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OPEN PEER REVIEW

The Effect of Aloe Vera and Honey Dressings on Preventing Pressure Injuries in High-Risk Elderly ICU Patients: A Randomized Clinical Trial

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About this report

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1 Original submission

3 comments · 18 May 2024 – 11 Jun 2024

Referee 1 Reviewer

MINOR REVISION 18 May 2024

Please explain more about how to prepare aloe vera gel.
Did you encounter any complications while studying the groups? What action did you take in case of complications?

Referee 2 Reviewer

MINOR REVISION 19 May 2024

Your manuscript contains useful and scientific information that will definitely be helpful for health care providers and patients. This manuscript can be accepted with minor changes.
Please correct these points:
1. The term randomized clinical trial should be mentioned in the title.
2. Explain the randomization method.
3. A CONSORT flow diagram should be drawn.
4. It would be better to specify the location of the dressing in the picture.
5. How was the aloe vera gel extracted? The scientific name of the species should be mentioned.
6. Where was the honey prepared? Please explain.
7. In line 131, the IRCT code must be linked to the official website of the registrar.
Example
Correct: Clinical Trial Code: IRCT00000161 (Link: https://ClinicalTrials.gov/NCT00000161)
Wrong (because this code is NOT linked to its webpage): Clinical Trial Code: IRCT00000161
8. In line 135, it would be better to include the abbreviation for analysis of variance (ANOVA).
9. In line 141, "No significant difference was determined in other demographic variables among the three groups ($p<0.05$)." Should this be ($p<0.05$) or ($p>0.05$)?
10. In the results section, determine whether there was a significant difference between honey and aloe vera dressings.

Referee 3 Reviewer

MAJOR REVISION 11 Jun 2024

Dear Author,
Thank you for submitting your manuscript to the JNMS.
There are some important issues regarding the scientific quality and clarity of your manuscript. You can find the comments in the attached file. Please address each comment carefully and highlight the changes in your manuscript in red font accordingly. You should also provide a point-by-point response to the comments in a separate document.
I appreciate your interest in our journal and your contribution to the field of research.
Sincerely,

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Revision 1

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

Greetings and Regards

Thanks to the very useful comments of the respected reviewers, the answers to the comments are organized in the following tables and sent to your service.

	Reviewer's comments	Our answers
Reviewer 3:	Please explain more about how to prepare aloe vera gel.	Line 113: The Aloe Vera gel used for patients in the Aloe Vera gel group was 100% concentration and produced by the Seagull Company, located in Karaj, Iran. Dressing application in this group was performed by one of the researchers (AF).
	Explain, did you have any complications while studying the groups? What action did you take in case of complications?	Line 133: Before initiating the use of prophylactic dressings, a sensitivity test was conducted by a nurse on the patients' forearms. After 24 hours without any complications, the dressings were applied to the sacrum. None of the patients tested positive for allergies, as the dressings were placed on healthy skin, and no complications were observed during the study.
Reviewer 4:	The term randomized clinical trial should be mentioned in the title	Line 2: The Impact of Aloe Vera and Honey Dressings on Preventing Pressure Injuries in High-Risk Elderly ICU Patients- A Randomized Clinical Trial
	Explain the randomization method	Line 127: The patients were selected and included in the study by the random sampling method of ball and bag, which was done by one of the nurses who was not aware of the studied groups, then they were divided into three groups using the computer randomization method
	Consort Flow Diagram should be drawn	(Figure 1 attached on the last page) It is worth mentioning that one person in the Aloe Vera gel dressing group passed away, and another person in the honey dressing group was removed from the study due to

		transfer to another department. The researcher continued sampling until the desired sample size was achieved. Notably, there were no dropouts in the simple gauze dressing group
	It is better if you specify the place of dressing in the picture	(Figure 2 attached on the last page) Schematic photos were used due to compliance with ethical rules and not having permission to publish photos of patients.
	How to extract aloe vera gel? The scientific name of the species should be mentioned	Line 113: The Aloe Vera gel used for patients in the Aloe Vera gel group was 100% concentration and produced by the Seagull Company, located in Karaj, Iran. Dressing application in this group was performed by one of the researchers (AF).
	Where did honey prepare? Please explain	Line 116: The honey used was prepared by the Shshbaloothoney Company, located in Qazvin, Iran. This honey meets the standards set by the Ministry of Health and has been verified through relevant laboratory reports. Shshbaloothoney is a reputable brand in the field of bee product production (including honey, royal jelly, and pollen) as well as the breeding of queens and bees. The company holds brand registration number 255059, an exploitation license from the Jihad Agriculture Organization under number 117762, and a health and operation permit for the workshop numbered 28/53/209747-2038-1078. Dressing in this group was performed by one of the researchers (AF).
	In line 131 IRCT code must be linked to the official website of the registrar.	Line 167: IRCT20190326043114N1 (Link: https://irct.behdasht.gov.ir/trial/38934)
	In line 135 the abbreviated name is better to mention, analysis of variance (ANOVA)	Line 161: Mean and standard deviation, One-Way ANOVA and chi-square tests

		were used for data analysis. Data were analyzed using SPSS v23, and the significance level was considered to be less than 0.05.
	In line 141 “No significant difference was determined in other demographic variables among the three groups (p<0.05).” (p<0.05) or (p>0.05)???	Line 173: No significant difference was determined in other demographic variables among the three groups (p>0.05).
	In the result section Determine whether there was a significant difference between honey and aloe vera dressing?	Line 183: The results of the chi-square test indicate that the frequency distribution of pressure injuries in the two groups—aloe vera and honey—is nearly identical, and they do not exhibit a statistically significant difference (p-value > 0.05). From a clinical perspective, it’s noteworthy that no pressure injuries occurred in the aloe vera group, while there were 3 positive reports in the honey group and 7 in the simple gauze group. Based on this research, aloe vera appears to be more effective than honey in preventing pressure sores. However, further studies are necessary to confirm this statistically significant effect
	Please explain more about how to prepare aloe vera gel.	Line 113: The Aloe Vera gel used for patients in the Aloe Vera gel group was 100% concentration and produced by the Seagull Company, located in Karaj, Iran. Dressing application in this group was performed by one of the researchers (AF).
Reviewer 5:	Revise the text as: “The Impact of Aloe Vera and Honey Dressings on Preventing Pressure Injuries in High-Risk Elderly ICU Patients ”	Line 1: Due to the rule of not using abbreviations in the title, we had refrained from writing the word ICU. Nevertheless, your order was carried out. The title was changed to: The Impact of Aloe Vera and Honey Dressings on Preventing Pressure Injuries in High-Risk

		Elderly ICU Patients- A Randomized Clinical Trial
	Revise this as:” The aim of this study was to investigate the impact of using aloe vera and honey on the prevention of pressure injuries among elderly patients admitted to an intensive care unit in Qazvin, Iran in 2022.” The whole manuscript needs English editing.	Objectives of abstract, line 8: The aim of this study was to investigate the impact of using aloe vera and honey on the prevention of pressure injuries among elderly patients admitted to an intensive care unit in Qazvin, Iran in 2022.
	Write type of clinical trial	Method of abstract, line 11: In this randomized, single-blind clinical trial…
	High risk of what? Write it.	Method of abstract, line 12: moderate to high risk of developing pressure ulcers
	Revise this paragrapg as: In today's society, the global aging population is continually growing, resulting in a rise in the number of elderly individuals requiring hospitalization. This increase in hospitalizations has led to a higher demand for intensive care units for elderly patients. Numerous studies have identified old age as a primary risk factor for the development of pressure injuries, making elderly patients in intensive care units particularly susceptible to such wounds.”	Line 32: In today's society, the global aging population is continually growing, (4), resulting in a rise in the number of elderly individuals requiring hospitalization. This increase in hospitalizations has led to a higher demand for intensive care units for elderly patients (5). Numerous studies have identified old age as a primary risk factor for the development of pressure injuries, making elderly patients in intensive care units particularly susceptible to such wounds (6, 7).
	Most studies need more references. Reference number 6 is not enough.	Line 36: Study No. 7 was added and further explanations were

		provided with more references
	Write about the prevalence of pressure injuries in ICU patient especially in elderly patients. Write about the high-risk patients in ICU. Who are the high-risk patients to pressure ulcer in ICU?	Line 37: Approximately 57% to 60% of pressure injuries occur within the first two weeks of hospitalization, with 70% affecting individuals over 70 years old (8). Prolonged and severe pressure leads to reduced blood supply, tissue ischemia, and ultimately cellular death(9). Risk factors include immobility, pressure on bony prominences at angles greater than 45 degrees, vascular obstruction, and systemic conditions like malnutrition and reduced mobility due to fractures, paralysis, or surgery (10). Elderly individuals are particularly vulnerable due to age-related skin changes, decreased immunity, and thinning of the epidermal layer. Identifying high-risk groups for pressure injuries—such as the elderly and hospitalized patients, particularly in specialized care units—is crucial (11). These individuals require specialized healthcare services with a focus on pressure injury prevention (12).
	Make this text summarizes as “Two studies found that silicone foam prophylactic dressings significantly reduced the risk of pressure injuries in high risk patients and elderly patients. However, accessing these dressings can be difficult and expensive in less developed countries like	was replaced in line 55.

	Iran. Researchers are now looking into cheaper alternatives such as olive oil, fish oil, and ChitoHeal gel, which have shown effectiveness in preventing pressure injuries and wounds.”	
	Write more about the use of honey in pressure ulcers. What is the gap of knowledge? Explain what is unknown that made you to do this research.	Line 64: Almost all types of wounds, such as abrasions, abscesses, amputations, bedsores, burns, abdominal wounds, fistulas, diabetes, and perineum injuries, respond to honey treatment. Using honey as a wound treatment stimulates the healing process and quickly clears infections. Additionally, honey promotes tissue regeneration and reduces inflammation (30-32)..... . According to the studies conducted so far, no one had investigated the preventive effect of honey and aloe vera dressings on healthy skin.
	The methods section should describe how you conducted your study in enough detail to allow others to replicate it. You should include the :following subsections • Study design: Explain the type.....	We have organized the method section according to this comment
	Write about the validity and reliability of the Braden scale in Iran.	Line 103: Two recent studies were added for validity and reliability of Braden scale (33,34)
	Write about validity and reliability of Pressure injury staging system in Iran.	The compression injury classification tool is based on the involved layers of the skin and is provided to the researcher in the

		form of images, and the compression injury is diagnosed based on the involved layer and the corresponding image. Because the diagnosis was made by only one person, there was no need for inter-rater reliability. Pressure Injury Grading Tool The instrument was developed in 2014 by the American Pressure Ulcer Advisory Panel and the European Pressure Ulcer Advisory Panel. Based on this, pressure injury is divided into six stages (Stage 1: Non-blanchable erythema of intact skin, stage 2: Partial-thickness skin loss with exposed dermis, stage 3: Full-thickness skin loss, stage 4: Full-thickness skin and tissue loss, Unstageable Pressure Injury: Obscured full-thickness skin and tissue loss and Deep Tissue Pressure Injury: Persistent non-blanchable deep red, maroon or purple discoloration) in severity. Reference: National Pressure Ulcer Advisory Panel. European pressure ulcer advisory panel and pan pacific pressure injury alliance. In: Haesler E, editor. Prevention and Treatment of Pressure Ulcers: Quick Reference Guide. Perth, Australia: Cambridge Media; 2014.
	Write PRISMA flow diagram for the research samples.	Line 130: We drew Consort's flowchart for clinical trial studies and attached it as Figure 1
	What is the brand of aloe vera gel and from which company? Write it.	We have added a paragraph titled "How to prepare Aloe Vera and Honey" in line ---

	What is the brand of honey from which company? Write it.	Line 113: We have added a paragraph titled "How to prepare Aloe Vera and Honey" in line ---
	Write Ethics code.	Line 166: (IR.QUMS.REC.1397.403).
	Revise this as” The literature review found no similar studies on the combined use of aloe vera and honey dressings for preventing pressure injuries. Some studies have examined the effects of using aloe vera gel topically on the skin and for preventing pressure injuries”	Line 195: was replaced in line ---
	Write the year of the study after the name of the authors for example: Hekmatpou et al., (2018). Do this in the whole manuscript.	We applied to all the mentioned references
	Move the reference number to the end of the sentence.	We applied to all the mentioned references
	Compare your research findings with the results of other studies and explain why honey was not effective.	Line 2019: Although no specific studies directly examined the preventive effect of honey on pressure injuries, existing research has explored honey’s impact on skin problems.No study was found regarding the preventive effect of honey on the formation of pressure ulcers. In the study of Yapucu Güneş et al. (2007), who investigated the effect of honey dressing on the treatment of pressure ulcers, the healing of wounds in the intervention group was 4 times better than the

		control group (40). Simber et al. (2014) found no significant difference in healing scores between honey cream and phenytoin treatments for episiotomy wounds (41). Another study by Mehrabani et al. (2013) compared honey dressing with hydrocolloid dressing for pressure ulcers, revealing similar effectiveness (42). Due to its ease of preparation, cost-effectiveness, and natural properties, honey dressing is recommended as a favorable option for pressure ulcer healing. Additionally, Zaleh Nikova et al. (2019) demonstrated that honey dressings promote faster wound healing, reduced size, and less pain intensity in non-healing wounds among elderly patients receiving home care (43) …….. Given the variations in the study area, skin examined, and study duration between our research and other studies, it is crucial to conduct additional investigations for more precise results on the effectiveness of honey in preventing pressure injuries. These studies should involve diverse statistical populations and larger sample sizes
	Write about the study limitations.	Line 249: In this study, one of the existing limitations was nurses' lack of familiarity with preventive dressings. To address this limitation, we provided necessary training to all nurses in this area. Additionally, due to time

		constraints imposed by the study being in the form of a thesis, a longer study was not feasible.
	Write about the use of research findings in Nursing.	Line 260: It is anticipated that the findings from this study will contribute to improved preventive care, enhance education for families of bedridden patients transitioning back home with similar conditions, and inspire innovative ideas in the realm of preventive care, ultimately leading to cost reduction.
	Delete table 3 and 4. Just Write the results of Table 3 and 4 in the Results section.	Line 180: The results of chi-square test showed that in two groups of honey and simple gas, the frequency distribution of pressure injury is almost the same and they do not show a statistically significant difference. (p-value>0.05). The results of the chi-square test indicate that the frequency distribution of pressure injuries in the two groups—aloe vera and honey—is nearly identical, and they do not exhibit a statistically significant difference (p-value > 0.05). From a clinical perspective, it’s noteworthy that no pressure injuries occurred in the aloe vera group, while there were 3 positive reports in the honey group and 7 in the simple gauze group. Based on this research, aloe vera appears to be more effective than honey in preventing pressure sores. However, further studies are necessary to confirm this statistically significant effect

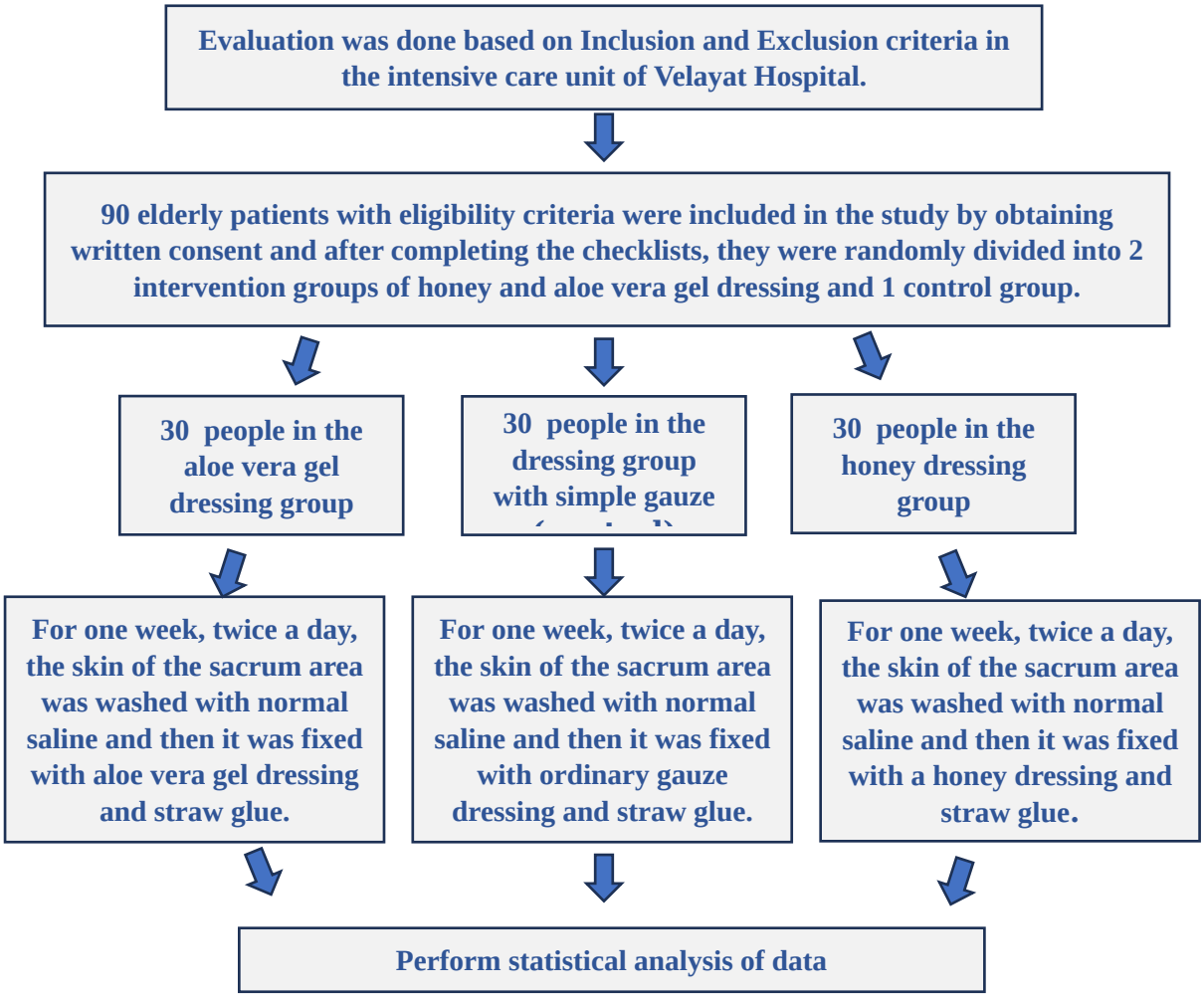


Figure 1: Consort Flow Diagram

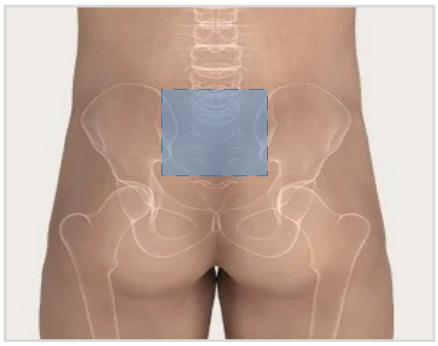


Figure 2: Place of dressings

2 Revision 1

1 comment · 6 Jul 2024

Referee 3 Reviewer

MINOR REVISION 6 Jul 2024

Dear Author,

Thank you for sending your revised manuscript. I appreciate the time and effort you have put into addressing the comments and suggestions from the previous review.

After reviewing the revised manuscript, I have found that it still needs some revisions as indicated in the attached file.
With regards

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Revision 2

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

Hello

Thank you for your useful and helpful comments in improving our manuscript. We applied the commented changes to the text and highlighted it in green

1- **Where is figure 1? It is not in the manuscript. Please provide it.**

Figure 1 is the CONSORT diagram that is given on the 14 page.

2- **Provide reference of the company website.**

https://www.akhavilab.com/fa/product/cat/2-%D8%B3%DB%8C-%DA%AF%D9%84.html# (1).

3- **What kind of honey did you get from this company? For example, orange spring honey, acacia honey, arsebaran honey, thyme honey or barberry honey**

We bought thyme honey from this company

4- **Shahbloot Honey, or Shshbaloothoney? revise it.**

According to the official website of Shahbaloothoney, is correct.

5- **Provide reference of the company website.**

https://www.shahbaloothoney.com/

6- **Delete this from the text and mention it in the CONSORT diagram in figure 1.**

Done.

3 Revision 2

1 comment · 20 Jul 2024

Referee 3 Reviewer

MINOR REVISION 20 Jul 2024

Dear Author,

Thank you for sending your revised manuscript. I appreciate your efforts in addressing previous comments.
After reviewing it, I found it still needs minor revisions.
Please edit the manuscript according to the attached file and resubmit for further review.

Best regards,

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Revision 3

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

Hello

Thank you for your useful and helpful comments in improving our manuscript. We applied the commented changes to the text.

1. **Delete “used”**

   Done (page 6. Line 113)

2. **Delete this sentence: “Based on this research, aloe vera appears to be more effective than honey in preventing pressure sores. However, further studies are necessary to confirm this statistically significant effect.**

   Done (page 9. Line 179)

4 Revision 3

1 comment · 24 Jul 2024

Referee 3 Reviewer

ACCEPT 24 Jul 2024

Dear author,
The manuscript is accepted.
With regards