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Assessment of the Effect of Topical 'Scrophularia Striata' Solution on Healing of Peristomal Wound in Patients Referring to Tehran Ostomy Association, 2023

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ABSTRACT

This study investigates the effects of topical solution of *Scrophularia Striata* in the healing process of peristomal skin wounds in patients attending the Stoma. One hundred participants from June 2023 to September 2023 were selected using convenience sampling and randomly assigned to two groups (experimental and control) in blocks using software. The experimental group was instructed to apply the topical solution of *Scrophularia Striata* once daily, saturating the ulcer area completely using an applicator on the peristomal skin, repeating this process every day for 14 consecutive days. The control group received the usual Stoma Center instructions (using chamomile ointment). The study compared the impact of topical solution of *Scrophularia Striata* on Ostomy Skin Tool to assess ulcer-healing progress between the two groups. The analysis revealed that on the 21 days post-intervention. The wound ulcer improvement in the experimental group was significantly greater than in the control group ($p < 0.001$). The results of the study indicate that the topical solution of *Scrophularia Striata* has been effective and more efficient in improving peristomal skin wounds compared to other routine treatments in these patients. Considering the impact of this solution on peristomal skin ulcer healing, its use is recommended.

1 | Introduction

An ostomy is a surgically created passage that allows the discharge of faeces from the digestive system, performed temporarily or permanently to improve patients' quality of life. A stoma is created, where a part of the large intestine (colostomy), small intestine (ileostomy) or urinary system (urostomy) is brought to the surface of the abdomen, and a surgically created passage (ostomy) is formed, and the intestine (stoma) is brought up to the surface through the opening in the skin.

This opening is covered with a pouch that collects the waste [1, 2]. A stoma may be created for various medical conditions, including colon or rectal cancer, Crohn's disease, obstructive conditions, and inflammatory bowel diseases [2]. According to the Iranian Ostomy Association, there are over 30000 ostomy patients in Iran. In the United States, over a million patients live with an ostomy, and this number continues to rise [3]. The most common complication for ostomy patients is peristomal skin complications (PSCs) due to contact with faeces [4].

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Summary

- This study investigates the effect of a topical solution of *Scrophularia Striata* on peristomal skin wound healing in stoma patients, addressing a common complication that impacts patients' quality of life.
- The goal of this manuscript is to evaluate the effectiveness of *Scrophularia Striata* solution compared to routine treatments for improving wound healing in peristomal skin.
- Using a randomised clinical trial approach with a pre-test to post-test design, the study assessed wound healing in two groups: one receiving *Scrophularia Striata* and the other following standard stoma care instructions.
- Results indicated a significant improvement in wound healing for the group treated with *Scrophularia Striata* compared to the control group, with a reduction in symptoms such as skin discolouration and tissue overgrowth.
- The findings support the use of *Scrophularia Striata* as an effective, non-chemical option for enhancing peristomal wound healing in stoma patients, with potential for broader application in chronic wound care.
- Explore the effect of topical solution of *Scrophularia Striata* in the healing process of peristomal skin wounds in stoma patients.
- Topical solution of *Scrophularia Striata* on the healing process of peristomal skin wounds in stoma patients.

The skin around the stoma can be affected by various factors such as faecal contact, physical damage from removing faecal collection bags, skin infections due to different microorganisms, skin irritation from chemical agents used for skin cleansing, and other risk factors like diabetes [5]. The most common cause of irritation to the peristomal skin is faecal leakage, especially when the stool is liquid and contains digestive enzymes, which can severely irritate the skin, leading to symptoms such as redness, bleeding areas, pain, itching, and burning. It is important to check the skin for these signs each time the pouch is changed. Mechanical irritation is another common cause, often related to improper removal of the adhesive pouch, which can damage the epidermal layer, resulting in painful and red areas. Additionally, allergic reactions to products used by the patient, such as adhesives, can cause skin irritation, either immediately after use or even months or years later [6, 7]. International guidelines emphasise the importance of a comprehensive approach to managing peristomal skin complications. Key recommendations include the use of validated tools for assessing skin conditions, which help standardise communication and improve care quality [8]. Patient and family education is crucial, focusing on pre- and post-operative care, recognising potential skin issues and understanding proper stoma management. Proper selection of ostomy products, such as pouches and skin barriers, is recommended to minimise skin contact with effluents and ensure a secure fit, thereby reducing the risk of leaks. Timely intervention is also advised for managing complications like moisture-associated dermatitis [9]. Research conducted in the United States indicates that more than one-third of ostomy

patients develop peristomal skin problems within 90 days after ostomy surgery [3]. Untreated peristomal skin complications can disrupt ostomy function, and conventional treatments involving steroid and chemical medications come with high costs and side effects for patients. Recent studies show an increasing trend among patients towards using herbal remedies due to lower costs and fewer side effects [10].

For example, in Iran, the use of chamomile for wound treatment is common, both because it is readily available and cost-effective [11].

One of the herbal plants found in specific regions of Kurdistan and Ilam, in Iran, is '*Scrophularia Striata*', locally known as 'Teshnedari'. This plant has been traditionally used for its wound healing and anti-inflammatory properties, especially for the treatment of ear infections [12]. *Scrophularia Striata* contains compounds rich in Iridoid Glycosides, particularly Aucubin and Catalpol, known for their various biological properties such as anti-tumour, anti-inflammatory and antimicrobial effects [13]. A study by Sharifi et al. demonstrated that topical application of the extract of '*Scrophularia Striata*' accelerates the healing process of episiotomy wounds in women [14]. However, there is a lack of research on the effects of *Scrophularia Striata* on peristomal skin wounds. Therefore, considering the indigenous use of this plant for wound healing and the high prevalence of peristomal skin complications and related concerns in ostomy patients, this study aimed to determine the impact of topical *Scrophularia Striata* solution on the healing process of peristomal skin wounds in patients with permanent ileostomy referred to the Ostomy Association in 2023.

2 | Materials and Methods

2.1 | Study Subjects

The present study was a randomised controlled clinical trial with a pre-test to post-test design along with a control group. The research population consisted of all patients with permanent ileostomy attending the Tehran Ostomy Association in 2023. The sample size was determined using the formula $(n \geq 2 \frac{(z_{\alpha/2} + z\beta)^2 \sigma^2}{(\mu_1 - \mu_2)^2})$, calculating the effect size of the difference in mean overall wound healing score in two groups based on the study by Sharifi et al. [14], considering a type I error of 0.05, a test power of 80%, and accounting for a 20% sample dropout, resulting in 50 samples in each group. One hundred participants from June 2023 to September 2023 were selected using convenience sampling and were randomly assigned to two groups (experimental and control) in blocks using software.

2.1.1 | Inclusion Criteria

Participants were eligible for the study if they met the following criteria:

- Age above 18 years
- No use of medications affecting wound healing (e.g., corticosteroids, anti-inflammatory steroids)

- Absence of infection symptoms (e.g., fever, discharge)
- No need for surgery or wound debridement
- No history of skin diseases (e.g., lupus, psoriasis, dermatitis)
- No radiotherapy or chemotherapy in the past 4 months
- No sensitivity to *Scrophularia Striata*

2.1.2 | Exclusion Criteria

Participants were excluded from the study if they met any of the following conditions:

- Need for emergency surgery
- Unwillingness to continue participation in the study
- Requirement for medications that could impact study results (e.g., steroids, antibiotics)

Sampling in the current study was conducted in two stages. In the first stage, samples were included in the study based on the inclusion criteria. The second stage involved random allocation of samples to two groups. A fourfold block random sampling method was utilised for this purpose. All enrolled patients were informed and signed consent forms, complying with the requirements of the World Medical Association Helsinki Declaration; the study was approved by the ethics committee (with code IR.SBMU.PHARMACY.REC1402.008).

2.2 | Measurement

The data collection tools included a form for collecting demographic and clinical characteristics of patients (including questions regarding age, gender, marital status, education level, medical history, previous hospitalizations, patient insurance, disease diagnosis, history of smoking and medication history) and a tool for assessing the response to peristomal skin treatment. The tool for evaluating the response to peristomal skin treatment is a specialised tool for assessing the skin around the stoma, providing a standard description of three changes in the peristomal skin: (skin colour changes, skin erosion, excessive tissue growth). Each of these indicators is scored from zero to three based on the least to most severe intensity, and the scores are then added. These three components are scored based on the percentage of involvement under the stoma bag adhesive and the severity of bleeding, itching, pain, burning, and moisture (Table 1).

The peristomal skin assessments were conducted by two experienced wound care nurses, both certified in stoma care management. Each nurse performed assessments independently, and although they had similar qualifications, no formal inter-rater reliability test was conducted. The absence of a formal inter-rater reliability test may introduce variability in the assessments. This limitation was taken into account during the analysis and is discussed further in the limitations of the study.

The tool for evaluating the response to peristomal skin treatment was a translated and culturally adapted version of the

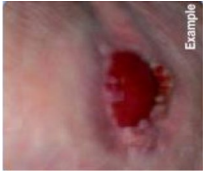
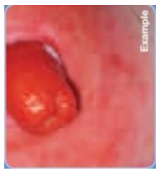
Ostomy Skin Tool. This ensured that the tool was suitable for the local population and accurate in assessing peristomal skin conditions. The validity of the OST tool in a study titled 'Effect of Chamomile Extract on Prevention of Peristomal Skin Complications' conducted in Iran in 2020 has been confirmed [4, 17]. To assess the content validity in this study, questionnaires were provided to 10 members of the faculty of nursing and midwifery at Shahid Beheshti University, wound care therapists, and specialised nurses in this field. After making revisions and obtaining approval for the questionnaires by the research team, they were employed. Additionally, to determine reliability, a preliminary study was conducted, and the questionnaires were completed by 20 individuals with characteristics relevant to the research, using Cronbach's alpha coefficient. The Cronbach's alpha coefficient (α) for the tool was found to be 0.76.

2.3 | Methods

The researcher, after referring to the Stoma Association, conducted sampling based on the study inclusion criteria. The samples were allocated into two groups using a random method. A four-block random sampling method was utilised for this purpose. According to the four blocks, each patient was randomly placed in either Group A (intervention) or Group B (control). For example, after randomly selecting a block like BABA, patients were randomly assigned to control, intervention, control, and intervention groups. The number of individuals assigned to each group was approximately equal. In addition to random allocation, concealment of sequence was also carried out. For this purpose, a random sequence was first created, then several envelopes were prepared based on the research sample size, and each of the created random sequences was recorded on a card placed inside the envelopes. To maintain the random sequence, numbering was done on the external surface of the envelopes in the same order. Finally, the sealed envelopes were placed in a box in sequence. At the time of participant registration, based on the order of participants meeting the study criteria, one of the envelopes was opened in order, and the assigned group for that participant was revealed. Participants were then sequentially and randomly assigned to the desired group through the random blocks. Subsequently, demographic and clinical data forms were collected in both control and intervention groups. Initially, using the stoma assessment tool, the skin around the stoma was examined and recorded by the researcher in both groups. Then, the patients in the intervention group were educated to apply a topical solution of *Scrophularia Striata* on the skin around the stoma at a specified time (every 24 h) using an applicator and repeat this process for 14 consecutive days. In this study, patients were thoroughly trained on how to properly apply the pouch and care for the skin around the stoma. The education included correct pouch placement, preventing leakage, and protecting the skin from contact with stool. Additionally, patients were regularly monitored throughout the study, and during each pouch change, the condition of the pouch and the peristomal skin was examined to promptly identify and address any potential leakage or skin damage.

The daily pouch changes were implemented to achieve three key objectives: first, to prevent external factors like leakage from worsening the wound by ensuring better control over

TABLE 1 | OST tool rating.

Area of discoloration	Severity of discoloration	Area of erosion	Severity of erosion	Area of overgrowth	Severity of overgrowth
Normal skin (absence of any visible change and damage to epidermis) If the area of discoloration score is 0, the skin is normal and the total score must be (0 + 0) Score = 0	Slight redness or other discoloration of the peristomal skin 	No erosion/excoriation If the area erosion score is 0, the score for domain 2 must be 0 + 0 Score = 0	Damage to the top layer of the skin (the epidermis) 	No tissue overgrowth If the area tissue overgrowth score is 0, the score for domain 3 must be 0 + 0 score = 0	Tissue overgrowth that interferes with application of the adhesive 
Less than 25% of the skin covered by the adhesive is affected Please assess severity Score = 1	Score = 1 	Less than 25% of the skin covered by the adhesive is affected Please assess severity Score = 1	Score = 1	Less than 25% of the skin covered by the adhesive is affected Please assess severity Score = 1	
Between 25% and 50% of the skin covered by the adhesive is affected Please assess severity Score = 2	Deep red or highly macerated skin potentially causing further complication Score = 2	Between 25% and 50% of the skin covered by the adhesive is affected Please assess severity Score = 2	Damage to the dermis causing excessive moisture or bleeding Score = 2 	Between 25% and 50% of the skin covered by the adhesive is affected Please assess severity Score = 2	Tissue overgrowth that interferes with application of the adhesive and causes bleeding and or pain 

Note: Reference of Table 1: <https://www.coloplast.ca/> [15, 16].

wound conditions and reducing the risk of infection; second, to guarantee the effectiveness of the *Scrophularia Striata* solution by enabling full absorption through daily reapplication; and finally, to maintain controlled and consistent trial conditions, minimising uncontrollable variables across participants. While stool leakage was not quantitatively recorded, routine clinical assessments did not indicate significant differences in stool contact with the skin between groups. Future studies should incorporate direct measurement of stool leakage to assess its role in peristomal wound healing.

Considering the traditional method of using *Scrophularia Striata* as a boiled topical solution for wound healing and improvement, this herb was also used in this study as a topical solution. To prepare the product, a pharmacist who is also a member of the research team (the third author of this article) prepared a hydroalcoholic extract (70%) of *Scrophularia Striata* under laboratory conditions and then removed the solvent. The use of The *Scrophularia Striata* solution was chosen based on its traditional usage in the form of a boiled decoction for wound healing. This solution, similar to its historical use, allows for faster and more effective absorption of its active compounds, promoting quicker wound recovery. The final formulation of the dried extract was prepared as an aqueous solution with a concentration of 7%. All stages were carried out under sterile conditions using sterile containers and materials. The topical solution was stored in the refrigerator before use. The control group also received the usual ostomy centre instructions, which included applying chamomile ointment once every 24 h. In the control group, chamomile ointment was applied sparingly, and sufficient time was allowed for absorption before attaching the adhesive pouch. This approach ensured optimal adhesion and mimicked routine clinical practice.

During the intervention, the skin around the stoma was assessed using skin examination tools on Days 3 and 21, with in-person evaluation of the patient's skin on those days, and virtual assessment of the skin around the stoma on Days 7 and 14 through photos sent by patients. While the experimental group had a slightly higher proportion of university-educated individuals and a lower proportion of illiterate participants compared to the control group, these differences were not statistically significant and did not affect the study's outcomes.

After providing both groups with instructions, all patients were asked follow-up questions to ensure they fully understood the educational content. This process allowed us to confirm that patients comprehended how to apply the treatment or manage their stoma care, regardless of their literacy level. Therefore, written instructions were supplemented with verbal explanations to ensure proper understanding for all participants.

Three patients dropped out from the control group and four patients from the experimental group during the study period. The reason for one patient's withdrawal was surgery, and the others were due to a lack of willingness to continue cooperation. It is worth mentioning that continuous education was provided to patients through virtual communication channels such as WhatsApp.

2.4 | Statistical Analysis

The data were analysed using descriptive statistics (mean, standard deviation, frequency) and inferential tests (Chi-square, Fisher's exact test, paired *t*-test, independent *t*-test) with SPSS software version 16. This study was approved by the ethics committee of Shahid Beheshti University of Medical Sciences (with code IR.SBMU.PHARMACY.REC.1402.008). Patients voluntarily entered the study to adhere to ethical principles, and they could withdraw from the study at any time if desired. Informed consent was obtained from all patients. Confidentiality of all data and ethical use of information sources were also maintained.

3 | Results

According to the results, the mean age in the experimental group patients was 48.56 ± 5.60 years, and in the control group it was 49.91 ± 7.22 years. Most patients in the experimental group (56.5%) and control group (61.7%) were male and married. Most patients in both the experimental group (34.8%) and the control group (27.7%) had education below high school diploma level. Although the experimental group had a slightly higher percentage of university-educated participants (23.9% vs. 19.1%) and a lower proportion of illiterate individuals (13% vs. 19.1%), these differences were not statistically significant ($p = 0.729$, $\chi^2 = 1.410$, $df = 3$), as shown in Table 2.

Independent *t*-test results showed no statistically significant difference between the two groups in terms of mean age ($p = 0.318$). According to the Chi-square test, the two groups did not differ significantly in terms of gender, marital status, education level, history of illness, hospitalisation history, and smoking history. Also, based on Fisher's exact test, there was no significant difference between the two groups in terms of insurance status, medical diagnosis or reason for ostomy, and they were homogeneous ($p > 0.05$) (Table 2).

The mean and standard deviation of wound healing rate scores in patients before intervention in the experimental group were 2.72 ± 5.56 and in the control group were 2.68 ± 5.36 , which did not show a statistically significant difference based on independent *t*-test ($p = 0.71$). After the intervention, the mean and standard deviation of wound healing scores in the experimental group reached 3.19 ± 2.09 and in the control group reached 4.29 ± 2.39 , which showed a statistically significant difference based on independent *t*-test, with a better wound healing rate in the experimental group ($p < 0.001$). Comparing the mean scores and standard deviations of wound healing rate in patients before and after the intervention in both the experimental and control groups using paired *t*-test indicated a significant difference from pre-test to post-test time ($p < 0.001$) (Table 3).

Independent *t*-test results showed that the mean changes in wound healing scores in patients in the experimental group were significantly higher than in the control group ($p = 0.003$) (Table 4) and (Graph 1).

TABLE 2 | Frequency distribution of demographic characteristics of ostomy patients in the research in two groups and results of comparison of means.

Variable	Categorisation	Experimental group (n = 46)	Control group (n = 47)	p	Test type
Age (years)	20–35 years	6 (13%)	8 (17%)	0.318	Independent <i>t</i> -test
	36–50 years	22 (47.8%)	14 (29.8%)		
	51–65 years	18 (39.1%)	25 (53.2%)		
Gender	Male	26 (56.5%)	29 (61.7%)	0.676	Chi-squared test
	Female	20 (43.5%)	18 (38.3%)		
Marital status	Single	5 (10.9%)	9 (19.1%)	0.580	Chi-squared test
	Married	32 (69.6%)	30 (63.8%)		
	Widow	9 (19.6%)	8 (17%)		
Education level	Illiterate	6 (13%)	9 (19.1%)	0.729	Chi-squared test
	High School (No degree)	16 (34.8%)	13 (27.7%)		
	Diploma	13 (28.3%)	16 (34%)		
	University degree	11 (23.9%)	9 (19.1%)		
History of illness	Yes	35 (76.1%)	33 (70.2%)	0.641	Chi-squared test
	No	11 (23.9%)	14 (29.8%)		
Hospitalisation history	Yes	30 (65.2%)	33 (70.2%)	0.661	Chi-squared test
	No	16 (34.8%)	14 (29.8%)		
Insurance	Yes	45 (97.8%)	44 (93.6%)	0.617	Exact Fisher's test
	No	1 (2.2%)	3 (6.4%)		
Medical diagnosis	Cancer	41 (89.1%)	43 (91.5%)	0.109	Exact Fisher's test
	Fistula	4 (8.7%)	1 (2.1%)		
	Polyp	0 (0%)	3 (6.4%)		
	Other	1 (2.2%)	0 (0%)		
Smoking history	Yes	23 (50%)	30 (63.8%)	0.212	Chi-squared test
	No	23 (50%)	17 (36.2%)		

TABLE 3 | Mean and standard deviation of wound healing rate around the stoma before and after intervention.

Wound healing rate	Group	Before intervention		After intervention		Test results of paired <i>t</i> -test		
		Mean	Standard deviation	Mean	Standard deviation			
Experimental group		5.56	2.72	3.19	2.09	$p < 0.001$	df = 45	$t = 6.30$
Control group		5.36	2.68	4.29	2.39	$p < 0.001$	df = 46	$t = 5.08$
Independent <i>t</i> -test results		$t = 0.36$ df = 91 $p = 0.71$		$t = -2.36$ df = 59 $p = 0.020$				

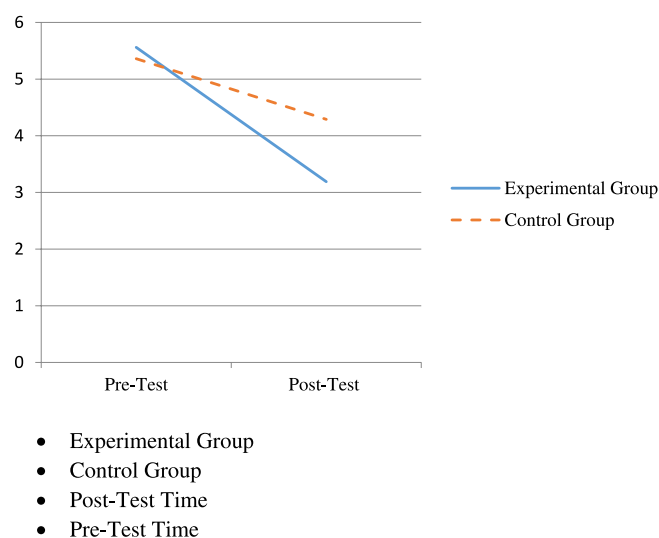
4 | Discussion

This study aimed to determine the effect of topical solution of *Scrophularia Striata* in the wound healing process around the stoma. During a 21-day follow-up, a significant

statistical difference was observed between the group using the *Scrophularia Striata* solution and the control group. The findings also indicated that the skin around the stoma improved in both the experimental and control groups, but the improvement in the experimental group using the *Scrophularia Striata*

TABLE 4 | Trend of changes in mean and standard deviation of wound healing scores in patients.

Variable	Experimental group		Control group		Independent test		
	Mean	Standard deviation	Mean	Standard deviation	<i>p</i>	df	<i>t</i>
Wound healing rate	−36.2	55.2	−06.1	−43.1	003.0	91	−05.3

**GRAPH 1** | The trend of changes in the mean and standard deviation of wound healing rate scores from pre-test to post-test time.

solution was significantly different from the control group receiving routine stoma centre instructions, with a much greater degree of improvement in the intervention group. The observed efficacy of the *Scrophularia Striata* solution in the experimental group could be attributed to several factors. First, *Scrophularia Striata* is known for its antimicrobial and anti-inflammatory properties, which could have directly contributed to the reduction of peristomal skin complications. This plant contains active compounds such as iridoid glycosides, including Aucubin and Catalpol, which are known to have potent antimicrobial and anti-inflammatory effects. These properties likely played a significant role in enhancing wound healing by reducing infection and inflammation around the stoma site.

Moreover, another potential factor that could have contributed to the improved outcomes in the experimental group is the solution's absorption into the skin. The solution form of the treatment may have allowed for better absorption, resulting in a more effective and sustained action at the site of application. Additionally, because the solution dries relatively quickly, it may have facilitated better adhesion of the ostomy pouch, thereby reducing the risk of leakage and subsequent skin irritation.

Moving forward, it would be beneficial for future studies to include a detailed diagnosis of the peristomal skin condition for each participant. This would allow for a more nuanced analysis of the treatment's effectiveness based on the specific skin issues being addressed, and would help to clarify whether the primary benefit of the *Scrophularia Striata* solution is due to its antimicrobial, anti-inflammatory properties, or its impact on pouch

adhesion. Based on the conducted analysis, this report is the first clinical randomised controlled trial evaluating the effect of the *Scrophularia Striata* solution on wound healing around the stoma.

The present study focused on determining the impact of the topical application of *Scrophularia Striata* solution on wound healing around the stoma in patients with ileostomy who were referred to the Iranian Ostomy Association in 2023. There have been very few clinical studies on the clinical effects of the *Scrophularia Striata* solution, possibly due to the limited growth of this plant in specific regions of Iran.

Bagheri et al. conducted a study in 2023 entitled 'The Antimicrobial and Healing Effect of *Scrophularia Striata* Boiss Hydroalcoholic Extract on First- and Second-Grade Pressure Wounds in Patients with Brain and Spinal Cord Injury: A Randomized Clinical Trial'. According to the results of this study, the alcohol extract of *Scrophularia Striata* administered twice daily in two experimental groups showed higher efficacy in wound healing and reducing the time to complete wound recovery in patients compared to other medication groups, which included the use of (*Scrophularia Striata* + Phenytoin, Phenytoin + Phenytoin, and Phenytoin + Eucerin). The results were in line with the findings of this study [18].

Haddadi et al. (2019) also conducted a research study on the level of wound healing in laboratory conditions using an alcohol solution of *Scrophularia Striata*. The study aimed to investigate the impact of the hydrochloric extract of *Scrophularia Striata* on the survival, proliferation, and migration of human skin fibroblasts and human umbilical vein endothelial cells [13]. The results indicated that the topical solution of *Scrophularia Striata* promoted wound healing by stimulating fibroblast and endothelial cell growth and migration. The beneficial compounds in *Scrophularia Striata*, such as iridoid glycosides and flavonoids, known for their antimicrobial, anti-inflammatory, and healing properties, facilitated faster wound recovery. These results were consistent with a previous study by Sharifi et al. in 2017 on the effect of *Scrophularia Striata* plant on episiotomy wound healing in primiparous women. This study aimed to determine the effect of the *Scrophularia Striata* cream on the healing process of episiotomy wounds, which was conducted on 40 primiparous women for 10 days [14]. The results showed that the *Scrophularia Striata* cream has a better and faster effect. Shohani et al. (2009) conducted a study on the healing properties of hydroalcoholic extract of *Scrophularia Striata* on open skin wounds in rabbits in Iran. The study divided the samples into six groups, with three groups receiving the hydroalcoholic extract of *Scrophularia Striata* (with concentrations of 2%, 5%, and 10%), one group receiving topical Phenytoin, and two groups serving as controls. The study demonstrated that *Scrophularia Striata*, with its anti-inflammatory properties and effects on collagen and fibroblasts,

led to accelerated skin wound healing, with higher purity of the plant yielding better results [19].

The study demonstrated improvement in all evaluated indicators using the OST tool, including changes in skin colour, skin peeling, and excessive tissue growth after the intervention. The total scores of these three units in the intervention group were lower than those of the control group. It is important to note that no adverse effects such as sensitivity, infection, burns, or dryness at the wound site were observed in any of the research units. In Iran, *Scrophularia Striata* is classified as a traditional herbal remedy rather than a pharmaceutical drug. As such, it has not undergone formal regulatory approval similar to conventional medications. However, it has been widely used in traditional medicine for wound healing, and no adverse effects such as irritation, allergic reactions, or burning were reported in this study. Despite these positive findings, further large-scale clinical trials are needed to fully assess its safety profile and obtain formal regulatory approval for medical use.

An unexpected aspect of the study was the colour of the solution, which, due to its green colour, had a deterrent effect on some patients. However, with the explanations provided to the patients, their mindset about *Scrophularia Striata* solution was revised.

This study has several limitations that should be considered. First, due to the study design and implementation method, which required wound healing assessments at specific time intervals, some patients were unable to attend the stoma centre on time. This may have affected the consistency and accuracy of wound evaluations.

Another key limitation is the lack of blinding for the stoma care nurses who conducted the wound assessments. Although both nurses were experienced and performed independent evaluations, the absence of blinding may have introduced assessment bias, potentially influencing the objectivity of the results.

Similarly, although patients who had received radiation therapy within 4 months prior to the study were excluded, their long-term history of radiation exposure was not documented. Given that radiation can have lasting effects on skin integrity and wound healing, future research should include comprehensive radiation exposure histories to assess their potential influence.

Another limitation of this study is the reliance on clinical assessment for diagnosing peristomal skin infections. Although experienced wound care specialists conducted evaluations, no microbiological cultures or laboratory confirmation tests were performed. This may have led to the inclusion of patients with subclinical infections. Future studies should incorporate objective diagnostic methods, such as microbial cultures or PCR-based testing, to improve diagnostic accuracy.

In this study, the assessment of peristomal skin was conducted by two experienced stoma care nurses, both certified in stoma care management. While both assessors had similar qualifications and experience, no formal inter-rater reliability test was performed. This is considered a limitation, as such testing could have improved the reliability and consistency of the assessments.

Finally, the primary focus of this study was to evaluate the effect of the *Scrophularia Striata* herbal solution on the healing of peristomal skin wounds. As a result, systemic parameters such as nutritional markers, haemoglobin, liver enzymes, and oxygenation—which are closely related to overall body condition—were not specifically considered. Future research should explore the potential influence of these factors to provide a more comprehensive understanding of peristomal wound healing.

Although diabetes is an important factor influencing wound healing, specific markers of glycaemic control, such as HbA1c levels, were not systematically recorded in this study. Future research should consider incorporating these parameters to better assess their impact on peristomal skin healing.

To monitor the wound healing process, a combination of in-person evaluations and remote photographic assessments was used. This hybrid approach allowed for consistent tracking while accommodating patients who could not attend in person.

One of the strengths of this study is the use of an environmentally friendly and self-cultivating product. This makes *Scrophularia Striata* not only effective but also economically viable and sustainable.

The findings of this research provide a solid foundation for future investigations into the effects of *Scrophularia Striata* on other types of chronic wounds. In this study, the method of application was based on traditional practices. Future research could explore alternative pharmaceutical forms, such as ointments, creams, or lotions containing *Scrophularia Striata* extract.

Additionally, comparing the efficacy of *Scrophularia Striata* solution with other complementary treatments for wound care would be valuable. Further studies could also focus on evaluating patient perceptions and satisfaction with the product.

5 | Final Conclusion

The research results regarding the research hypothesis, which focused on the effect of topical solution of *Scrophularia Striata* on improving peristomal skin wounds, indicated that the *Scrophularia Striata* solution proved to be effective and more efficient in healing peristomal skin wounds compared to other routine treatments in these patients. This finding is consistent with previous studies that have demonstrated the anti-inflammatory, antimicrobial, and healing effects of *Scrophularia Striata*. Considering the impact of this solution on improving peristomal skin wounds, its use is recommended.

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Ethics Statement

This study was approved by the Ethics Committee of Shahid Beheshti University of Medical Sciences with the ethics code IR.SBMU.PHARMACY.REC.1402.008.

Consent

Written informed consent was obtained from all participants prior to enrolment in the study. All procedures were conducted in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The authors have nothing to report.

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