

Original Research

Effect of Foot Reflexology on Laboratory Tests after Kidney Transplantation Surgery: A Secondary Analysis of a Parallel Randomized Controlled Trial Study

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Abstract

Foot reflexology has improved numerous physical and psychological symptoms in patients. The researchers in this study aimed to investigate the effect of foot reflexology on laboratory parameters, intake/output/weight and medication regimen after kidney transplant surgery. The research was a secondary analysis of a parallel randomized controlled trial. The research



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included patients who were admitted to the transplantation ward. The stratified randomization approach divided 53 eligible patients into two groups: foot reflexology and control. The intervention group was given 30 minutes of foot reflexology daily for three days while the control group received no reflexology. The intervention began on the second day following surgery. The demographic information questionnaire and information about laboratory tests and intake, output and weight were extracted from patients' records before, immediately and one week after the intervention. Before the kidney transplantation surgery and during the intervention, the laboratory tests of the two groups of foot reflexology and control laboratory tests were similar. During the intervention, no significant differences in intake, output, and weight values were found between the two groups of foot reflexology and control ($P > 0.05$). The present study showed that foot reflexology had no particular effects on laboratory tests, intake/output, weight and diet of patients after kidney transplantation. Further studies are needed to achieve more accurate results in this area.

Keywords

Foot reflexology; kidney transplantation; laboratory tests

1. Introduction

The rising prevalence and burden of chronic diseases are one of the most significant challenges confronting global health systems in the twenty-first century [1]. Due to his/her health status, illness, and treatment, a person with chronic kidney disease assumes the role of a patient in life [2]. Chronic kidney disease is a pathophysiological process with various causes that ultimately leads to decreased number and function of nephrons [3]. This chronic disease is spreading due to the high prevalence of diabetes and hypertension worldwide [4] and has exceeded the growth rate of the population in the world [5], so that the number of these patients has been estimated to be 3,500,000 in 2020 [6]. The disease is also growing in Iran and has a growth rate of 15% per year [7].

Renal replacement therapy is needed for patients with end-stage renal disease who cannot live without it. Hemodialysis, peritoneal dialysis, and kidney transplantation are also options for treatment [8]. For patients with end-stage renal disease, kidney transplantation is preferred and in many cases, the most successful form of renal replacement therapy. Patients with end-stage renal failure who receive a kidney transplant have a better chance of surviving [9]. Kidney transplants can free patients from long-term dependence on dialysis [10]. At the end of 2014, the world's total number of renal transplant recipients was estimated to be about 684000. In the Middle East, Iran has the largest number of kidney transplants. In Iran, more than 32,000 people received kidney transplants in 2014, with 2500-2700 cases added annually [1].

Some pre-and postoperative care measures are taken for patients undergoing kidney transplant surgery [6]. Preoperative care for kidney transplant recipients includes complete physical examinations to diagnose and treat any conditions that may cause problems after the transplant, tissue type, blood type, and antibody control to determine coordination between donor/recipient tissues and cells, and other diagnostic tests should be performed to identify specific cases that require treatment prior to transplantation [11]. Postoperative care for kidney transplant recipients

include control of blood tests, control of fluid balance and electrolyte input and output, administration of immunosuppressive drugs to reduce transplant rejection, control of vital signs, control of urinary output, respiratory care, relief of pain, anxiety and fatigue, and diet [6, 12]. However, patients, undergoing kidney transplant surgery and being admitted to the kidney transplant ward for several days/weeks, are exposed to some physical, mental and spiritual problems that affect their quality of life [13, 14].

Various methods are used to reduce the patient's physical, and mental problems in the transplant ward, and after transplant surgery [15], including invasive procedures such as epidural anesthesia and abdominal block and non-invasive methods such as foot reflexology [16]. Reflexology is a natural and ancient treatment [16] that changes the flow of energy throughout the body through the pressure of the fingers, especially the thumb on the sole [17]. Foot reflexology can have significant effects on the body's systems such as improving blood circulation, improving the body's homeostasis system, increasing the quality of sleep and increasing the immune system [18]. Reflexology is effective in reducing post-cesarean section pain and anxiety [19], improving the symptoms of premenstrual syndrome [20], relieving nausea and vomiting in cancer patients after chemotherapy [21], relieving constipation in older adults [22], reducing fatigue in patients with multiple sclerosis [23], eliminating urinary retention after surgery [24], improving the quality of life of patients with breast cancer [25] and lowering blood pressure in patients with stroke [26].

Samarehfekri et al. (2022) found that foot reflexology reduces pain and fatigue and improves sleep in patients undergoing kidney transplantation [14]. Usually, the result of foot reflexology has focused more on the variables related to psychological disorders and less on the effect of foot reflexology on chemical changes in the body.

Although the available evidence suggests that foot reflexology has been used in various conditions to improve numerous physical and psychological symptoms, limited studies have examined the effect of reflexology on the laboratory parameters of patients undergoing reflexology. Given the importance of proving the safety of complementary medicine interventions, especially reflexology, in patients with special conditions, the present study aimed to analyze secondary data from a clinical trial to determine whether foot reflexology was effective in laboratory tests after kidney transplant surgery.

2. Materials and Methods

2.1 Study Type and Setting

This study is a secondary data analysis of a parallel-randomized controlled trial conducted to assess the effect of foot reflexology on laboratory tests after kidney transplantation surgery.

2.2 Sample Size and Sampling

According to a pilot study (5 samples in each group), (on the fourth-day post-surgery, the mean and standard deviation in the pilot reflexology group was 3.2 ± 2.17 and the mean and standard deviation in the pilot control group was 5.2 ± 1.3), the sample size was estimated to be 21 individuals for each group with a confidence coefficient of 95%, and type II error of 10%. In each group, 25 samples were chosen due to the possibility of dropout. The pilot samples were used in the final analysis, which is remarkable. Furthermore, according to a power analysis performed with G*Power

software, 46 participants (23 per group) would be needed to detect an effect size of 0.2 (power = 90%, $p = 0.05$). Inclusion criteria were the minimum age of 15 years old, the first turn of the kidney transplantation, no ulcers or injuries in feet, especially the sole, complete postoperative consciousness, no history of using foot reflexology, no addiction to drug use or alcohol, and no mental disorder [14]. Patients were randomly assigned the intervention and control groups using the stratified randomization process, with gender and age (± 2) as strata. To put it another way, the first sample was randomly assigned either to the intervention or control groups (using the lottery), and the rest were randomly assigned based on the matching variables. The first author assessed the participants according to the inclusion criteria and allocated them into groups (Figure 1).

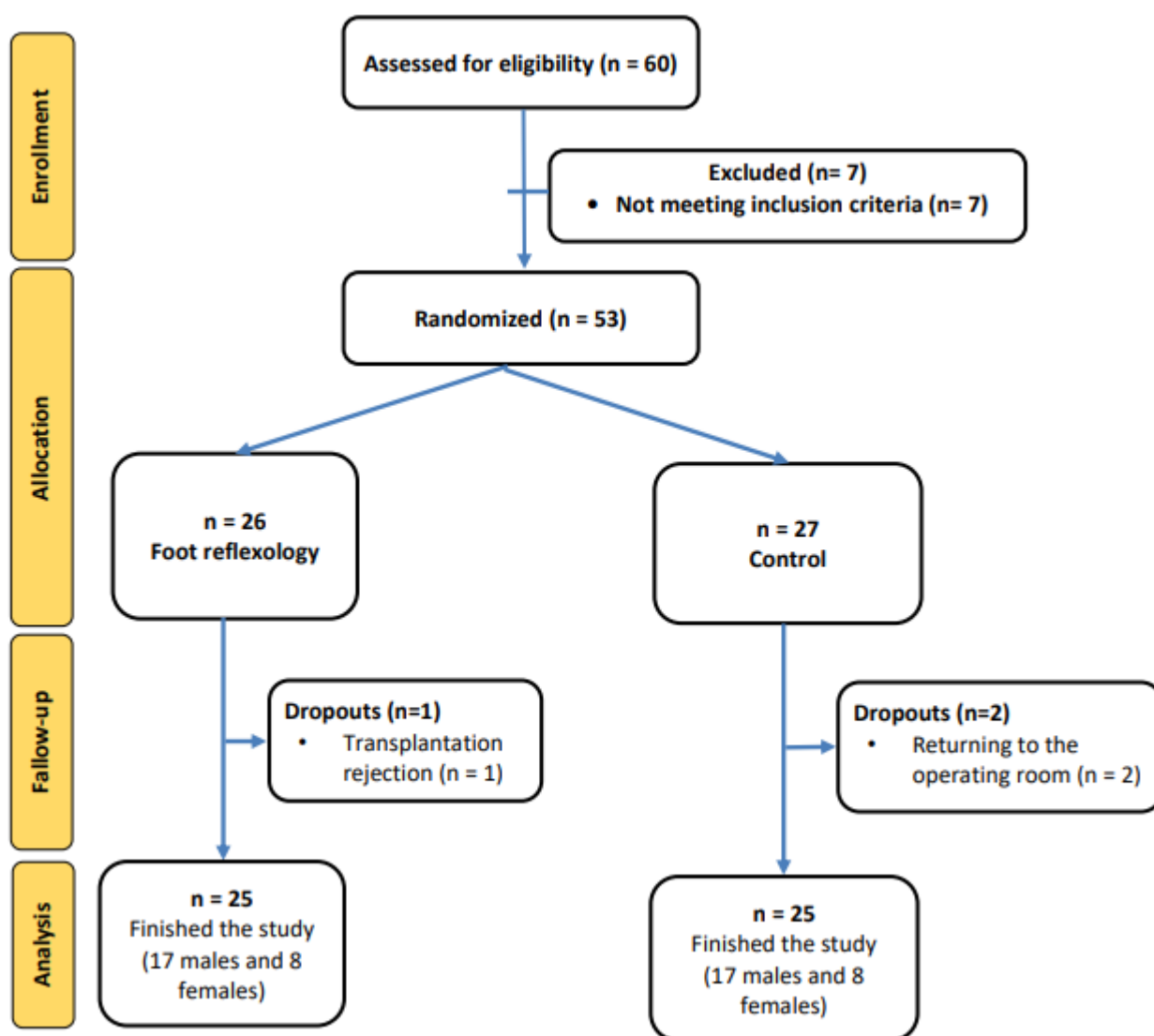


Figure 1 The flow diagram of the study.

2.3 Data Collection Tools

The data collection tool was a four-part questionnaire, including demographic and medical history information, the sedation and analgesia checklist, laboratory tests checklist, intake/output/weight and medication regimen checklist. Age, sex, marital status, educational level, family income, smoking history, type of dialysis, date of procedure, name of the surgeon, the period

of kidney failure, underlying diseases such as digestive, diabetes, hypertension diseases, and the patient's medications (narcotics and sedation) were all included in the demographic questionnaire. Midazolam, ketamine, fentanyl, thiopental, lidocaine, morphine, diclofenac, and acetaminophen were the sedatives and analgesics on the checklist.

The laboratory checklist included routine tests before kidney transplantations, including complete blood cell count, urea nitrogen, creatinine, sodium, potassium, calcium, glucose, liver enzymes, albumin, and coagulation tests. In addition, complete blood cell count, blood urea nitrogen, creatinine, sodium, potassium, and calcium are the laboratory tests checked daily in the study setting. Upon entering the transplant ward, patients underwent relevant tests repeated 4 hours later. The tests were done again at 6 pm and 10 pm on the same day, at 6 am and 4 pm on the first day, and 4 pm on the second day. The relevant tests were done daily. The amount of blood taken from the patient was 5 cc each time. All tests were performed in the laboratory of Afzalipour Hospital, sent to the relevant department through the system, and recorded in the patient's medical record.

Intake/output/weight and medication regimen checklist was checked every 1 hour on the first day, every 2 hours on the second day, every 3 hours on the third day, and finally every 6 hours. Then it was registered in the special charts of the transplant ward.

2.4 Data Collection

After receiving approval from the hospital manager and the transplantation staff, the researcher went to the research setting and began sampling. The medical record and, if necessary, patient interviews were used to determine demographic and background information. Then, they were randomly divided into intervention and control groups based on the inclusion criteria. The laboratory tests were measured on the first day of surgery to have the basic data. We began the intervention on the second day to ensure that patients' conditions were stable and the researcher's presence in the ward did not interfere with routine care. The intervention was conducted for three consecutive days. The length of the intervention was considered 3 sessions (daily) by reviewing similar studies and consulting with the surgeon. Again, laboratory tests, intake, output, weight, and medication regimen were assessed in both groups on all three days of intervention.

2.5 Intervention Protocol

The intervention group received reflexology starting the second day after surgery in the late evening shift, and at least 4 hours after the patient received sedatives [16, 27, 28]. The evening shift was selected because of the proximity to the patient's sleep hours and the low workload of staff. Prior to reflexology, the patient's privacy was respected. The researcher sat on a chair at the foot of the patient's bed and applied reflexology while the patient was comfortable in a quiet and bright atmosphere. First, the researcher warmed her hands and used a soft wet napkin to wipe the patient's feet. The feet were then gently massaged for three minutes [29]. The researcher applied pressure to the pituitary and pineal gland points with one hand on the back of the big toe. She used her left hand to hold the heel and her right thumb to pressure the spinal points [30]. With her thumb, she rotated the patient's outer edge of the foot back and forth [31]. The massage was done at a slow pace in a normal rhythm and with a moderate amount of pressure. The patient's self-reporting determined the pressure level that they did not experience any discomfort while applying pressure.

The reflex zone massage lasted for nine minutes. Finally, the foot was gently massaged for 3 minutes just as it had been at the start of the treatment. As a result, the protocol was conducted three times (30 minutes each session) for a total of 15 minutes [32, 33] on each foot [34]. The reflexology was performed without the use of any lubricant. Iranian Art Massage Institute (<https://artmassage.ir/>) accepted the reflexology procedure, which is noteworthy. In the control group, no reflexology was used and the transplantation department's routine care was taken. A nurse, who had no idea about the samples' allocation, completed the patient's pain, fatigue, and quality of sleep scales by interviewing the participants immediately after the intervention and one week later. It should be remembered that the first researcher carried out all interventions. A 24-hour reflexology course was taught by a Chinese medicine specialist to the first researcher. Furthermore, the first researcher gained certification from the Iranian Art Massage Institute (<https://artmassage.ir/>).

2.6 Data Analysis

The data were analyzed with SPSS 18. At the start of the analysis, independent t-test (or Mann-Whitney U), Chi-squared, or Fisher's exact tests were used to see how close the two groups were regarding underlying and confounding variables. Repeated measures ANOVA test was used to determine the mean difference in laboratory values within and between the two groups at different times. Repeated measures ANOVA test was used to determine the mean difference in intake, output, and weight values within and between the two groups at different times. Chi-squared or Fisher's exact tests were used to determine the difference in medication regimen between the two groups at different times. The significant value was considered 0.05.

2.7 Ethical Considerations

The ethics committee of Kerman University of Medical Sciences accepted the study protocol (No. IR.KMU.REC.1397.071, IRCT20170116031972N6; <https://en.irct.ir/trial/31687>). Before enrolling in the study, the researchers outlined the research goals and procedure to the participants, and all eligible participants signed written informed consent.

3. Results

The participants in the foot reflexology group had a mean age of 38.12 ± 12.87 , while those in the control group had a mean age of 38.56 ± 12 . The majority (81.32%) of the samples in both groups were female. No significant difference was found between the two groups in the variables of sex, marital status, education level, and income level ($P > 0.05$). Furthermore, the two groups revealed no significant difference in clinical variables, such as duration of kidney failure (month), duration of dialysis (month), type of dialysis, history of diabetes, hypertension, heart diseases, and smoking ($P > 0.05$). Both groups had the same surgeon conduct the operation and took the same drugs during kidney transplantation. It is worth noting that the whole surgical process took about 3 hours. Before the kidney transplantation procedure, no significant difference was found in the results of laboratory tests between the two groups of foot reflexology and control ($P > 0.05$).

No significant difference was observed between the two groups of foot reflexology and control in the results of laboratory tests during the intervention ($P > 0.05$) (Table 1 and Table 2).

Table 1 The mean score of laboratory values in intervention and control groups.

Laboratory tests		Group	Intervention		Control	
			Mean	SD	Mean	SD
Hemoglobin	The first day of surgery		9.55	1.84	9.96	2.31
	The first day of intervention (Second day post surgery)		9.37	1.66	9.04	1.85
	The second day of intervention		9.10	1.73	9.21	1.45
	The third day of intervention		9.42	2.02	9.27	1.73
Platelets	The first day of surgery		156480	48441.65	149880	51077.0
	The first day of intervention (Second day post surgery)		150680	40558.31	131200	41622.31
	The second day of intervention		149680	46400.18	141200	53004.72
	The third day of intervention		209800	293212.95	126920	45719.18
White Blood Cells	The first day of surgery		10544	3522	10240	3450
	The first day of intervention (Second day post surgery)		11012	3482	9448	2762
	The second day of intervention		10058	2864	8834	3069
	The third day of intervention		89512	3094	7642	2568
Blood Glucose	The first day of surgery		133.92	55.41	144.0	53.76
	The first day of intervention (Second day post surgery)		143.52	65.57	130.32	43.72
	The second day of intervention		142.8	91.84	130.0	57.49
	The third day of intervention		120.12	59.40	115.0	40.97
Sodium	The first day of surgery		134.16	3.96	135.84	7.68
	The first day of intervention (Second day post surgery)		136.44	4.54	135.72	5.75
	The second day of intervention		134.32	7.15	135.28	5.28
	The third day of intervention		134.64	6.14	134.96	4.74
Potassium	The first day of surgery		4.27	0.55	4.46	0.69
	The first day of intervention (Second day post surgery)		4.27	0.57	4.36	0.76
	The second day of intervention		4.01	0.54	4.05	0.57
	The third day of intervention		3.96	0.45	3.76	0.37

Calcium	The first day of surgery	3.88	0.54	3.76	0.45
	The first day of intervention (Second day post surgery)	3.89	0.46	3.83	0.71
	The second day of intervention	4.05	0.55	4.08	0.58
	The third day of intervention	4.11	0.58	4.02	0.56
Blood Urea Nitrogen	The first day of surgery	90.44	28.27	87.76	24.58
	The first day of intervention (Second day post surgery)	83.76	37.60	78.12	38.15
	The second day of intervention	86.0	48.38	79.96	37.63
	The third day of intervention	94.12	54.17	80.24	41.02
Creatinine	The first day of surgery	5.86	3.57	5.22	1.32
	The first day of intervention (Second day post surgery)	4.04	2.39	3.55	1.90
	The second day of intervention	3.48	2.55	2.96	1.89
	The third day of intervention	3.24	2.68	2.63	1.77

SD: Standard Deviation.

Table 2 Comparison of laboratory values in intervention and control groups at different times.

Source of change		Sum of Squares	df	F	P value	Partial Eta Squared
Hemoglobin	Time	2.39	1.76	2.17	0.13	0.04
	Group*Time	1.61	1.76	1.47	0.24	0.03
	Hb on the first day of surgery	2.62	1.76	2.39	0.10	0.05
	Group	5.11	1	1.52	0.22	0.03
	Error	158.24	47			
Platelets	Time	36302793350	1.05	1.25	0.27	0.026
	Group*Time	44285169530	1.05	1.52	0.22	0.03
	Plt on the first day of surgery	23479593360	1.05	0.81	0.38	0.017
	Group	42488910690	1	2.38	0.13	0.048
	Error	838966339000	47			
White Blood Cells	Time	7.24	1.64	1.18	0.30	0.025
	Group*Time	0.45	1.64	0.07	0.90	0.002
	WBC on the first day of surgery	28.06	1.64	4.57	0.019	0.09
	Group	58.15	1	3.92	0.054	0.08
	Error	696.91	47			
Blood Glucose	Time	15092.45	1.49	5.31	0.01	0.10
	Group*Time	812.32	1.49	0.29	0.69	0.006
	BG on the first day of surgery	18466.68	1.49	6.50	0.006	0.12
	Group	9908.80	1	1.83	0.18	0.04
	Error	254066.23	47			
Sodium	Time	13.05	2	0.43	0.65	0.009
	Group*Time	21.10	2	0.69	0.50	0.015
	Na on the first day of surgery	15.32	2	0.50	0.61	0.01
	Group	2.42	1	0.04	0.84	0.001
	Error	2801.77	47			
Potassium	Time	0.38	2	1.46	0.24	0.03
	Group*Time	0.40	2	1.54	0.22	0.03
	K on the first day of surgery	0.85	2	3.25	0.04	0.065
	Group	0.40	1	0.83	0.37	0.02
	Error	22.82	47			
Calcium	Time	0.16	1.53	0.46	0.58	0.01
	Group*Time	0.07	1.53	0.20	0.76	0.004

	Ca on the first day of surgery	0.11	1.53	0.32	0.68	0.007
	Group	0.01	1	0.02	0.88	0.00
	Error	30.56	47			
Blood urea nitrogen	Time	1563.49	2	3.11	0.05	0.06
	Group*Time	598.35	2	1.19	0.31	0.025
	BUN on the first day of surgery	1068.91	2	2.12	0.12	0.04
	Group	1832.28	1	0.40	0.53	0.009
	Error	212584.47	47			
Creatinine	Time	0.11	1.27	0.16	0.75	0.003
	Group*Time	0.28	1.27	0.42	0.57	0.009
	Cr on the first day of surgery	4.49	1.27	6.72	0.007	0.12
	Group	4.73	1	0.38	0.54	0.008
	Error	588.71	47			

Hb = Hemoglobin; Plt = Platelets; WBC = White Blood Cells; BG = Blood Glucose; Na = Sodium; K = Potassium; Ca = Calcium; BUN = Blood urea nitrogen; Cr = Creatinine; df = Degree of freedom; F = Repeated measure ANOVA.

No significant difference was observed between the two groups of foot reflexology and control in the results of intake, output, and weight values during the intervention ($P > 0.05$) (Table 3 and Table 4). No significant difference was observed between the two groups of foot reflexology and control in the results of diet (diabetic, low salt, high-protein, regular and liquid, soft, solid) during the intervention ($P > 0.05$).

Table 3 The mean score of intake, output and weight values in intervention and control groups.

Laboratory tests		Group		Control	
		Intervention	SD	Mean	SD
Intake (ml)	The first day of intervention (Second day post surgery)	8367.6	3492.85	9225.2	3004.89
	The second day of intervention	5926.2	2429.57	6380.0	2103.86
	The third day of intervention	4357.6	1561.07	4590.4	1190.84
Output (ml)	The first day of intervention (Second day post surgery)	6456.0	5185.12	7262.6	3866.99
	The second day of intervention	5445.0	2624.66	5468.4	2209.9
	The third day of intervention	3712.4	1632.43	4248.0	1785.5
Weight (kg)	The first day of intervention (Second day post surgery)	67.34	15.15	67.62	13.56
	the second day of intervention	67.34	14.81	67.46	14.43
	The third day of intervention	67.76	14.30	67.64	13.97

SD: Standard Deviation.

Table 4 Comparison of intake, output and weight values in intervention and control groups at different times.

Source of change	Sum of Squares	df	F	P value	Partial Eta Squared	
Intake	Time	474825891.0	1.51	69.42	<0.001	0.59
	Group*Time	2509460.0	1.51	0.37	0.64	0.01
	Group	9935640.17	1	0.91	0.34	0.02
	Error	521630597.3	48			
Output	Time	207275930.3	1.46	14.34	<0.001	0.23
	Group*Time	3954967.0	1.46	0.27	0.69	0.01
	Group	7770264.0	1	0.51	0.48	0.01
	Error	733249545.3	48			
Weight	Time	2.41	1.47	0.22	0.73	0.005
	Group*Time	1.01	1.47	0.09	0.85	0.002
	Group	0.33	1	0.001	0.98	0.00
	Error	29243.36	48			

On the first, second, and third days of intervention, the medication regimen of participants included vial albumin, vial Thymoglobulin, amp ceftriaxone, amp Recombinant Erythropoietin, amp heparin Sodium, amp methylprednisolone, amp Iron Sucrose, infusion furosemide, insulin NPH and regular, tab amlodipine, tab Aspirin, tab atorvastatin, tab and cap Calcium carbonate, tab carvedilol, tab Mycophenolate Mofetil, tab co-trimoxazole, tab folic acid, tab Mycophenolate Mofetil, tab pantoprazole, tab prednisolone, tab Tacrolimus, tab Valganciclovir, cap Cyclosporine, supp clotrimazole. No significant difference was observed between the two groups of foot reflexology and control in the results of the medication regimen on the first, second, and third days of intervention ($P > 0.05$).

4. Discussion

The current study found no significant difference in the results of laboratory tests between the two groups of foot reflexology and control during the intervention. Furthermore, no significant difference in I/O and weight was observed between the two groups of foot reflexology and control during the intervention. No study has examined the effect of foot reflexology on laboratory parameters, fluid intake and diet in patients undergoing kidney transplant surgery. In general, only a few studies on other people have been conducted, which we will discuss further below. Mohamed et al. (2016) studied patients with hypertension. They found a statistically significant decrease in serum creatinine in the reflexology group but no statistically significant difference in Na, K and Ca levels between the groups before and after the intervention [35]. The results of this study can be both consistent and inconsistent. The inconsistency of these two studies can be due to the differences in the sample size, the study population, and the method. Silva et al. (2018) demonstrated that foot reflexology did not affect blood glucose levels in people with type 2 diabetes [36]. Song et al. (2015) found that reflexology did not affect cortisol levels in healthy study participants [37]. Reflexology could not affect cortisol and blood glucose levels, so these studies can

be considered consistent with the present study. However, these studies differed in terms of study type, methodology, study population and type of laboratory parameters.

Dođru et al. (2020) studied patients undergoing angiography and angioplasty and found a significant difference in cortisol levels within both reflexology groups, but no significant difference in the control groups [38]. Yodsirajind et al. (2016) studied older people with type 2 diabetes and indicated that foot reflexology affected HbA1c and the intervention group had lower hemoglobin levels than the control group [39]. The results of these studies are inconsistent with that of the present study because of the differences in the sample size, the study population and the methodology. In addition, only one laboratory parameter was examined in these studies.

Reflexology is a safe touch-based technique integrated into various parts of the world and used by up to 30% in China [40]. Reflexology may be easily taught to healthcare professionals and families. This involves applying pressure to specific areas of the feet or hands (reflex points), thereby stimulating nerve points that mediate electrochemical messages [30]. Activation of neurons by direct pressure reduces tension and stress and maintains body balance [27]. Such anxiety reduction seems accomplished by parasympathetic activation and inhibiting the sympathetic nervous system by stimulating various reflex points [41, 42]. These effects may therefore reduce the associated catecholamine elevation. States a common hypothesis. That reflexology causes the release of endorphins in the body [43], promoting feelings related to health and well-being. However, the mechanism of action of reflexology is not yet known.

Studies have shown that the hormonal stress response is associated with the release of cortisol. Functional menstrual disorders such as polycystic ovary syndrome are associated with increased cortisol. There is evidence that reflexology can positively affect menstrual patterns [44]. Therefore, reflexology may potentially correct hormonal balance in the same way as mind-body approaches similar to mindfulness and exercise [45].

There is another hypothesis about reflexology. Recent research has focused on the adaptation of sensory cells to mechanical stimuli [46], which may be largely innervated by autonomic nervous system fibers, thereby influencing metabolic behavior. Further studies have supported this view of manual manipulation of fascia affecting the autonomic nervous system [47].

The literature review showed that the effect of reflexology on laboratory parameters, fluid intake and diet has not been done, so more research is needed in this field to confirm the results. Also, the present study paid special attention to the effect of reflexology in patients undergoing kidney transplant surgery. Therefore, considering the various problems and limitations in the treatment and life of patients undergoing kidney transplant surgery, it is necessary to conduct more studies in this regard in other patients and larger groups.

The researcher faced some limitations in this study. The transplant ward had two bedrooms, so the patients of the intervention and control groups might be placed in a single room. This situation happened only once during the study. A partition was used to reduce the effect of the intervention on the control group and a nurse was asked to stay with the patient during the intervention. Considering that in the literature review, no study was found about the effect of reflexology on fluid intake and diet, caution should be taken in interpreting the results and more studies are needed to confirm the results.

5. Conclusions

The current study found no significant difference between the two groups of foot reflexology and control in the results of laboratory tests, input/output values, weight and diet results during the intervention. Further studies are needed to achieve more accurate results in this area.

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Author Contributions

AS and MD contributed to making the idea, data gathering, supervise the project, analysis of data, drafting the manuscript, and approving the final version of the manuscript to be submitted; MZ, AS, HKM and ARA revise the draft and approve the final version of the manuscript to be submitted.

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Competing Interests

The authors have declared that no competing interests exist.

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