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The Effect of Administration of Baby Oil on the Severity of Pruritus in Hemodialysis Patients

Sima Mokhtarabadi[1], Maryam Shahabinejad[2], Tabandeh Sadeghi[3], Majed Kazemi[4]

1. MSc Student of Medical Surgical Nursing, School of Nursing and Midwifery, Rafsanjan University of Medical Sciences, Rafsanjan, Iran
2. Instructor, Department of Medical Surgical Nursing, School of Nursing and Midwifery; Geriatric Care Research Center, Rafsanjan University of Medical Sciences, Rafsanjan, Iran
3. Assistant Professor, Department of Pediatric Nursing, School of Nursing and Midwifery; Non-Communicable Diseases Research Center, Rafsanjan University of Medical Sciences, Rafsanjan, Iran
4. Associate Professor, Department of Medical Surgical Nursing, School of Nursing and Midwifery; Non-Communicable Diseases Research Center, Rafsanjan University of Medical Sciences, Rafsanjan, Iran

*Correspondence: Maryam Shahabinejad, Department of Pediatric Nursing, School of Nursing and Midwifery; Non-Communicable Diseases Research Center, Rafsanjan University of Medical Sciences, Rafsanjan, Iran. Email: m_shahabi@rums.ac.ir

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ABSTRACT

Background: Pruritus is one of the most common complications in the hemodialysis patients affecting their quality of life. This study aimed to determine the effect of baby oil on reducing pruritus severity in these patients.

Methods: This clinical trial was conducted on the patients referred to one of the dialysis centers of Kerman, Iran, 2016. A total of 80 patients were selected through convenience sampling method and randomly assigned into two groups of intervention and control. In the intervention group, for four weeks (12 sessions), the researcher applied 3-5 ml of baby oil on the itchy skin for 15 min at the selected center. Data collection was carried out using visual analogue scale (VAS) to measure the pre- and post-intervention pruritus severity. Data analysis was performed in SPSS, version 18, using descriptive statistics, Chi-squared test, as well as independent and paired t-tests.

Results: In the pre-intervention stage, the mean pruritus severity score of the intervention and control groups were 5.87±2.43 and 6.21±2.29, respectively, which altered to 3.37±2.11 and 6.28±1.96 after the intervention, respectively (P<0.001). Accordingly, there was a significant difference between the groups in terms of pruritus severity (P<0.001).

Conclusion: Regarding the results of the present study, administration of baby oil decreased pruritus severity in the hemodialysis patients. This cost-effective agent is not associated with major adverse effects; therefore, its administration is recommended.

1. Introduction

Globally, hemodialysis is the most conventional treatment for renal failure.[1, 2] In addition to the dialysis-associated diseases, these patients are challenged with several complications, including fatigue, vertigo, anxiety, depression, as well as sleep and dermal disorders.[3, 4] Pruritus is one of the most common skin disorders among the patients with end-stage renal disease, which disturbs the mental and physical health status, for instance it causes sleep disorders.[5, 6]

Although pruritus is not life-threatening, it can affect quality of life among patients.[7, 8] Meanwhile, the prevalence of pruritus increases along with disease severity. According to the literature, pruritus severity in patients was changed from 25%-33% (prior to the dialysis) to 60%-86% (after initiating of therapy).[9] Based on the evidence, there are various etiologies for pruritus in hemodialysis patients.[6, 10, 11]

However, it seems that one of the main causes of this symptom is xeroderma due to insufficient removal of waste metabolites, sweating disorders (e.g, anhidrosis), sweat and sebaceous glands atrophy, increased level of vitamin A in epidermis, and fluid restriction.[12] Given the various causes of pruritus, different treatments are recommended for relieving, including medications (such as oral gabapentin, high molecular weight sericin polymer) and photo and massage therapies, as well as omega-3 fatty acids.[6, 7, 13-15]

Nevertheless, choosing an effective and appropriate treatment with considering patients' condition is still a challenge for the healthcare

system due to various responses to different treatment modalities. Several patients cannot tolerate medicines due to the insufficient disposal of medicinal metabolites.[16] Given the fact that 97% of the patients with pruritus suffer from xeroderma, it seems that administration of emollients with high moisturizing properties might be effective.[6, 17]

Baby oil contains liquid paraffin with high moisturizing properties; accordingly, it can relieve or even treat this condition properly. In the previous studies conducted on the use of moisturizers, conflicting results were obtained. Two studies performed by Karadag et al. in 2014, Japan, and Lin et al. in 2012, Turkey, which confirmed the positive effects of baby oil on decreasing pruritus severity due to insufficient removal of waste metabolites in hemodialysis patients.[5, 18]

In terms of the effect of other substances with high moisturizing properties, similar to the baby oil, Afrasiabifar et al. in 2016 demonstrated their positive effects on pruritus, whereas Shahgholian et al. in 2013 reported no impact on it.[6, 16] Moreover, Ghaderi et al. in 2006 demonstrated that local adminitration of moisturizers had no effect on the pruritus caused by the insufficient disposal of waste metabolites.[19] Given the contradictory results of the previous studies and lack of evidence of using baby oil in Iran, this study aimed to determine the effect of baby oil on pruritus severity in hemodialysis patients.

2. Methods

2.1. Design

This clinical trial was conducted on the patients referred to one of the dialysis centers of Kerman, Iran, 2016.

2.2. Participants and settings

The study sample size was estimated about 70 members according to a study conducted by Karadag et al.[18] in 2014 and using the following formula:

$$n = \frac{2(Z_1 - \frac{\alpha}{2} + Z_1 - \beta)^2(\sigma)^2}{d^2} = \frac{2(1.96+1.28)^2(1/8)^2}{(1/4)^2} = 34/69$$

Finally, 80 patients were enrolled into the study regarding the 10% sample attrition. Then, the subjects were randomly assigned into two groups of intervention and control (40 members for each group) using minimization method.[20]

For randomized allocation of the participants, they were first separated considering the important variables of the study (e.g., pruritus severity and gender) and the eligible patients were included. This process was carried out by randomized assigning of the first participant to either intervention or control groups (through coin tossing), which was followed by allocation of the next subject to the group with lower sum of variables (pruritus severity and gender).

Accordingly, if there were two males with pruritus score of 3 (according to the visual analogue scale (VAS)) in the intervention group, the third male subject with the same score would be allocated to the control group with no similar member. In case of equal number of males with the pruritus score of 3 in the groups, the sample allocation was performed by coin tossing (to determine the subject's group).

The patients aged between 18 to 60 years old, who undergo hemodialysis three times per week with bicarbonate solution and polysulfone filter, and had experienced pruritus at least for two weeks (with the score of 3) without the history of kidney transplant.[21] The exclusion criteria entailed kidney transplant during the study, tendency to use other methods to decrease pruritus, and absence in one or more intervention sessions.

2.3. Instruments

In this study, demographic characteristics form (including age, gender, and filter type, as well as duration of dialysis and pruritus) and VAS (to measure pruritus severity) were utilized. The VAS, which is a straight horizontal line of 10 cm, was developed by Wahlgren in 1995.[21] This valid and reliable instrument is used in various studies to estimate pruritus severity. The VAS score is ranged from 0 (lack of pruritus) to 10 (the most severe pruritus) and the patients were asked to express their pruritus severity on the scale by finger. [22, 23]

2.4. Data Collection

Regarding the ethical considerations, the researchers visited the dialysis centers every day in three shifts, and the eligible patients were allocated to the intervention and control groups. It is worth mentioning that the pre-test VAS score more than 3 was considered as an inclusion criterion, which was evaluated at the time of subject selection.

The control group received the routine care of the selected center for pruritus treatment, while the subjects in the intervention group received baby oil in addition to the routine medicines.

In this study, the baby oil (Firooz Co, Iran) containing liquid paraffin was applied three times for four weeks with previous arrangement with the patients at the selected dialysis center. After cooling

to room temperature, 3-5 ml of the baby oil was applied on the itching site for 15 minutes. At the end of the intervention, pruritus severity was reassessed by VAS in both intervention and control groups. The study steps are demonstrated in diagram 1.

It has not escaped our notice that, the subjects entered the study at different days and shifts; therefore, the contact between the participants of both groups was controlled as far as possible.

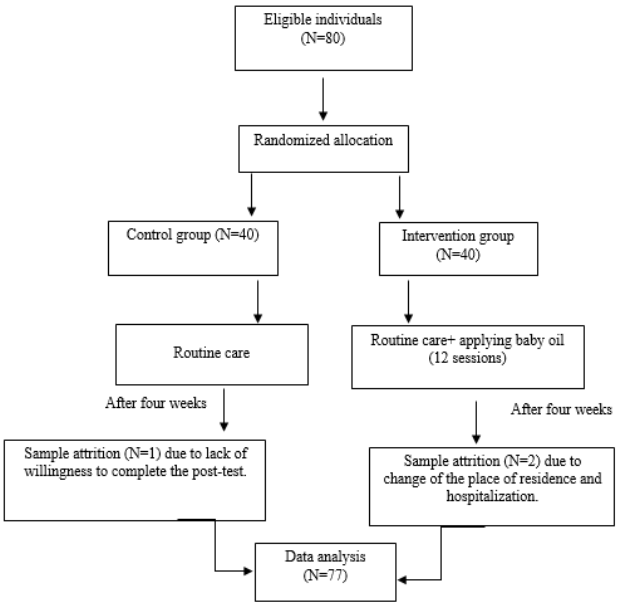

Diagram 1. Study steps (CONSORT diagram)

2.5. Ethical considerations

Prior to the study, its objectives were explained to the participants and a written informed consent was obtained from them. In addition, they were ensured that they could withdraw from the study at any time without any negative effect on their treatment process, and their privacy was respected by using shield. A male researcher was responsible for applying the intervention on the male patients and vice versa. At the end of the intervention and observing its positive impact, the subjects in the control group were trained about using the baby oil.

2.6. Statistical analysis

Data analysis was performed in SPSS version 18 using descriptive statistics, Chi-squared (to compare both groups in terms of gender and filter type), and independent and paired t-tests to compare the groups regarding the quantitative variables (e.g., age, duration of dialysis and pruritus, and pruritus severity), as well as pre- and post-intervention pruritus score. In all the measurements P-value less than 0.05 was considered statistically significant.

3. Results

In this study, one subject from the control group and two participants from the intervention group were excluded due to unwillingness to complete the post-test and change of their place of residence or hospitalization, respectively. Ultimately, the study was conducted on 38 subjects in the intervention group and 39 participants in the control group. The demographic characteristics are presented in Table1, according to which no significant difference was observed between the study groups regarding the evaluated variables.

According to Table 2, the severity of pruritus significantly decreased after the intervention ($P<0.001$), and a significant difference was observed between the intervention and control groups considering the mean and standard deviation of pruritus severity ($P<0.001$).

Table 1. Demographic and clinical characteristics of the participants

Variable	Group	Intervention (N=38)	Control (N=39)	P-value
Gender	Male	29(76.3)	31(79.5)	0.737*
	Female	9(23.7)	8(20.5)	
Filter type	PS13	15(39.5)	16(41.0)	0.939*
	PS16	7(18.4)	6(15.4)	
	PES130	16(42.1)	17(43.6)	
Duration of dialysis (month)	M±SD	35.39±31.53	37.31±29.03	0.782**
Duration of pruritus (month)	M±SD	22.76±22.07	19.29±22.79	0.500**
Age (year)	M±SD	54.11±6.23	53.21±6.43	0.535**

*Chi-squared; **Independent t-test;
PS: Polysulfone; PES; Polyethersulfone

Table 2. Comparison of the study groups in terms of pre- and post-intervention mean pruritus severity scores

Variable	Group	Pre- intervention M±SD	Post- intervention M±SD	P-value*	Changes M±SD
Pruritus severity	Intervention	5.87±2.43	3.37±2.11	<0.001	2.50±1.64
	Control	6.21±2.29	6.28±1.96	0.765	-0.08±1.60
	P-value**	0.533	<0.001		<0.001

*Paired t-test; **Independent t-test

4. Discussion

According to the results of the present study, the use of baby oil led to decreased pruritus severity in the dialysis patients. In a study conducted by Karadag et al. in 2014, the application of baby oil on the dialysis patients' skin three times a week for one month had a positive effect on pruritus severity, and there was a significant difference between the intervention and control groups in this regard.[18] This finding was in line with our results; however, the mentioned study used a different method to measure pruritus severity and the combination of baby oil was not completely similar in the two studies.

In a study carried out by Lin et al. in 2012, it was marked that baby oil diminished pruritus severity in hemodialysis patients due to its moisturizing properties. However, the mentioned study was different from the current one with respect to having three study groups of cold baby oil, baby oil at room temperature, and routine care. According to the results of the aforementioned study, a significant difference was observed between the intervention groups and the control group regarding the treatment of pruritus. Meanwhile, no significant difference was found between the two intervention groups.[5] Therefore, it could be concluded that thermal changes in baby oil had no effect on assuaging pruritus severity, and the only effective factor was their moisturizing properties.

According to the literature, there is no definitive etiology for pruritus.[6, 10-11] Nevertheless, our results and those of several other studies indicated that xeroderma is one of the apparent causes of pruritus since use of moisturizers alleviated pruritus severity in uremic patients. In a study conducted by Aramwit et al. in 2012, the effects of sericin ointment with moisturizing properties was compared with placebo, which demonstrated that pruritus severity significantly decreased after six weeks of treatment.[13]

Chen et al. in 2006 confirmed that the use of gamma-linoleic acid significantly decreased pruritus severity in comparison to placebo.[24] Moreover, Matsumoto and Okada in 2004 ascribed that the mean pruritus severity score significantly reduced after two weeks of using an emollient containing a high water content, whereas there was no significant difference between pruritus severity scores in the control group before and after the study.[25]

Furthermore, Szepietowski et al. in 2005 reported that application of creams containing physiological lipids and endogenous cannabinoids had a positive impact on reducing pruritus severity. In the mentioned study, the mean pruritus severity score after the intervention was significantly lower in comparison to the pre-intervention phase. In addition, after two weeks of follow up, it was noted that pruritus still increased, but this growth in severity was lower compared to the pre-intervention stage.[26]

Given the fact that the baby oil used in the current study had moisturizing properties, and

regarding the similarities between this compound and physiological lipids, endogenous cannabinoids, and emollients containing high water content, the above-mentioned results can be applied to confirm our findings.

To the best of our knowledge, no study was conducted to evaluate the effect of baby oil on pruritus severity; nonetheless, several studies were found that assessed the impact of other moisturizers in this regard. In a study performed by Afrasiabifar et al. in 2016, it was confirmed that the application of sweet almond oil with high moisturizing properties reduced pruritus severity.[16]

Shagholian et al. in 2013 conducted a study to evaluate the effect of combination of aromatic and non-aromatic oils extracted from sweet almond oil with high moisturizing properties on pruritus severity and found no positive impact; therefore, the results of the mentioned study were inconsistent with our findings.[6] Additionally, Ghaderi et al. in 2006 used moisturizers for two months and observed no specific effect on the mean pruritus severity score in hemodialysis patients.[19] This discrepancy in results might be due to using different compounds with diverse moisturizing features and different administration methods.

5. Conclusion

Administration of baby oil, as a cost-effective and available non-pharmacological treatment, lowered pruritus severity in the hemodialysis patients. Moreover, further studies are recommended to compare different brands of baby oil. One of the major limitations of this study was the psychological causes of pruritus, such as stress and anxiety, which could not be controlled in this study and no accurate instrument was found to rule out this problem.

Conflicts of interest

The authors declare no conflicts of interest.

Authors' contributions

Sima Mokhtarabadi: Data collection, study implementation, compilation of the primary manuscript, Maryam Shahabi: Study design, article compilation and corresponding author, Tabandeh Sadeghi: Study design, participation in research compilation, scientific edit of the article, Majid Kazemi: Monitoring the study implementation, participation in research compilation, scientific edit of the article.

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