European Journal of Oncology Nursing 32 (2018) 12–19

Contents lists available at ScienceDirect

European Journal of Oncology Nursing

journal homepage: www.elsevier.com/locate/ejon

Reflexology in the management of chemotherapy induced peripheral neuropathy: A pilot randomized controlled trial

Seda Kurt[a,*], Gulbeyaz Can[b]

[a] Trakya University, Faculty of Health Sciences, Department of Medical Nursing, Edirne, Turkey
[b] Florence Nightingale School of Nursing Istanbul University, Istanbul, Turkey

ARTICLE INFO

Keywords:
Peripheral neuropathy
Reflexology
Chemotherapy
EORTC QLQCIPN-20
BPI

ABSTRACT

Purpose: The current experimental study aimed to evaluate the effectiveness of reflexology on the management of symptoms and functions of chemotherapy-induced peripheral neuropathy (CIPN) in cancer patients.
Method: This study was conducted as a randomized controlled trial in 60 patients (30 experimental and 30 control patients) who had chemotherapy-induced Grade II-IV peripheral neuropathy complaints from July 2013 to November 2015. Data were collected using the patient identification form, European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire Chemotherapy-Induced Peripheral Neuropathy (EORTC-CIPN-20) form, and BPI (used for related chemotherapy-induced peripheral neuropathy symptoms).
Results: The majority of the patients were being treated for gastrointestinal or breast cancer and were primarily receiving Eloxatine- or taxane-based treatment. It was found that reflexology applications did not lead to differences in either group in terms of peripheral neuropathy severity and incidence ($p > 0.05$) and only led to improvement in sensory functions in the experimental group ($p < 0.05$).
Conclusions: It was determined that reflexology is not an effective method in the management of patients' activity levels, walking ability etc. and motor, autonomic functions related CIPN, but reflexology is effective method in the management of patients' sensory functions related CIPN. Key Words: Peripheral neuropathy, reflexology, chemotherapy, EORTC QLQ-CIPN-20, BPI.

1. Introduction

Cancer is an important health problem in the World (WHO, 2016; The Ministry of Health Turkey, 2016). Depending on type and stage of the disease surgical treatment, chemotherapy, radiation therapy, hormone therapy and targeted therapy can be the main treatment approaches for most of the patients but the side effects of the treatment can deteriorate the patients' quality of life. Fatigue, vomiting, diarrhea, skin changes and peripheral neuropathy can be important side effects for many patients (Kurt and Ünsar, 2011; Yıldırım, 2007).

Chemotherapy induced peripheral neuropathy (CIPN) can particularly increase the risk of falls in patients by limiting the patient's physical functions (Can, 2008; Yıldırım, 2007; Saklı and Demir-Zencirci, 2013). This side effect frequently occurs in patients who received platinums (cisplatin, carboplatin and oxaliplatin), taxanes (docetaxel, cabazitaxel), plant alkaloids (vinblastine, vincristine, etoposide) based therapy (American Cancer Society, 2015; Park, 2014). CIPN is a dosage-dependent toxicity and the incidence of CIPN is 10–100%. Sensory loss or paresthesia interferes with activities of daily living and self-care, in patients with grad 3 or 4 peripheral neuropathies. The severity of the peripheral neuropathy can be reduced with dose reduction or cessation of the medicine, in some patients. However, in others it may take a very long time to relieve or may become permanent symptom (Argyriou, 2007; Kannarkata et al., 2008; Biedrzycki, 2010).

In the literature, many studies have been conducted to prevent or manage chemotherapy realted peripheral neuropathy. However, the efficiency of pharmacological approaches has been evaluated in most of the studies. The positive effects of the reflexology, massage (Ihn Sook, 2006; Nicholas et al., 2017) and acupuncture (Ho and Roblew, 2011; Nicholas et al., 2017) in management of the peripheral neuropathy particularly have been demonstrated in diabetes and HIV related peripheral neuropathy (Ihn Sook, 2006; Nicholas et al., 2017; Stephenson et al., 2000; Yıldırım, 2007). In a limited number of studies conducted with cancer patients, the efficiency of acupuncture (Donald et al., 2011; Schroeder et al., 2012), exercises (Wampler et al., 2005) and massage (Cunningham, 2011) was evaluated or submitted as case reports. The results of these studies suggested that these approaches might be effective in management of CIPN.

* Corresponding author. Tel.: +90 284 2133042/2123; fax: +90 212 4400000/27002.
E-mail addresses: sedakurt81@gmail.com (S. Kurt), gulbeyaz@istanbul.edu.tr (G. Can).

https://doi.org/10.1016/j.ejon.2017.11.001
Received 12 July 2017; Received in revised form 30 October 2017; Accepted 1 November 2017

In a patient with stage III esophagealoesophagus adenocarcinoma, the efficiency of massage (effleurage, petrissage) was reported in Grade II peripheral neuropathy by the management of docetaxel-cisplatin. In this case report it was stated that the grade II peripheral neuropathy was downgraded to grade I at the end of the massage, because the increased temperature accelerates the blood flow in that area (Cunningham, 2011). In different case reports, it was also emphasized that an exercise program might be effective in decreasing peripheral neuropathy related to paraesthesia. Pain and balance scores were improved by an exercise program in this case (Wampler et al., 2005). Acupuncture decreases the peripheral neuropathy related to analgesia and improves the sleeping pattern (Donald et al., 2011) and cures the peripheral neuropathy related to pain, paraesthesia and formation over the long term (Wong and Sagar, 2006). However, there are no randomized controlled trials in which the efficiency of these approaches in CIPN management has been investigated.

Reflexology for neuropathy works with the help of chemical and electrical stimulus that are sent by menas of nervous systems to balance organs and parts in far reaching areas of the body. With neuropathy, reflexology has a great option of gently activating the damaged nerve fibers to send and receive correct nervous signals. Through pressure techniques, a stable rhythmic stimulus of information is sent and received through the central nervous system. There is a certain improvement in the blood and lymph circulation in the body and in the nerve response, and a general sense of wellbeing after the treatment of reflexology (Domenico, 2007; Tabur and Basaran, 2009; Soutar, 2012; Tuğay, 2010; Wilhelm, 2003). There are only a few studies in the literature evaluating peripheral neuropathic effects of reflexology, and these studies have shown that reflexology reduces the severity of peripheral neuropathy symptoms. (Se Young et al., 2012; Ben Horin et al., 2017). Depending on these results, this study was planned to assess the effect of reflexology in management of the CIPN.

1.1. Study hypothesis

H_1: Reflexology is an effective approach in the management of chemotherapy-induced peripheral neuropathy.

2. Sample and methods

2.1. Study design and participants

This pilot randomized controlled trial (RCT) study was conducted at the outpatient chemotherapy unit in Trakya University Balkan Oncology Hospital located in Edirne, Turkey, between July 2013 and November 2015.

The sample size for the study was calculated based on the prevalence of the CIPN (10–100%). The acceptable value for α and β was set as 0.05 and 0.20, respectively. The improvement in the peripheral neuropathy is expected to be 30% by reflexology application. The required sample was determined to be minimum 30 for each group. Patients who have grades 2–4 CIPN and have no any contraindications for reflexology application were invited to the study. Patients were excluded from the study if they had any condition that could significantly interfere with reflexology application, such as a bone or vertebra metastasis.

Ninety-six patients attended to the study with simple sampling method. Patients were assigned to the experimental group (n = 46) and the control group (n = 50), using a randomization list prepared on the computer by the researcher. At the beginning of study verbally information and training brochure about the CIPN were given to all patients. The reflexology massage was applied to the experimental group. The massage was applied on cervical area, located at the inner upper side of each foot, by finger with worm-like movements and pressure was apply on the brain area located under the big toe of both foot (Fig. 1) by researcher (certified reflexologist) or relatives (educated by researcher), 20 min, twice a day, for six weeks. The standard care protocol of the clinic was used for patients in the control group (n = 50). During the study, some of the patients did not complete the questionnaires, some of them did not attend the reflexology massage or discontinued reflexology massage, and some of them did not attend the second or third meetings. So, the study was completed with 60 patients (30 experimental and 30 control patients) (Fig. 2).

Fig. 1. Foot Reflexology Chart (cervical and brain region) For Peripheral Neuropathy.

2.2. Instruments and data collection

Three interviews were conducted with the patients: These include the first meeting at the first sight, the second meeting is in the 3rd week and the third one is in the 6th week. The results of the study were obtained in accordance with the Research Flow Chart (Fig. 3). At the first meeting, the patient identification form, NCI-CTCAE v4.0 toxicity cretaria, European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire Chemotherapy-Induced Peripheral Neuropathy (EORTC QLQ-CIPN-20) quality of life form and the brief pain inventory (BPI) were completed and patients referred to physician for neurological examination. At the second visit the NCI-CTCAE v4.0 toxicity criteria, EORTC QLQ-CIPN-20 and BPI Scales were completed. At the third visit the NCI-CTCAE v4.0 toxicity cretaria, EORTC QLQ-CIPN-20 and BPI Scales were completed and patients were referred to physician for neurological examination again.

2.2.1. Patient identification form

This form was prepared by the researcher and consists of two main sections: the patient's personal characteristics (sex, age, education level, occupation, marital status etc.) and the characteristics concerning the disease and treatment (disease diagnosis, disease status, year of the diagnosis, Eastern Cooperative Oncology Group ECOG performance score, received chemotherapy protocol, treatment cure etc.).

NCI-CTCAE v4.0 toxicity criteria

Toxicity Level	
Grad 1	Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.
Grad 2	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental activities of daily living
Grad 3	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care activities of daily living
Grad 4	Life-threatening consequences; urgent intervention indicated.
Grad 5	Death related to Adverse Event