Using Chamomile Solution or a 1% Topical Hydrocortisone Ointment in the Management of Peristomal Skin Lesions in Colostomy Patients: Results of a Controlled Clinical Study

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Abstract

Peristomal skin complications interfere with stoma appliance use and negatively affect patient quality of life. To find an alternative to long-term peristomal skin treatment involving corticosteroid products, a prospective study was conducted to compare the effect of a German chamomile solution to topical steroids on peristomal skin lesions in colostomy patients. Persons seeking care for the treatment of a peristomal skin lesion were assigned to a treatment regimen of once-a-day hydrocortisone 1% ointment (n = 36) or twice-a-day chamomile compress (n = 36) application. Treatments were assigned by matching patient demographic, history, and skin condition variables. At baseline, no significant differences between the variables were observed. Forty-two (42) of the 72 patients were female. Most participants had their stoma for more than 1 year (18.14 months in the chamomile and 17.69 months in the steroid group). Lesions were assessed every 3 days for a maximum of 28 days. Lesions healed significantly faster in the chamomile than in the hydrocortisone group (mean time to healing 8.89 ± 4.89 and 14.53 ± 7.6 days, respectively; $P = 0.001$). Stoma patient symptoms (pain and itching) also resolved more expediently in the chamomile than in the hydrocortisone group. Because corticosteroids are nonspecific anti-inflammatory agents, herbal extract use can prevent the side effects of long-term topical corticosteroid use. The results of this study suggest that German chamomile can be recommended to relieve itching and inflammation and that twice-daily application facilitates healing of peristomal skin lesions. Methods to facilitate the application of topical treatments without interfering with appliance adhesion or necessitating frequent appliance removal should be refined. Additional randomized studies are needed to confirm the results of this study.

Key Words: peristomal, skin lesions, topical, chamomile, controlled clinical study

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Potential Conflicts of Interest: none disclosed

Every year, thousands of people worldwide undergo a surgical diversion procedure that results in an intestinal or urological stoma[1] — ie, an artificial opening from the gastrointestinal or urinary tract to the outside of the body.[2–5] A stoma facilitates survival of a variety of injuries and pathologic processes.[4,6] The Iran Ostomy Association estimates as many as 30,000 people in Iran have a stoma; of these, 70% are colostomies, 20% ileostomies, and 10% urostomies.[7] As many as 800,000 people in the US[8] and approximately 100,000 in the UK have a stoma; in the UK, approximately 20,000 new stomas are created each year.[6] The peristomal skin of persons with a stoma is at high risk for irritation. Despite advances in ostomy care, evidence suggests that peristomal skin conditions are a common complication in these patients.[5,8-10] Depending on the stoma type, peristomal skin problem rates of between 30% and 60% have been reported[11,12]; peristomal skin complications are the most common reason ostomy patients visit an outpatient wound, ostomy, and continence nursing service.[10] Results of a case control study by Nybaek et al[13] indicated that 45% of stoma patients presented with a skin problem.

Skin excoriation can occur for many reasons, including mechanical and chemical irritation and bacterial infection.[6,14] These skin conditions can range from mild abrasions to full-thickness wounds that make it extremely difficult to manage the stoma and achieve a degree of comfort.[1,6,9,11,14] Peristomal skin disorders inevitably interfere with appliance adhesion,

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thereby facilitating leakage of stoma effluent and further exacerbating inflammation.[2,6,15] A leaking appliance causes embarrassment and compromises self-esteem, confidence, and adaptation to life with a stoma.[16]

Many peristomal skin problem management options are available but research comparing these strategies is limited.[5] Treatment may involve the use of compresses, topical corticosteroid preparations, or barrier products and preparations.[9,16] However, the long-term use of topical corticosteroid therapy is associated with side effects such as the development of atrophic and telangiectasic skin conditions.[17] Because corticosteroids also may affect the healing process, treatment options with fewer side effects are desirable. Some evidence[13,18,19] indicates that plant extracts may have a beneficial effect on wound healing. According to clinical studies,[20,21] chamomile has been shown to have anti-inflammatory, antibacterial, and bacteriostatic properties and was found to facilitate granulation tissue formation and epithelialization of ulcers.

Two types of chamomile generally are used in traditional herbalism: German or Hungarian chamomile (*Matricaria recutita*, *Chamomilla recutita*, and *Matricaria chamomill*) and Roman or English chamomile (*Anthemis nobilis* or *Chamaemelum nobile*). German chamomile is considered more potent and medically superior to Roman chamomile because it contains a higher proportion of the active chemical ingredient *chamazulene*.[22-25] This compound is a potent anti-inflammatory agent.[25] Roman chamomile has less chamazulene and a higher alcohol content than its German counterpart. Results of clinical studies[22-25] suggest that German chamomile is the better choice for healing skin conditions and other topical applications. Double-blind controlled clinical studies[26-29] have consistently shown positive results when using German chamomile in the treatment of atopic dermatitis, acute weeping skin disorders, pressure ulcers, and radiation- and chemotherapy-induced oral mucositis. A randomized controlled *in vivo* study[30] was conducted to compare the effect of topical *Chamomile recutita* ointment (0.04 mL/day) to untreated control on healing oral wounds. After 10 days, wounds in the treatment group had a higher percentage of collagen fibers and reepithelialized more expediently than wounds in the control group (P <0.05).

Because the sample size of most studies is small and the quality of the studies is generally poor, more research is needed to assess the efficacy of chamomile to manage skin conditions.[31] The purpose of this study was to compare the effects of managing peristomal skin lesions with German chamomile solution to topical steroid treatment in patients with a colostomy.

Literature Review

Martins et al[18] conducted an *in vitro* and *in vivo* study to compare the effects of German chamomile (*Chamomilla recutita*) and corticosteroids on wound healing. In all animals, the chamomile-treated wounds healed an average of 9 days before the other treatment group and healing was observed after 5 days of treatment in the chamomile group only; whereas, animals treated with corticosteroids only reached that stage of repair on day 14. Differences in healing rates between chamomilla and corticosteroids were statistically significant (P <0.05). In a double-blind study[29] involving 14 patients following tattoo removal, applying a standardized chamomile extract (50 mg α-bisabolol and 3 mg chamazulene/100mg) significantly (P <0.05) decreased wound area weeping and increased drying compared to the hydrophil gel placebo group.

In a clinical study of 161 patients with inflammatory dermatoses, Aertgeerts et al[27] observed equivalent outcomes comparing use of a cream containing German chamomile extract to 0.25% hydrocortisone and better outcomes than when using 0.1% diflucortolon and 5% bufexamax. Hur and Han[32] conducted a clinical trial to evaluate the effects of aromatherapy using essential oil (with lavender, myrrh, neroli, rose, grapefruit, Mandarin orange, and Roman chamomile) on postpartum perineal healing. The results suggest that postpartum aromatherapy for perineal care could be effective in healing the perineum. In a case series of 60 patients with peristomal dermatoses, Lyon et al[15] evaluated a topical aques/alcohol corticosteroid lotion. The results suggest the approach was effective in treating irritant dermatitis, pyoderma gangrenosum, psoriasis, and constitutional eczema.

Ostomy Wound Management 2011;57(5):28–36

Key Points

- The purpose of this study was to compare the effect of managing peristomal skin lesions with German chamomile solution or topical steroid treatment in patients with a colostomy.
- In each group, 36 participants with a variety of skin lesions were evaluated every 3 days for a maximum of 28 days.
- Symptom reduction (pain/itching) and healing was more expedient in the chamomile than in the hydrocortisone group.
- Controlled clinical studies to evaluate the efficacy of German chamomile for peristomal and other skin conditions are warranted.

Materials and Methods

Patient information. To compare the effect of German chamomile solution to 1% hydrocortisone ointment on healing peristomal skin damage in colostomy patients, it was estimated that a sample size of 36 patients in each group would need to be enrolled. The study population consisted of all patients who were members of the Tehran Ostomy Association, had a colostomy and a peristomal skin lesion, and were referred to

Table 1. Study participant demographic characteristics and stoma variables

	Chamomile group (n = 36)	Hydrocortisone group (n = 36)	*P*
Gender			
Male (n)	16	14	ns
Female (n)	20	22	ns
Age (years)[a]	54.89 ± 5.91	54.5 ± 5.53	ns
Body mass index[a]	24 ± 3.01	23.8 5± 2.9	ns
Onset of peristomal skin problem[a,b]	1.64 ± 0.76	1.69 ± 0.75	ns
Type of appliance			
One-piece appliance (n)	25	24	ns
Two-piece appliance (n)	11	12	ns
Time between appliance changes (days)[a]	1.78 ± 0.8	1.83 ± 0.8	ns

a average ± SD; b number of weeks before study enrollment; ns = not significant

Table 2. Baseline peristomal condition variables

	Chamomile group (n = 36) n (%)	Hydrocortisone group (n = 36) n (%)	*P*
Grade of skin damage[a]			
Erythema	4 (11.1)	5 (13.9)	ns
Erythema and edema	9 (25)	9 (25)	ns
Erythema and papule	10 (27.8)	12 (33.3)	ns
Vesicle	6 (16.7)	5 (13.9)	ns
Wound	7 (19.4)	5 13.9)	ns
Size of skin damage			
<2	2 (5.6)	3 (8.3)	ns
2.1–4	7 (19.4)	10 (27.8)	ns
4.1–8	14 (38.9)	13 (36.1)	ns
8.1–13	13 (36.1)	10 (27.8)	ns
Exudate amount			
None	23 (63.9)	26 (72.2)	ns
Scant	2 (5.6)	2 (5.6)	ns
Small	4 (11.1)	3 (8.3)	ns
Moderate	7 (19.4)	5 (13.9)	ns
Large	0	0	ns
Pain intensity			
1–3	13 (36.1)	14 (38.9)	ns
4–7	14 (38.9)	16 (44.4)	ns
8–10	9 (25)	6 (16.7)	ns
Itching			
Present	28 (77.8)	30 (83.3)	ns
Absent	8 (22.2)	6 (16.7)	ns
Edges			
Indistinct, none clearly visible	3 (8.3)	5 (13.9)	ns
Distinct, outline clearly visible, attached,	23 (63.9)	23 (63.9)	ns
Well defined, not attached to wound base	10 (27.8)	8 (22.2)	ns

Baseline assessments were completed before randomization; ns = not significant

the Association over a 4-month period from January to June. All referred patients were assessed by a wound, ostomy, and continence nurse (WOCN) for the presence or absence of peristomal skin complication. Patients were eligible to participate if they were at least 2 months post colostomy surgery and 7 weeks had passed since their last chemo- or radiotherapy. Individuals with a history of relevant systemic or dermal disease that could affect healing, as well as patients using antibiotics or immunosuppressive drugs, were excluded from study participation. The study was approved by the ethics committee of Shahid Beheshti University of Medical Science in Iran.

Persons with some degree of peristomal skin breakdown who met the study inclusion criteria and provided informed consent were assigned to one of the two treatments. Study participation was voluntary and all eligible participants received an explanation of the study purpose and the products to be evaluated. Risks and benefits were explained before obtaining informed consent. Patients were assigned to treatment groups by matching the following variables: patient age, gender, body mass index, medication usage, type of colostomy, cause and history of the peristomal skin problem, pouch change frequency before treatment, and overall health condition before intervention. Specifically, these variables were included in a checklist and every other week, participants were randomly assigned to one of the two treatment groups.

Instrument. Data were collected using a three-part pen-and-paper instrument. The first part, completed by the patient, consisted of 23 demographic and stoma/peristomal skin variables. The second part included disease history and treatment characteristics. The third part included an observational checklist to evaluate participant skin and wound condition.[33-36] The second and third parts were completed by a practitioner. Skin condition assessment included the presence/absence of erythema, erythema and edema, erythema and papule, vesicle, or a wound. The size of the skin damage was determined using a ruler and, measuring the longest and widest aspect of the lesion in cm, recorded as area by multiplying length and width and grouped as: 0, <2, 2.1–4, 4.1–8, 8.1–13, or >13 cm^2. Wound or skin damage edges were assessed as follows: indistinct, diffuse, none clearly visible; distinct, outline clearly visible, attached, even with wound base; well-defined, not attached to wound base; well-defined, not attached to base, rolled under, thickened; or well-defined, fibrotic, scarred, or hyperkeratotic. The fifth domain, exudate amount, was assessed using

Table 3. Descriptive skin condition scores during treatment (n = 36 in each treatment group)

Treatment group and days since start of study.	Skin damage grade (range 1–5)	Size of skin damage (range 1–4)	Lesion edges (range 1–3)	Exudate amount (range 1–5)	Pain intensity (range 1–3)	Itching (range 1– 2)
			Mean (SD)			
Chamomile						
Day 3	3.44 (±1.96)	3.11 (+1.69)	2.28 (±0.97)	1.25 (±1.11)	1.78 (±0.42)	1.42 (±0.5)
Day 6	3.06 (±1.87)	2.69 (±1.47)	2.08 (±0.91)	1.30 (±0.91)	1.42 (±0.5)	1.25 (±0.4)
Day 9	2.22 (±1.81)	1.72 (±1.06)	1.53 (±0.77)	1.42 (±0.73)	1.25 (±0.44)	1 (±0)
Day 12	1.5 (±1)	1.25 (±0.5)	1.17 (±0.38)	1.17 (±0.38)	1 (±0)	1 (±0)
Day 15	1 (±0)	1 (±0)	1 (±0)	1 (±0)	1 (±0)	1 (±0)
Day 21	1 (±0)	1 (±0)	1 (±0)	1(±0)	1 (±0)	-
Hydrocortisone						
Day 3	3.89 (±1.24)	3.83 (±0.9)	2.5 (±0,74)	1.64 (±1.13)	2.78 (±0.72)	1.64 (±0.49)
Day 6	3.39 (±1.79)	3.19 (±1.58)	2.22 (±0.99)	1.61 (±1.10)	2.03 (±0.81)	1.5 (±0.51)
Day 9	3.25 (±1.93)	3.03 (±1.73)	2.22 (±0.99)	1.61 (±1.10)	1.69 (±0.62)	1.14 (±0.35)
Day 12	2.89 (±1.85)	2.44 (±1.05)	1.89 (±0.82)	1.42 (±0.97)	1.5 (±0.61)	1 (±0)
Day 15	2.19 (±1.91)	2.78 (±1.20)	1.25 (±0.5)	1.25 (±0.6)	1.22 (±0)	
Day 21	1.33 (±0.68)	1.39 (±0.77)	1.06 (±0.23)	1 (±0)	1 (±0)	

Table 4. Lesion time to healing by treatment group

Time to healing Days after treatment	Chamomile number of patients (%)	Hydrocortisone number of patients (%)	Total number of patients (%)	Statistical significance
3	12 (33.3%)	0 (0%)	12 (16.7%)	
6	1 (2.8%)	9 (25%)	10 (13.9%)	
9	9 (25%)	5 (13.9%)	14 (19.5%)	$Z = 2.206$
12	6 (16.7%)	1 (2.8%)	7 (9.7%)	$P = 0.001$
15	8 (22.2%)	8 (22.2%)	16 (22.2%)	
21	0 (0%)	5 (13.9%)	5 (6.9%)	
>21	0 (0%)	8 (22.2%)	8 (11.1%)	
Mean	8.89	14.53		
Standard deviation	4.89	7.16		

a transparent metric measuring guide with a concentric circle divided into four (25%) pie-shaped quadrants to determine percent of dressing involved with exudate. Sterile gauze was placed on the wound bed and covered by transparent adhesive dressing to provide a dry surface to allow for effective adhesive adherence of the pouching system. Exudate was scored as follows: 1 = none, tissues dry; 2 = scant, tissues moist, no measurable exudate; 3 = small, tissues wet, moisture evenly distributed in area, drainage involves ≤25% of dressing; 4 = moderate: tissues saturated, drainage may or may not be evenly distributed, drainage involves >25% to ≤75% dressing; 5 = large: tissues bathed in fluid, drainage freely expressed, may or may not be evenly distributed, drainage involves >75% of dressing. Finally, the presence or absence of itching was recorded and patients were asked to rate wound-related pain using the McGill pain-rating scale.[37]

The face validity of each item on the instrument was assessed by several nursing faculty members, two stoma nurses, one general surgeon, a dermatologist, and a physiologist. Reliability of the peristomal skin condition checklist was evaluated by two ET nurses, the primary investigator, and two MS nurses (nurses with additional training in wound care). Inter-rater reliability was good (Spearman coefficient r =0.92, $P = 0.001$).

Procedure. All patients with some degree of peristomal skin breakdown and who met the inclusion criteria participated in the study. All patients received a complete clinic assessment including an assessment of their stoma equipment. In all cases, a swab culture was obtained from the skin around the stoma and sent for microbiologic examination. Patients assigned to the chamomile group (n = 36) were instructed to apply German chamomile compresses twice a day. The chamomile solution was prepared by placing 6 g of air-dried and powdered flowerheads of *Matricaria chamomile* in a glass container and adding 150 cc of boiled water. The glass container was closed tightly to let the chamomile steep for 10 minutes and then the solution was filtered and applied to the gauze. The compresses then were placed on the wound for 1 hour. The 36 patients in the steroid group were taught to apply 1% hydrocortisone ointment once a day. All lesions were evaluated every 3 days for a maximum of 28 days.

Data evaluation. All variables were entered into an Excel spreadsheet. Descriptive and inferential statistical analyses were conducted using SPSS software 14 (SPSS, Chicago, IL). Independent *t*-test, chi-square test, and Fisher's exact test were

used to compare the demographic and disease variables between the two groups. Semiquantitative variables — eg, skin damage grade and size as well as condition of the lesion edges, amount of drainage, pain intensity, and itching — were grouped and analyzed using Mann-Whitney tests. A repeated measurement Mann-Whitney test was applied to compare the mean difference between scores.

Results

Seventy-two patients with peristomal skin breakdown participated — 36 (20 women, 16 men, mean age 54.89 years, range 40 to 65 years old) were treated with German chamomile and 36 (22 women, 14 men, mean age 54.50 years, range 40 to 65 years old) were treated with 1% hydrocortisone ointment (see Table 1). At baseline, no significant differences between the two groups were observed. Most participants (66%) in both groups were of normal weight. Average duration of colostomy was 18.14 months in the chamomile group and 17.69 months in the steroid group. Approximately half of all participants developed their skin problem less than 1 week before treatment (52.8% in the chamomile and 47% in the hydrocortisone group) and used a one-piece appliance (52.8% and 44.4%, respectively) (see Table 1). The reported average time between appliance changes was 1 day in the chamomile and 1.83 days in the hydrocortisone group. The most frequently reported causes of skin problems were noxious chemicals or irritants (50% of the chamomile and 41.7% of the hydrocortisone groups). The most commonly observed conditions were erythema and papules (27.8% in the chamomile and 33.3% in the hydrocortisone group), the majority of participants reported itching (77.8% in the chamomile and 83% in the hydrocortisone group), and most (63%) lesions did not have exudate (see Table 2).

Between-group comparison with repeated measures after treatment showed that on most measurement days, the lesions treated with the chamomile compresses improved more quickly than those treated with hydrocortisone ($P = 0.001$) (see Table 3). Mean time to healing was 8.89 days in the chamomile group and 14.53 days in the hydrocortisone group ($P = 0.001$) — complete healing was achieved by 100% of the chamomile group by day 15, while 76% of the hydrocortisone group achieved complete healing by day 21 (see Table 4). No significant difference in patients regarding erythema and papules, vesicle, and wounds on their peristomal skin was observed between groups 6 to 9 days after treatment.

Discussion

The results of this study suggest that chamomile-treated peristomal lesions heal more expediently than those managed with 1% hydrocortisone ointment, confirming previously reported beneficial outcomes when using German chamomile for the treatment of atopic dermatitis, acute weeping skin disorders, pressure ulcers, oral ulcers, dental plaque, and gingival inflammation.[18,19,21,26-30,41] Corticosteroids are nonspecific anti-inflammatory agents; the use of herbal extracts can prevent the side effects associated with excessive use of topical corticosteroids.

In this study, chemical irritation caused the observed skin problems in 50% of the chamomile and 41% of the hydrocortisone group. In a descriptive study of 35 stoma patients, Ratliff et al[38] observed a peristomal complication rate of 16%; the majority of lesions were classified as irritant dermatitis (69%). Most patients in the current study were in low- to middle-income groups and found to be using low-quality, ill-fitting stoma appliances. Peristomal skin exposure to feces and corrosive intestinal secretions are important risk factors for peristomal skin excoriation.[4,39] Both treatment groups were well matched at the start of treatment but lesions in the chamomile treatment group resolved significantly faster than those in the topical corticosteroid group.

Matricaria chamomile is a well-known ingredient in alternative medicine. It has been used for numerous purposes, from dermatological to gastrointestinal, neurological, and psychiatric.[40] Different clinical studies have evaluated the effectiveness of chamomile on wound healing. Glowania et al[29] showed a standard extract (50 mg α-bisabolol and 3 mg chamazulene/100 mg significantly ($P < 0.05$) decreased weeping in the wounds of 14 patients following tattoo removal. In this study, lesions treated with the German chamomile solution also exhibited an expedient reduction in the amount of exudate.[2] The difference in healing times reported in the Glowania study (13 ± 5.1 days in chamomile and 17.14 ± 5.5 days in the placebo group) are similar to those observed in the current study. Time to complete healing was 8.89 ± 4.89 days in the chamomile and 14.53 ± 7.16 days in the hydrocortisone group.

In a small clinical trial study[41] of eight patients with grade 2 , 3, and 4 pressure ulcers on the buttocks and ankle, those treated with essential oil healed more quickly than patients in the control group. In the current study, 100% of patients were healed by day 15 while 77.6% of patients in the hydrocortisone group healed 21 days after treatment. Similarly, 3-mm wide wounds in an animal model were healed after 5 days in the chamomile and 14 days in the corticosteroid treatment group[18] In the present study, patients who developed erythema with papules, vesicle, or a peristomal wound had less healing than those having only erythema or erythema with edema 6 to 9 days after treatment began, regardless of group, findings that support research by Moein.[42] Although topical corticosteroid therapy has been shown to facilitate healing in peristomal skin problems, adverse effects such as cutaneous atrophy and a propensity for systemic absorption limits its long-term use.[15,18] Herbal medications such as chamomile do not have the same adverse event profile, are easy to obtain and use, and are inexpensive; therefore, they are preferred by some practitioners.[18]

Limitations

The present study has a number of limitations. Ointments, creams, or oily lotions in which the active ingredients usually

are formulated impair adhesion of the stoma appliance and should be a consideration; in this study, topical hydrocortisone was applied at bedtime so as not to interfere with daytime activities. Also, in order to apply the chamomile compress, study participants had to remove their appliance twice a day, which is inconvenient and can cause skin irritation. In daily practice, the authors have recommended using proprietary scalp lotions as a vehicle for topical chamomile and applying it to the appliance adhesive before application. Future studies should explore methods to use topical medications underneath stoma appliances. Finally, although the two study groups were well matched, the treatments were not randomly assigned, limiting this study.

Conclusion

Improving and maintaining peristomal skin integrity is an important objective for ostomy patients and ostomy care professionals. Based on the results of this study, German chamomile can be recommended to relieve itching and inflammation and facilitate healing of peristomal skin lesions. The clinical benefits of using German chamomile in lieu of topical hydrocortisone and the side effects associated with its long-term use should be considered. Randomized controlled studies are needed to confirm current results and to provide further evidence for the efficacy and effectiveness of German chamomile.

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