

Original Article



Effect of Foot Massage on Patients with Chemotherapy Induced Nausea and Vomiting: A Randomized Clinical Trial

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Abstract

Introduction: Cancer is a global problem and it is a leading cause of death worldwide. Nausea, vomiting and retching (NVR) are one of the common side effects that are seen among the majority of the patients undergoing chemotherapy. Foot massage is a complementary therapy that reduces chemotherapy-induced nausea and vomiting and improves the quality of life among cancer patients undergoing chemotherapy. This study aim to measure the effectiveness of foot massage in reduction of nausea, vomiting & retching on patients undergoing chemotherapy treatment.

Methods: A randomized clinical trial study was used to assess the effect of foot massage on patients with Chemotherapy-induced nausea and vomiting among patients undergoing highly emetogenic chemotherapy. Simple random sampling by the lottery method was used to select newly diagnosed cancer patients who underwent highly emetogenic chemotherapy (N=82). Rhodes index of nausea, vomiting and retching questionnaire were used for data collection. SPSS 19, two-sample *t* test, paired *t* test and chi-square test were used for data analysis.

Results: Nausea, vomiting, and retching were significantly reduced in the experimental group compared to the control group after the intervention. There was a significant difference between pre-intervention and post-intervention scores within the group.

Conclusion: The findings of the study revealed that the foot massage therapy is effective in reducing chemotherapy-induced nausea and vomiting among patients undergone highly emetogenic chemotherapy. The study helped to conclude that foot massage can be considered effective intervention in chemotherapy patients.

Introduction

Nausea, vomiting and retching (NVR) are commonly seen among patients undergoing chemotherapy, even after the development of anti-emetic therapy, that alone is not enough to reduce chemotherapy-induced NVR, various other techniques are also used along with medications to reduce the symptoms.¹ Other therapies that can be used along with medications to reduce nausea, vomiting & retching are massage therapy, guided imagery, aromatherapy, reflexology, etc.² Massage therapy is reported to have a positive effect in reducing nausea, vomiting, retching, anxiety, and pain, among various other non-pharmacological therapies. Several massage therapy techniques have been used in various populations such as cancer patients, bone marrow transplantation patients, patients with lower back pain, patients who underwent abdominal surgery and patients with end-stage renal disease, to know the effect of foot massage on various parameters.³

The patients were administered anti-emetics normally used for NVR reduction.

New global cancer data 2018 suggests that the global cancer burden has risen to 18.1 million cases & 9.6 million cancer deaths.⁴ Based on the cancer statistics in India (2018), the estimated number of people living with the disease is around 2.25 million. New cancer patients registered every year is over 1157294 lakh and cancer-related deaths are 784821. Among all cancers, breast cancer comes in the first position of cancers among females. There were 2 million new cases of breast cancer in 2018.⁵ Massage can be considered as a part of complementary and integrative medicine.⁶ For cancer treatment, massage benefits by reducing the side effects caused by the treatment and improves the quality of life and wellbeing. Scientific studies that have looked the effect of various body massage on patients on chemotherapy treatment and patients underwent surgery have shown that massage helps to reduce side effects such as pain, fatigue, nausea,

anxiety, and depression.⁷ Swedish massage is a manual technique that consists of continuous systematic strokes and deep kneading and stretching to reduce stress and to loosen tight muscles.⁸

The procedure adopted for this study was to apply Swedish massage on a control of group of patients who underwent chemotherapy and measure the level of NVR using Rhodes index of nausea, vomiting and retching (RINVR) standard questionnaire. Three consecutive sessions of Swedish foot massage were applied and the RINVR was measured after 48 hours of the session. The standard questionnaire for evaluation of RINVR was adopted. The purpose of the study is to reduce the NVR by simple intervention along with a single antiemetic. Foot massage is a simple intervention & this type of study was not done in our setting.

Materials and Methods

A randomized clinical trial study was conducted in the Regional Cancer Center (RCC) of Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER). Sample of 82 newly diagnosed patients who all were undergoing chemotherapy for the first time were allotted by simple random sampling method (lottery method). Inclusion criteria includes, (i) Newly diagnosed cancer patients who were undergoing highly emetogenic chemotherapy in RCC, JIPMER. (ii) Patients who were more than 18 years of age and less than 70 years of age in both genders. (iii) Patients who were conscious and able to communicate in Tamil or English. Exclusion criteria includes, (i) Patients with concurrent radiotherapy. (ii) Patients having any neuromuscular problems of the lower extremities. (iii) Patients with esophageal and stomach malignancies.

A true experimental pretest-posttest research design was used and the patients were allotted to experimental and control groups using a simple randomization technique. The instruments used in the study consists of two parts; Part I consists of demographic variables and clinical variables and Part II consists of RINVR, a standardized scale developed by Verna Rhodes. RINVR score ranges from 0 to 32. The score of 0 indicated none NVR, 1-8 indicated mild NVR, 9-16 indicated moderate NVR, 17-24 indicated severe NVR, and 24-32 indicated the worst levels of NVR.⁹ Information about the patient and pretest was done by the interview method before undergoing chemotherapy and post-test was done by telephonic interview through phone call. Steps of Swedish foot massage used were effleurage, petrissage, tapotement and friction. The trial has been registered under CTRI (Clinical Trials Registry- India), and the CTRI registration number is CTRI/2018/10/015927. Patients who were undergoing first cycle of highly emetogenic chemotherapy and those who fulfill the inclusion criteria was selected as study participants randomly by the investigator. Sampling, pretest & intervention (foot massage) was done by the

investigator. The post test was done by investigator & co-investigator. The written consent was obtained from the study participants before involving in the study. The pretest and post test score ranges from 0 to 32.

Foot massage was given to the patients in three sessions, 20 minutes before starting chemotherapy, 20 minutes during chemotherapy and immediately after completion of chemotherapy. Each session took 20 minutes (10 minutes for each leg). And the post- test was done 48 hours after undergoing chemotherapy, through a phone call. In the control group pretest was done before undergoing chemotherapy, and they received routine care, and the posttest was done after the end of the study after undergoing routine care.

Both the control and experiment groups patients were administered regular medication for NVR reduction in equal amount. The only difference was the non-application of Swedish foot massage for the control group.

The sample size was estimated to be 82 participants i.e. each group consists of 41 participants. The sample size is calculated by using mean scores of NVR with the mean of 7.48 (1.82) and 8.88 (2.60) between experiment and control groups respectively and the power of the study is 0.8 with 5% level of significance. Both descriptive and inferential statistics were used in data analysis. In descriptive statistics, frequency & percentage was used for demographic data, and mean and the standard deviation was used for scores of the effectiveness of foot massage. In inferential statistics, the paired t-test was used to find the significant difference within the group and two sample *t* test was used to find a significant difference between the groups. In the non-parametric test, the chi-square test was used to associate the association between the categorical variables. All the statistical tests were done at 5% level of significance. The study process from recruitment to analysis is shown in Consolidated Standards of Reporting Trials (CONSORT) flow diagram (Figure 1).

Results

Statistical analysis showed that the study group were homogenous in relation to age, gender, marital status, place, occupation ($P > 0.05$). The clinical variables are listed in Table 1. No significant difference seen between the demographic variables and clinical parameters between the groups before intervention ($P > 0.05$). Table 2 reveals the frequency and percentage of pre-intervention scores of patients undergone chemotherapy. There was not statistically significant difference between groups regards of Rhodes index of NVR scores ($P > 0.05$). Table 3 reveals the frequency and percentage of post-intervention scores of the patient's undergone chemotherapy. There has been found a significant difference between the group in the Rhodes index of NVR scores ($P = 0.03$). Foot massage was shown to be effective in experimental group by having more number of patients in No NVR category (No = 13, 31.71%) compared to control group (No = 6, 14.64%) and

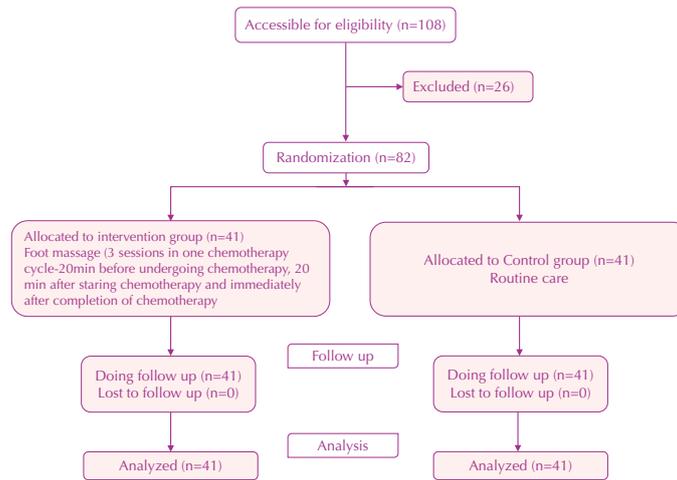


Figure 1. Flowchart of study.

Table 1. Clinical variables of patients undergoing chemotherapy (N= 82)

Clinical variables	Experimental group (n = 41)	Control group (n = 41)	χ ²	P value
	No. (%)	No. (%)		
Diagnosis			3.8	0.8
Ca. Breast	23 (56.1)	18 (43.9)		
Ca.Lung	3 (7.32)	1 (2.4)		
Ca.Ovary	5 (12.2)	9 (22.0)		
Ca.Colon	2 (4.8)	2 (4.9)		
Ca.Oral	2 (4.8)	3 (7.3)		
Ca.Cervix	3 (7.3)	3 (7.3)		
Others	3 (7.3)	5 (12.2)		
Stage of cancer			0.44	0.9
Stage 1	3 (7.32)	2 (4.88)		
Stage 2	19 (46.34)	21 (51.22)		
Stage 3	15 (36.58)	15 (36.58)		
Stage 4	4 (9.76)	3 (7.32)		
Duration of illness			5.59	0.06
1-3 months	35 (85.4)	26 (63.4)		
4-6 months	5 (12.2)	14 (34.2)		
7-9 months	1 (2.4)	1 (2.4)		

Table 2. Level of nausea, vomiting and retching of patients before administering chemotherapy intervention (foot massage) (N= 82)

Category	Experimental group (n = 41)	Control group (n = 41)	χ ²	P value
	No. (%)	No. (%)		
No NVR	40 (97.56)	37 (90.24)		
Mild NVR	1 (2.44)	4 (9.76)	1.9	0.2
Moderate NVR	0 (0.00)	0 (0.00)		

NVR, nausea, vomiting and retching.

Table 3. Level of nausea, vomiting and retching of patients undergone chemotherapy after intervention (foot massage) (N= 82)

Category	Experimental group (N = 41)	Control group (N = 41)	χ ²	P value
	N (%)	N (%)		
No NVR ^a	13 (31.71)	6 (14.64)		
Mild NVR	26 (63.41)	26 (63.41)	7.1	0.03*
Moderate NVR	2 (4.88)	9 (21.95)		

NVR, nausea, vomiting and retching.

less number of patients in moderate NVR category in experimental group (No = 2, 4.88%) compared to control group (No = 9, 21.95%). Table 4 shows the comparison of the mean and standard deviation of Pre and post test scores between the experimental and control groups. Posttest mean scores of the experimental group (3.5) and control group (5.9) showed statistically significant with $P < 0.01$. It signifies that foot massage was beneficial in reducing nausea, vomiting, and retching in newly diagnosed patients undergoing highly emetogenic chemotherapy.

The association of demographic variables and clinical variables with post-intervention RINV scores not statistically significant except between marital status and post RINV score ($P < 0.001$). There was no association seen between post-intervention RINV score and clinical variables of the patients.

Discussion

The 90.24% of the control group and 97.5% of the experiment group exhibited no symptoms of NVR prior to chemotherapy treatment. After administering chemotherapy, the symptoms of NVR were measured in both the control group and the experimental group. About 31.71% of the experiment group and 14.64% of the control group had no NVR. The chance of not suffering NVR after chemotherapy was very high in the patients who received Swedish foot massage. The results indicate that 63.41% of patients suffered mild NVR in both the experiment and control groups after administration of chemotherapy. The result shows that there is no significant difference between those who received Swedish foot massage and those who did not receive the Swedish foot massage, in the category of persons suffering mild level of NVR. Moderate level of NVR was noticed in 4.88% of the experiment group who received Swedish foot massage and in 21.95% of the control group patients who did not receive Swedish foot massage. The overall observation is that Swedish foot massage reduces the moderate level NVR significantly (by 17.07%, the difference between 21.95% and 4.88%). Another significant observation is that Swedish foot massage increased the percentage of patients suffering no NVR.

In this study result showed statistical significance in the post-intervention RINV scores among the experimental and control group ($P < 0.01$) with a mean difference of 2.4

and a chi-square value of 2.8. Prapti et al., conducted a similar study on nausea, vomiting, and retching of patients with cervical cancer undergoing chemotherapy in Bali, Indonesia. A significantly higher NVR scores was seen among subjects who had experienced motion 12.69 (2.60) than those who did not 9.23 (2.86) and the difference was statistically significant ($t = 4.98, P < 0.010$).³

In this current study, Swedish foot massage was provided during the first cycle of highly emetogenic chemotherapy in 3 sessions (20 minutes before starting chemotherapy, 20 minutes during chemotherapy and 20 minutes after chemotherapy). Post-intervention RINV score showed a reduction in the mean value of the experimental group 3.5 (3.4) compared to the control group 5.9 (4.3). Which implies that Swedish foot massage was effective in reducing chemotherapy-induced nausea and vomiting in highly emetogenic chemotherapy patients. Grealish et al., conducted a quasi-experimental cross over a study on 87 in patients with mixed cancer. The Swedish foot massage was given in two occasions on each foot for 10 minutes, in both occasions, nausea scores were comparatively lower in the massage group in both pre and post-test ($P < 0.01$).⁹ In this study, 82 patients were enrolled in two groups (41 in each group) and foot massage was provided to the experimental group in 3 sessions (20 minutes each) of the first cycle of highly emetogenic chemotherapy. The post-intervention result of the experimental group showed, 31.72% patients had no NVR and only 4.88% had moderate NVR, compared to the control group of 14.44% and 21.95% respectively, which was shown statistically significant ($P = 0.03$). Billhult et al., have also conducted a randomized controlled trial on "Massage relieve nausea in women with breast cancer who are undergoing chemotherapy". The result showed nausea score was significantly lower in the massage group than that of the control group ($P = 0.025$) with approximately 2.17 fold in the number of subjects indicating an improvement between the massage group (31.71%) and the control group (14.64%).¹⁰

Conclusion

The study findings revealed that the treatment is effective in reducing chemotherapy-induced NVR among the patients undergoing highly emetogenic chemotherapy. Chemotherapy-induced nausea and vomiting are triggered

Table 4. Comparison of mean and standard deviation of pre and post intervention (foot massage) score of experimental and control group (N = 82)

RINV score in study groups	Mean (SD)	Mean difference	χ^2	P value
Pretest		0.44	1.2	0.3
Experimental group	0.20 (1.3)			
Control group	0.64 (1.9)			
Posttest		2.4	2.8	<0.01*
Experimental group	3.5 (3.4)			
Control group	5.9 (4.3)			

RINV, Rhodes index of nausea, vomiting and retching.

*Statistically significant

Research Highlights

What is the current knowledge?

Several literatures are available regarding drugs' efficacy in reduction of chemotherapy induced nausea and vomiting rather than complementary therapy.

What is new here?

Foot massage along with antiemetics has a better compliance in preventing chemotherapy induced nausea and vomiting

by cytotoxic agents in chemotherapy drugs. The study helps to conclude that foot massage can be considered a safe, effective, and low cost intervention in chemotherapy patients.

Acknowledgement

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Ethical Issues

Research proposal was approved by the Institute Ethical Committee (Human studies) JIPMER (NO: JIP/IEC/2018/024). All the records were maintained confidential and will be used only for academic purpose and the identity of the patients were not revealed anywhere in the study.

Conflict of Interest

The authors declared no potential conflicts of interest.

Authors' Contributions

CA involvement in the study are concepts, design, definition of intellectual content, clinical search, clinical studies, data analysis, statistical analysis, manuscript preparation, manuscript editing, manuscript review and guarantor. MJK has been involved in concept design, clinical studies, experimental studies, data acquisition and data analysis. BD has been involved in concept design in clinical search, review the data analysis and clinical studies

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