td>9</td>
<td>2.00</td>
<td>1.98</td>
<td>0.11</td>
</tr>
<tr>
<td>12</td>
<td>1.52</td>
<td>1.69</td>
<td>0.418</td>
</tr>
<tr>
<td>Friedman statistical test P</td>
<td>0.001</td>
<td>0.001</td>
<td></td>
</tr>
</tbody>
</table>

Comments: P ≤ 0.05 was considered as a significant.
period of 12 months. In 42%–47% of patients, several physical complications occurred during this period, including chronic dermatitis, mechanical damage, Candida infection, allergic reactions and pyoderma gangrenosum. In another study of this researcher, it was found in 220 patients with stoma (urinary tract), in 13% of patients who developed skin ulcers around the stoma, that chemical substances, infections or allergic reactions were the cause. In the study by Salvaladena in 2013, of the 43 adults with colostomy, 63% had peristomal complications. The problems occurred within the period of 21–40 days after surgery. The most common skin problems were thus skin damage and moisture related skin infection. The study by Pitman (2014) involved 71 stoma patients; 52%–84% of participants had at least one ostomy complication in the first 60 days after surgery. The most commonly reported complications were leakage (60%), dermatitis (50%), subject pain (42%), retardation (39%), and bleeding (32%). In the study by Meinener et al. (2012), 3017 patients from 18 countries participated. The PUSH was used as an assessment tool. The result showed that 1742 persons or about 60% of the study participants had skin complications. However, further studies are needed prior to the clinical use of Adib herbal ointment to treat or combat colostomy skin problems.

6. CONCLUSIONS

Based on the results of this study, it can be said that Adib herbal ointments such as Comfeel and Conveen ointments can help heal skin ulcers around the stoma. Therefore, Adib ointment, like other common treatments, can be used to improve the skin around the stoma.

Conflict of interest
The authors declared that they have no competing interests.

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