# Effect of moist heat versus cold therapy on leg muscle cramp among patients on hemodialysis: randomized control trial

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**Abstract:**

***Background:*** *Muscle cramps that occur during hemodialysis can result in shortening of treatment or reduction of fluid removal which may lead to inadequate clearance of waste products, fluid overload which significantly increase mortality risk.* ***Aim of the current study*** *was to investigate the effect of moist heat versus cold therapy on leg muscle cramp among patients on hemodialysis.* ***Design:*** *A randomized control clinical trial design was utilized to accomplish this study purpose.* ***Research hypothesis****:* ***H1 &H2:*** *The intervention groups who received either moist heat or cold therapy will have a significant lower mean pain and muscle cramp intensity score compared to the control group who received routine hospital care.* ***H3& H4****: There will be a difference between applying moist heat versus cold therapy on mean pain and muscle cramp intensity score among the intervention groups* ***Sample:*** *A sample of 90 adult male and female patients who met the inclusion criteria was invited to share in the research.* ***Results:****There were significant reduction in the intensity of pain and muscle cramp in the study groups more than control group. Moreover, moist heat therapy group was more effective than cold therapy to reduce intensity of pain and muscle cramp for patients on hemodialysis.* ***Conclusion:*** *moist heat and cold therapy are effective to reduce intensity of pain and muscle cramp for patients on hemodialysis* ***. Recommendation:*** *Further studies are required to explicate the effectiveness of heat vs cold therapy on leg muscle cramp among hemodialysis and pretonieal dialysis with large sample size of patients in different health care settings.*

***Key words:*** *moist heat, cold therapy, leg muscle cramp & hemodialysis*

## Introduction:

Kidney is the vital organ, plays an important role in the maintenance of homeostasis mechanism in the human body (Nall, 2017). Prolonged loss in the kidney function with a glomerular filtration rate less than 15/ml/min/1.73 $m^2$ for 3 months are classified as end-stage renal disease (Hinkle & Cheever, 2014). End Stage Renal Disease (ESRD) is an irrevocable progressive renal disease that removes the body power for balancing fluids and electrolytes and causes high concentration of creatinine and blood urea nitrogen ( Poornazari, Dehghani, Shahbazi, & Sardashti, 2017). End stage renal disease limits functional capacity and produce

many complications in different body systems as cardiovascular, endocrine, digestive and musculoskeletal that influences quality of patient's life ( Nivetha, Aruna, & Gowri, 2017).

One of the main replacement therapies for chronic renal failure is hemodialysis. Worldwide statistics showed that 9,20,000 patients are undergoing hemodialysis per day, which constitutes about 7 to 8% of the total population (Kottgen, Floeg, Busch, & Titze, 2015). Hemodialysis (HD) is a machine used to remove many of toxins responsible for uremic syndrome and prolongs survival. Hemodialysis works on the principles of the diffusion of solutes and ultrafiltration of fluid across a semi-permeable membrane. It is usually done for twice or thrice in a week with each session lasting about three to five hours (Lekha, Abraham & Malarvizhi, 2017). During hemodialysis many complications may occur like hypotension, muscle cramps, fatigue, and nausea (Isaac & Jacob, 2016).

Muscle cramp is one of the most complications that may affect about 33 to 86% of patients during HD, which results in discomfort, inadequate dialysis dose and early termination of HD session (Lekha, 2016). One study showed that (11.3%) of patients with pain shortened at least one dialysis session, and (5.6%) shortened sessions at least once a month (Aitken, McLellan, Glen, Serpell, Mactier, & Clancy, 2013). Other author added muscle cramps can induce reduction of fluid removal result in inadequate clearance of waste products, fluid overload, and also hypertension that may increase mortality risk ( Daugirdas, Blake & Ing, 2014).

Muscle cramps are sudden, recurrent, tonic or clonic painful, involuntary muscle contractions that may restrict patient's movement during hemodialysis session, it can involve the legs, most commonly in the feet, but can also involve arms and hands, as well as abdominal muscles (Isaac & Jacob, 2016). The etiology of muscle cramps in hemodialysis patients is not well known, but there were several factors as hypovolemia, electrolyte abnormalities, hypotension, dialysis prescription (blood flow rate and ultrafiltration), and dialysate composition (Mastnardo,et al. 2016). Other author reported that intradialytic hypotension or tissue hypoxia and elevation of serum creatine kinase may lead to an abnormal utilization of energy by muscles and thus result in muscle cramps (Ulu & Ahsen, 2015).

Evidence based practice suggests that there is a need for special attention regarding diagnosis and management of muscle cramps during HD session to avoid early termination of HD procedure and also to improve health related quality of life (Lekha, 2016). Non-pharmacological management is the cornerstone to reduce and treat muscle cramps and also to minimize pharmacotherapy adverse effect (Lekha, Abraham & Malarvizhi, 2017).Non pharmacological intervention for muscle cramps includes Local massage of the affected muscle , application of moist heat therapy or ice that provide comfort, stretching exercises before dialysis, performing mild exercise such as riding a stationary bicycle during dialysis and minimizing alcohol and caffeine intake (Raymond, Colette, 2011& Mastnardo,et al. 2016 ).

Heat therapy works by improving circulation to a particular area due to increased temperature which can relive discomfort and increase muscle flexibility. It can also relax and soothe muscles and heal damaged tissue. There are two different types of heat therapy; dry heat and moist heat. Dry heat or conducted heat therapy includes heating pads, dry heating packs, and

even saunas. Moist heat or convection heat includes steamed towels, moist heating packs, or hot baths. Moist heat may be slightly more effective than dry heat as well as require less time for application (Petrofsky et al., 2013). In addition, heat therapy can also lessen nerve sensitivity, increase blood flow, increase tissue metabolism, decrease muscle spindle sensitivity to stretch, cause muscle relaxation, and increase flexibility ( Lindsay, Bearne, & Hurley, 2010). Heat therapy can also stimulate the cutaneous thermo receptors that are connected to the cutaneous blood vessels, causing the release of bradykinin which relaxes the smooth muscle resulting in vasodilation. Muscle relaxation occurs due to decreased firing rate of the gamma efferent, and alpha motor neuron thus lowering the threshold of the muscle spindles and increasing afferent activity resulting in muscle relaxation and decrease in muscle tone, so muscle cramps can be reduced (Hendee, 2013).

Cold therapy works by reducing blood flow to a particular area by initially causing vasoconstriction followed by vasodilatation ('hunting reflex'), reducing tissue metabolism, oxygen utilization, inflammation and connective tissue extensibility which can significantly reduce pain, especially around a joint or a tendon. It can temporarily reduce nerve activity, which can also relieve pain. There are different ways to apply cold therapy to an affected area as ice packs or frozen gel packs, coolant sprays, ice massage, ice baths. It should not be used more than 20 minutes at a time (Hiroharu, Kiichiro, 2010). Moreover, heat and cold therapy produce analgesia via the pain gate theory and reduce muscle cramp or spasm. Prior the application of heat and cold therapy, skin testing to establish normal cutaneous sensation is recommended as both heat and cold therapy have a measurable effect on surface and intra-articular temperature of joints, skin micro-circulation and core temperature to reduce risk of skin damage (Hendee, 2013).

Nurses are considered as integral part of health care team who are responsible for caring patients on hemodialysis machine. They also have a role in protection, controlling and training the patient and their families regarding complications of hemodialysis and how it can be prevented or reduced such as muscle cramps, air emboli, insufficient ultra filtration, hypotension, and vomiting (Isaac & Jacob, 2016). Dialysis nurses have to increase their knowledge and improve their skills regarding renal failure and its treatment and how to use the dialysis apparatus efficiently and also they are essential for monitoring, identification, intervention, and prevention of patient's complication because they considered as an important features of quality nursing care in the hemodialysis treatment. Moreover, Nurses and other health care providers should share the interest in maximizing positive outcome that can be achieved by intervening the patient's problems during hemodialysis procedure. Therefore in this study, the researchers are interested to elicit the effect of moist heat versus cold therapy on leg muscle cramp among patients on hemodialysis.

**Significance of the study:**

Chronic renal failure (CRF) is a global health burden with a high economic cost to health care systems. All stages of CRF are associated with increased risks of morbidity, premature mortality and/or decreased quality of life (Hill et al., 2016). Ten percent of the total population in the world is affected by chronic renal failure and millions die each year as result of renal failure complications (World Kidney Day, 2015).

In Egypt, the estimated annual incidence of chronic renal failure is about 74 per million and the total prevalence of patients on dialysis is 264 per million (El-Arbagy, Yassin, Boshra, 2016). According to the annual statistics of Cairo university hospitals, the number of admitted patients having renal failure in Kasr El-Aini hospital, was 11549 and 10001patients respectively in 2016 and 2017. Number of hemodilysis sessions was 33636 and 36382 respectively in 2016 and 2017(Main Management Department statistics and Medical Records Department of Cairo university hospitals , 2017). Hemodialysis is now a standardized therapy and used as a life-sustaining therapy for patients who have end stage renal disease. Hemodialysis patients with moderate or severe pain have a higher prevalence of irritability, inability to cope with stress, decreased social support and decreased life satisfaction and they were three times more likely to withdraw from dialysis as compared to those without pain (Koncicki, Brennan, Vinen & Davison, 2015).

From the clinical experiences, the researchers found that muscle cramps are common among patients undergoing HD and interfere with the delivery of the HD treatment. There were two surveys of HD patients revealed that 77% of those patients during the first survey and 56% during the second survey reported having muscle cramps within one month ( Lynch, Abate, Suh & Wadhwa,2014). In addition, other study finding of 623 patients on hemodialysis revealed that 74.3% of them reported having muscle cramps (Caplin, Alston, & Davenport, 2014). Non pharmacological treatment strategies for muscle cramps revolve around pain reduction in order to maintain normal function and activity. Heat and cold therapy modalities are often used to facilitate this outcome despite prevalent confusion about which modality (heat vs cold) to use and when to use it and duration of the use. Most recommendations for the use of heat and cold therapy are based on empirical experience, with limited researches or evidence to support the efficacy of heat vs cold therapy on leg muscle cramp among patients on hemodialysis. This study provide information for nurses on the appropriate use of heat and cold therapies based on the mechanisms of action, physiological effects, and the medical evidence to support their clinical use. Moreover, this study will objectively quantify the effect of moist heat vs cold therapy on leg muscle cramp among patients on hemodialysis. Data derived from this study may be utilized to help nurses to assess intensity of muscle cramp, provide the required care for reliving or reducing muscle cramps. Also it is hoped that the findings of this study might help in improving quality of patients care and establish evidence based data that can promote nursing practice and research.

**Theoretical framework:**

Wiedenbach's helping art of clinical nursing theory is used as the theoretical framework to assess the effectiveness of moist heat versus cold therapy on reduction of leg muscle cramp among patients on hemodialysis. The theoretical framework was developed by Ernestine Wiedenbach in 1964. the concept of Wiedenbach’s art of nursing, is the prescriptive theory for nursing which describes a desired action toward an explicit goal. It consists of three factors: Central purpose, prescription and realities. A nurse develops a prescription based on a central purpose and implements it according to the realities of the situation (Lekha, 2016 and Petiprin, 2016).

**Central purpose**: It refers to what the researchers want to accomplish. It is the overall goal. The central purpose of the study is the reduction of muscle cramps after giving moist heat versus cold therapy. **Prescription:** It is the plan of care for a patient. It includes the action and the rationale for that action which fulfils the central purpose. In this study moist heat versus cold therapy was used for the study groups. The procedure was done for fifteen minutes and the muscle cramps were assessed using cramp questionnaire chart and Pain Numeric Rating Scale. **Realities:** The realities that affect the purpose in the given circumstance. It refers to the physical, emotional and spiritual factors that involves in nursing actions. According to Wiedenbach (1964), nursing practice consists of identifying a patient's need for help, ministering the needed help, validating the need for help (Doss, 2014). **Identification**: In this study it refers to the selection of the sample and the assessment of muscle cramps. **Ministration:** In this study, it refers to the administration of moist heat versus cold therapy to the study groups and the routine care to the comparison group. **Validation:** Evaluating the patient after performing moist heat versus cold therapy for reduction in the muscle cramps during the hemodialysis session. In this study the assessment of muscle cramps before and after administering the moist heat versus cold therapy helps to validate.

## Material and Methods

### Aim of the study

This study aimed to investigate the effect of moist heat versus cold therapy on leg muscle cramp among patients on hemodialysis.

### Research hypotheses

In order to accomplish this study aim, five hypotheses were formulated:

**H1:** The intervention groups who received either moist heat or cold therapy will have a significant lower mean pain intensity score compared to the control group who received routine hospital care.

**H2:** The intervention groups who received either moist heat or cold therapy will have a significant lower mean leg muscle cramps intensity score than the control group who received routine hospital care.

**H3**: There will be a difference between applying moist heat versus cold therapy on mean pain intensity score among the intervention groups

**H4**: There will be a difference between applying moist heat versus cold therapy on mean leg muscle cramp intensity score among the intervention groups

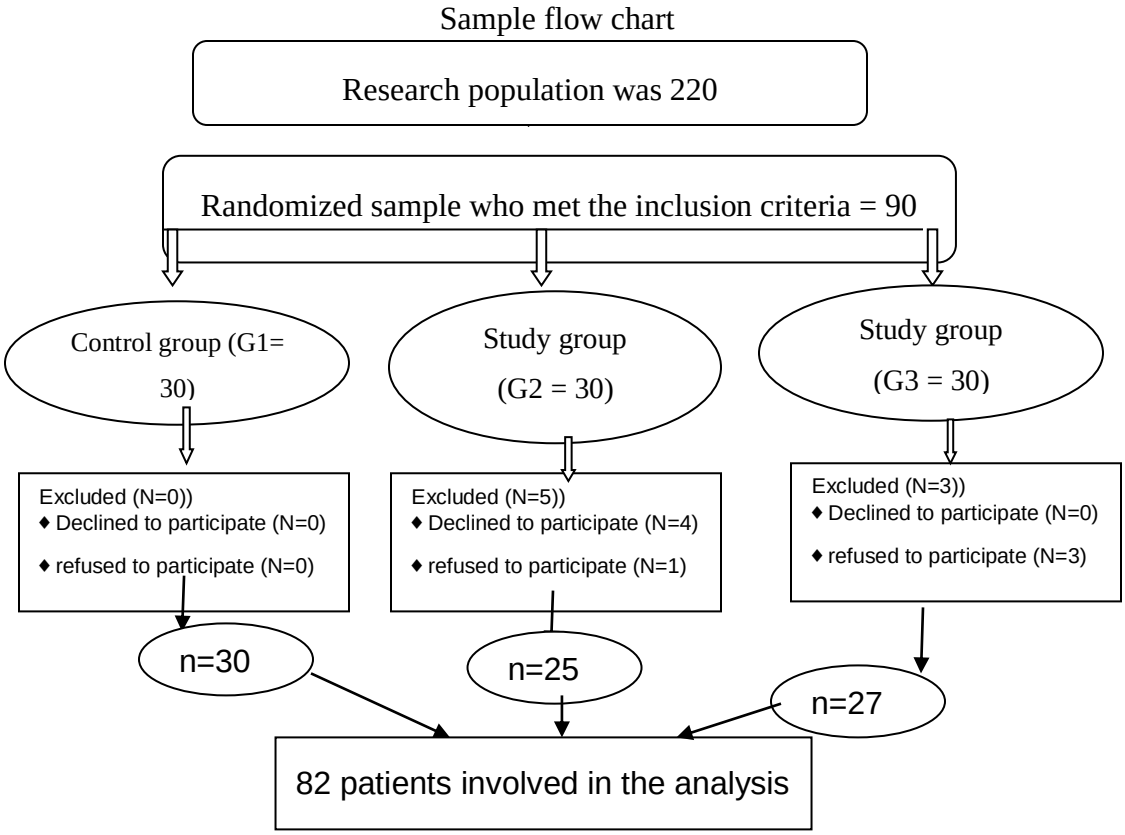
### Design

A randomized control clinical trial design was utilized to accomplish this study purpose.

### Sample

The research population included all the patients admitted to the Nephrology-Dialysis-Transplantation Center in one of the biggest Teaching Hospitals in Cairo City, Egypt. Besides, the research samples were the patients who met the following inclusion criteria: (1) Patients on hemodialysis management, for more than three months for three sessions per week, (2) Patients who reported muscle cramps during hemodialysis session, (3) Patients who are alert and cooperative. While exclusion criteria included: (1) Patients with femoral catheter, (2) Patients

with any lower limb disability. (3) Patients with vascular disease or had surgery at the lower limbs. The total sample size was calculated according to Epi Info program, 2008; as research population was 220 patients, with an expected frequency of 30%, a worst acceptable frequency of 20% and 10% sample attrition, based on sample size program, the sample size equals 80 patients at 95% confidence level. A sample of 90 adult male and female patients who met the inclusion criteria was invited to share in the research. Patients were randomly allocated into three groups as the 1st patient was assigned in the control group (G1), the 2nd patient was in the group2 (G2), and the 3rd patient was in group3 (G3) and so on, utilizing this technique as one of the commonly used simple random methods.




**The three groups investigated in this study were:**
Control group [G1, n = 30], who received the routine hospital care (decreased fluid removal, give calcium gluconate intravenously and give intravenous fluid infusion) and two intervention groups [G2 = 25 & G3 = 27], who followed routine hospital care alongside moist heat or cold therapy. G2 received fifteen minutes of moist heat, and G3 received cold therapy for fifteen minutes.

**Setting**
The study was conducted at Nephrology-Dialysis-Transplantation Center in one of the biggest Teaching Hospitals in Cairo City, Egypt.

**Instruments**

In order to accomplish the aim of the study, three instruments were used to collect the data:

1. **Demographic and Medical History Data Sheet:** This sheet was designed by the researchers to collect the baseline characteristics and medical data of the patients, it had 2 parts: part (1) related to demographic data such as; age, gender, marital status, education, employment status, and part (2) related to medical data such as duration of the disease, duration of hemodialysis session, numbers of hemodialysis sessions per week, when the patient experience the muscle cramps during hemodialysis session, location of muscle cramps.

2. **The cramp questionnaire chart Morris (2014):** It was designed to assess the level of muscle cramps during hemodialysis. It contains 5 questions that have various features of muscle cramps such as the frequency of muscle cramps, and duration of muscle cramps with total score ranging from (0-13) whereas, (0) score means no cramps, (1-4) mild cramps, (5-8) moderate cramps, and (9-13) severe cramps. The reliability of the tool was 'r' 0.93. Validity of the instrument was judged by the experts.

3. **Pain Numeric Rating Scale (PNRS):** Pain Numeric Rating Scale has a single 11-point numeric scale in which respondents select a number from 0 (no pain) to 10 (severe pain) to reflect the intensity of their pain. The scale has high test–retest, r =0.96 (Hawker, Mian, Kendzerska, French, 2011).

**Pilot Study**

Once permission was granted to proceed with the proposed study, a pilot study was conducted before starting data collection on 8 patients to assess its feasibility as well as the applicability of the tools. Patients who shared in the pilot study were excluded from the calculation of the study sample. The result of the pilot study confirmed that the study was feasible.

**Procedure of the study**

Official permission were granted from the head of the department to proceed with the study, the researchers initiated data collection. Patients meeting the inclusion criteria were interviewed individually, and assigned randomly into three groups, control group (G1) and two intervention groups (G2 & G3).

**This study was conducted in three phases as the following:**

**Assessment phase*:*** The researchers interviewed the patients, who met the inclusion criteria and willing to participate in the study, and explained the nature and the aim of the study, in order to obtain their informed consent. At this phase, demographic and medical data sheet, Cramp questionnaire chart as well as Pain Numeric Rating Scale were filled, in order to obtain baseline data.

**Intervention phase:** At this phase, the researchers were applying moist heat for group 2 through applying warm rubber bottle wrapped by warm moist towel for fifteen minutes immediately

when the patient reported cramping on the calf muscle, temperature of the warm water was measured by the water thermometer; it was ranged between 35 to 37.5°C. Group 3 received ice through plastic bag wrapped by towel for fifteen minutes immediately when the patient reported cramping on the calf muscle. These interventions were repeated each time the patient reported camp during the hemodialysis session for 2 weeks. On the other hand, if the patient reported any increase in pain intensity or feeling of cramp, the intervention was discontinued immediately and the patient was monitored until he/she feel much more better, after that, he/she was excluded from the study sample. Data collection phase was conducted over a period of four months, it was between September to December 2018)

**Evaluation phase:** Patients were followed up for two weeks, during each session patients were observed and whenever cramp occur, the patient received either moist heat or cold therapy, based on his intervention group. Cramp questionnaire charts as well as Pain Numeric Rating Scale were filled after each intervention was applied and the mean readings by the end of the 1st week was considered as the 1st post intervention reading, and the mean readings by the end of the 2nd week was considered as the 2nd post intervention reading.

**Ethical considerations**

An official approval and permission from the director of the hospital and the head of the department was obtained. It was emphasized that participation in the study is voluntary. Confidentiality of patient was assured through coding of all data. In addition, the patients were informed that they could refuse or withdraw from the study at any time without giving any reason.

**Data analysis**

The collected data was scored, tabulated and analyzed by personal computer using statistical package for the social science (SPSS) program version 20. Descriptive as well as inferential statistics utilized to analyze data pertinent the study. Descriptive statistics including frequency percentage distribution, means, and standard deviation was utilized. t-test used to compare quantitative data between two groups, and chi square test used to compare qualitative data among the two interventions and control groups. Moreover, ANOVA used to compare results of more than two groups. Level of significance was adopted at $p \leq 0.05$.

## Results

Results of the current study presented into three sections. Section I) presented the description of the study samples' demographic characteristics, hemodialysis related information, and description of the hemodialysis induced cramp of the control and the two intervention groups. Section II) Highlighted the comparison of mean scores of pain among the control and the two intervention groups along the study period. Section III) Emphasized the comparison of mean scores of muscle cramp intensity among the control and the two intervention groups along the study period.

**Section I) Description of the study samples' demographic characteristics, hemodialysis related information, and description of the hemodialysis induced cramp of the control and the two intervention groups.**

**Table (1): Frequency percentage distribution and comparison among control and intervention groups' demographic characteristics (n=82).**

| Variables | Control group (G1), n = 30 | | Intervention groups | | | | Test | p-value |
|---|---|---|---|---|---|---|---|---|
| | | | Moist heat (G2), n = 25 | | Cold therapy (G3), n = 27 | | | |
| | No. | % | No. | % | No. | % | | |
| Age (years): | | | | | | | | |
| 18- <30 | 4 | 13.4 | 4 | 16 | 5 | 18.6 | F | |
| 30- <45 | 11 | 36.6 | 2 | 8 | 7 | 25.9 | 1.53 | 0.22 |
| 45- <60 | 13 | 43.3 | 9 | 36 | 11 | 40.7 | | |
| ≥ 60 | 2 | 6.7 | 10 | 40 | 4 | 14.8 | | |
| Mean ± SD | 44.7±10.7 | | 50.6±15.1 | | 45.9±15.3 | | | |
| Gender: | | | | | | | | |
| Male | 16 | 53.4 | 17 | 68 | 16 | 55.6 | $X^2$ | 0.56 |
| Female | 14 | 46.6 | 8 | 32 | 12 | 44.4 | 0.333 | |
| Education: | | | | | | | | |
| Educated | 25 | 83.3 | 21 | 84 | 20 | 74.1 | $X^2$ | 0.42 |
| Uneducated | 5 | 16.7 | 4 | 16 | 7 | 25.9 | 0.84 | |
| Employment status: | | | | | | | | |
| Working | 7 | 23.3 | 8 | 32 | 7 | 25.9 | $X^2$ | 0.43 |
| Not-working | 23 | 76.7 | 17 | 68 | 20 | 74.1 | 0.64 | |

*P-value≤ 0.05 is significant at two tailed

Table (1) shows that 43.3%, 36%, and 40.7% of the control, moist heat and cold therapy groups had age ranged from 45 to less than 60 years. Male gender constitutes 53.4%, 68%, and 55.6% of the control group, moist heat and cold therapy groups respectively. Regarding education, 83.3%, 84% and 74.1% of the control group, moist heat group, and cold therapy group were educated. Moreover, 76.7%, 68%, and 74.1% of the control, moist heat, and cold therapy groups had no work. There was no statistically significant difference among the three study groups regarding demographic variables.

**Figure (1) percentage distribution of the marital status among the study sample (n=82).**

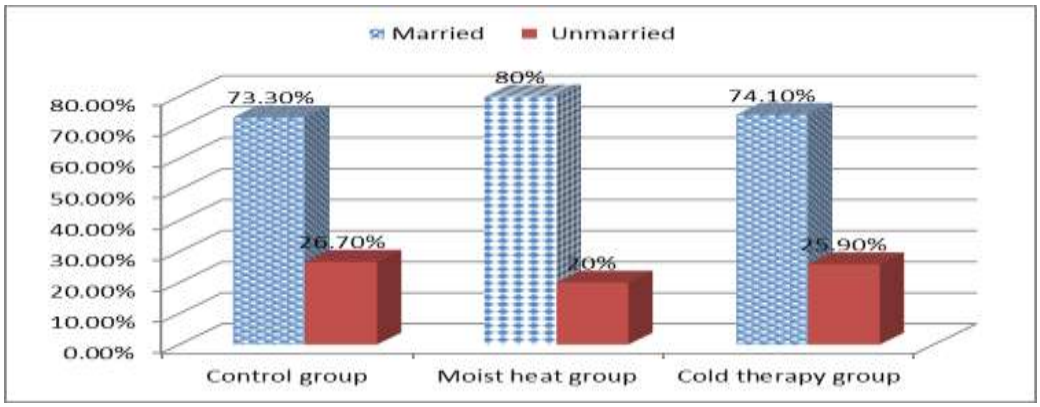



Figure (1) illustrates that 73.30%, of the control group, 80% of the moist heat group, and 74.10% of the cold therapy group were married with no statistically significant difference among the three study groups.

**Table (2): Frequency percentage distribution and comparison among control and intervention groups regarding hemodialysis related information (n=82).**

| Variables | Control group (G1) n = 30 | | Intervention groups | | | | $X^2$ | p-value |
|---|---|---|---|---|---|---|---|---|
| | | | Moist heat (G2) n = 25 | | Cold therapy (G3) n = 27 | | | |
| | No. | % | No. | % | No. | % | | |
| Duration of dialysis | | | | | | | | |
| < 5 years | 12 | 40 | 13 | 52 | 13 | 48.1 | 0.96 | 0.99 |
| 5- <10 years | 12 | 40 | 8 | 32 | 9 | 33.3 | | |
| ≥10 years | 6 | 20 | 4 | 16 | 5 | 18.6 | | |
| Time of dialysis \ hours | | | | | | | | |
| 3 hours | 7 | 23.3 | 4 | 16 | 4 | 14.8 | 0.856 | 0.43 |
| 4 hours | 23 | 76.7 | 21 | 84 | 23 | 85.2 | | |

*P-value≤ 0.05 is significant at two tailed

Table (2) articulates that 40% of the group 1, 52% of the group 2, and 48.1% of the group 3 were on hemodialysis for less than 5 years, with 76.7%, 84%, and 85.2% of the group 1,2, and 3 had hemodialysis session for 4 hours. Additionally, there was no statistically significant difference among the control group and the two intervention groups regarding hemodialysis related information.

**Figure (2) percentage distribution of the serum calcium level among control and intervention groups (n=82).**

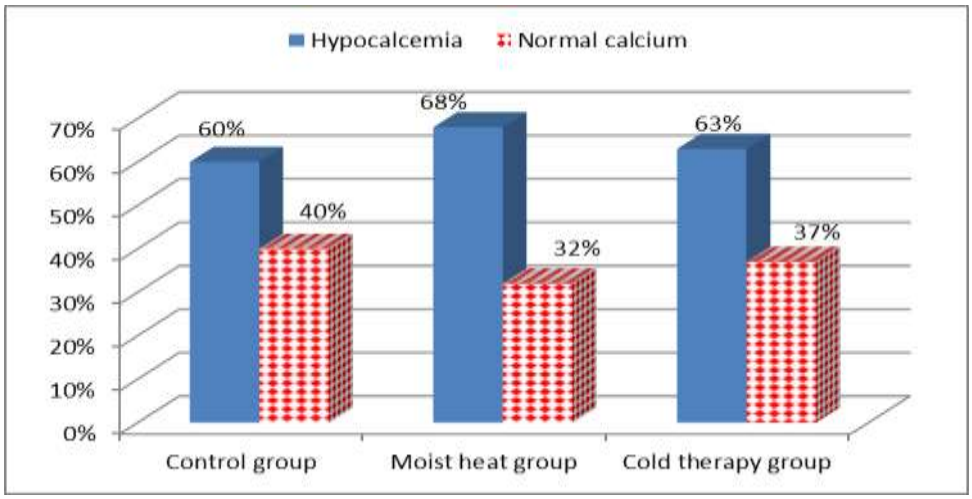



Figure (2) illustrates that 60% of the control group, 68% of the moist heat group and 63% of the cold therapy group had hypocalcemia, with no statistically significant difference among the three groups regarding the serum calcium level.

**Table (3) Frequency percentage distribution and comparison among control and intervention groups regarding description of the hemodialysis induced cramp (n=82).**

| Variables | Control group (G1) n = 30 | | Intervention groups | | | | $X^2$ | p-value |
|---|---|---|---|---|---|---|---|---|
| | | | Moist heat (G2) n = 25 | | cold therapy (G3) n = 27 | | | |
| | No. | % | No. | % | No. | % | | |
| **Frequency of muscle cramp\week** | | | | | | | 6.20 | 0.82 |
| ≥3 times\day | 2 | 6.7 | 3 | 12 | 2 | 7.4 | | |
| 2times\ day | 6 | 20 | 6 | 24 | 4 | 14.8 | | |
| Once\day | 1 | 3.3 | 2 | 8 | 2 | 7.4 | | |
| ≥3times\week | 2 | 6.7 | 1 | 4 | 5 | 18.6 | | |
| 2times\week | 14 | 46.6 | 10 | 40 | 12 | 44.4 | | |
| Once\week | 5 | 16.7 | 3 | 12 | 2 | 7.4 | | |
| ****Muscle cramp usually occur in** | | | | | | | 8.4 | 0.41 |
| Morning | 16 | 53.3 | 17 | 67 | 16 | 59.3 | | |
| Afternoon | 5 | 16.7 | 4 | 16 | 7 | 25.9 | | |
| Evening | 3 | 10 | 4 | 16 | 6 | 22.2 | | |
| Night | 11 | 36.7 | 9 | 36 | 11 | 40.7 | | |
| ****Muscle cramp usually occur in dialysis day** | | | | | | | 1.4 | 0.55 |
| Before dialysis | 5 | 16.7 | 2 | 8 | 4 | 14.8 | | |
| During dialysis | 22 | 73.3 | 21 | 84 | 25 | 92.6 | | |
| After dialysis | 17 | 56.7 | 10 | 40 | 14 | 51.8 | | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| ****Methods used to treat cramp** | | | | | | | | |
| Decrease fluid removal | 29 | 96.7 | 23 | 92 | 25 | 92.6 | | |
| Stand up | 5 | 16.7 | 3 | 12 | 6 | 22.2 | 1.35 | 0.99 |
| Massage or squeeze the extremity | 14 | 46.7 | 15 | 60 | 18 | 66.7 | | |
| Bring toes up | 8 | 26.7 | 7 | 28 | 9 | 33.3 | | |

*P-value≤ 0.05 is significant at two tailed
**These variables are not mutually exclusive

Table (3) shows that 46.6%, 40%, and 44.4% of the group 1,2 and 3 respectively reported that they have muscle cramp for 2 times per week, with 53.3%, 67% and 59.3% of the control, moist heat, and cold therapy groups had muscle cramp in the morning. In addition, 73.3% of the control group, 84% of the moist heat group, and 92.6% of the cold therapy group suffer from muscle cramp during dialysis session, with 96.7%, 92% and 92.6% of group 1,2, and 3 reported that the best method used to treat cramp was decreased fluid removal. Moreover, there was no statistically significant differences among the three study groups regarding the characteristics of the hemodialysis induced cramp.

**Figure (3) percentage distribution regarding to what extent muscle cramp restrict daily living activity (n=82).**

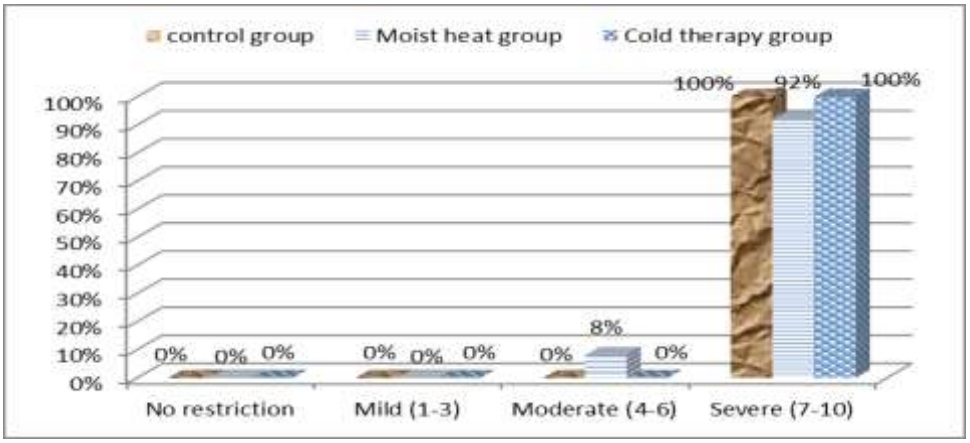



Figure (3) presents that 100% of the control and cold therapy groups and 92% of the moist heat group reported that muscle cramp severely restrict the activity of daily living.

**Section II) Comparison of mean scores of pain among the control and the two intervention groups along the study period.**

**Table (4) comparison of mean score of pain intensity in control and intervention groups during pre-intervention period (base line assessment) (n=82).**

| Study groups | Mean ± SD | t-test | p-value | ANOVA | p-value |
|---|---|---|---|---|---|
| Control group (G1)<br>Moist heat group (G2) | 8.2±2.1<br>8.8±1.8 | 1.363 | 0.186 | 2.635 | 0.078 |
| Moist heat group (G2)<br>Cold therapy group (G3) | 8.8±1.8<br>9±0.6 | 0.446 | 0.660 | | |
| Control group (G1)<br>Cold therapy group (G3) | 8.2±2.1<br>9±0.6 | 1.846 | 0.076 | | |

*P-value≤ 0.05 is significant at two tailed

Table (4) shows that there was no statistically significant difference among the three study groups in the pre intervention time in relation to pain intensity score (ANOVA=2.635, p-value=0.078).

**Table (5) comparison of mean score of pain intensity among the control and intervention groups by the end of the 1st week (post intervention 1)**

| Study groups | Mean ± SD | t-test | p-value | ANOVA | p-value |
|---|---|---|---|---|---|
| Control group (G1)<br>Moist heat group (G2) | 8.7±2.9<br>2.5±2.1 | 10.7 | 0.000* | 37.824 | 0.000* |
| Moist heat group (G2)<br>Cold therapy group (G3) | 2.5±2.1<br>7.2±2.9 | 6.656 | 0.000* | | |
| Control group (G1)<br>Cold therapy group (G3) | 8.7±2.9<br>7.2±2.9 | 2.126 | 0.043* | | |

*P-value≤ 0.05 is significant at two tailed

Table (5) presents that there was statistically significant difference among the three study groups by the end of the 1st week post intervention (ANOVA=37.824, p-value=0.000) regarding pain intensity score whereas, group 2 had the lower mean score (mean ±SD= 2.5±2.1) followed by cold therapy group (mean ±SD= 7.2±2.9).

**Table (6) comparison of mean score of pain intensity among the control and the intervention groups by the end of the 2nd week (post intervention 2)**

| Study groups | Mean ± SD | t-test | p-value | ANOVA | p-value |
|---|---|---|---|---|---|
| Control group (G1)<br>Moist heat group (G2) | 8.5±1.9<br>2±2.2 | 12.1 | 0.000* | 47.654 | 0.000* |
| Moist heat group (G2) | 2±2.2 | 8.527 | 0.000* | | |

| | | | | | |
|---|---|---|---|---|---|
| Cold therapy group (G3) | 6.9±2.9 | | | | |
| Control group (G1)<br>Cold therapy group (G3) | 8.5±1.9<br>6.9±2.9 | 2.112 | 0.044* | | |

*P-value≤ 0.05 is significant at two tailed

Regarding pain during the 2nd week, table (6) shows that there was a statistically significant difference between control group and moist heat group (t-test=12.1, p-value=0.000), and between moist heat and cold therapy group (t-test= 8.527, p-value= 0.000), moreover, there was a statistically significant difference between the control group and the cold therapy group (t-test= 2.112, p-value= 0.044).

**Section III) Comparison of mean scores of muscle cramp intensity among the control and the two intervention groups along the study period.**

**Table (7) comparison of mean score of muscle cramp intensity in the control and the intervention groups during pre-intervention period (base line assessment) (n=82)**

| Study groups | Mean ± SD | t-test | p-value | ANOVA | p-value |
|---|---|---|---|---|---|
| Control group (G1)<br>Moist heat group (G2) | 10.4±1.4<br>11±1.2 | 1.532 | 0.139 | 1.826 | 0.168 |
| Moist heat group (G2)<br>Cold therapy group (G3) | 11±1.2<br>10.5±0.9 | 1.864 | 0.075 | | |
| Control group (G1)<br>Cold therapy group (G3) | 10.4±1.4<br>10.5±0.9 | 0.130 | 0.898 | | |

*P-value≤ 0.05 is significant at two tailed

Table (7) shows that there was no statistically significant difference among the three study groups in relation to muscle cramp intensity score during the pre-intervention time (ANOVA= 1.826, p-value= 0.168).

**Table (8) comparison of mean score of muscle cramp intensity in the control and the intervention groups by the end of the 1st week (post intervention 1)**

| Study groups | Mean ± SD | t-test | p-value | ANOVA | p-value |
|---|---|---|---|---|---|
| Control group (G1)<br>Moist heat group (G2) | 10.1±1.7<br>4.3±2.5 | 9.588 | 0.000* | 34.7 | 0.000* |
| Moist heat group (G2)<br>Cold therapy group (G3) | 4.3±2.5<br>8.4±3.5 | 5.638 | 0.000* | | |
| Control group (G1)<br>Cold therapy group (G3) | 10.1±1.7<br>8.4±3.5 | 2.220 | 0.035* | | |

*P-value≤ 0.05 is significant at two tailed

Table (8) presents that there was statistically significant difference in relation to muscle cramp intensity score by the end of the 1st week between control group and moist heat group (t-test= 9.588, p-value= 0.000), also there was a statistically significand difference between moist heat group and cold therapy group (t-test= 5.638, p-value= 0.000). Moreover, there was a statistically significant difference between the control group and the cold therapy group (t-test= 2.220, p-value= 0.035).

**Table (9) comparison of mean score of muscle cramp intensity among the control and the intervention groups by the end of the 2nd week (post intervention 2).**

| Study groups | Mean ± SD | t-test | p-value | ANOVA | p-value |
|---|---|---|---|---|---|
| Control group (G1)<br>Moist heat group (G2) | 10±1.7<br>3.9±2.9 | 8.995 | 0.000* | 40.289 | 0.000* |
| Moist heat group (G2)<br>Cold therapy group (G3) | 3.9±2.9<br>7.9±3.1 | 5.328 | 0.000* | | |
| Control group (G1)<br>Cold therapy group (G3) | 10±1.7<br>7.9±3.1 | 3.011 | 0.006* | | |

*P-value≤ 0.05 is significant at two tailed

Table (9) illustrates that there was a statistically significant difference in muscle cramp intensity score by the end of the 2nd week between the control group and the two intervention groups whereas t-test= 8.995, p-value= 0.000 between the control group and the moist heat group, and t-test= 3.011, p-value= 0.006 between control group and cold therapy group. Additionally, there was a statistically significant difference between the moist heat group and the cold therapy group (t-test= 5.328, p-value= 0.000).

## Discussion

Muscle cramps are one of the main symptoms that patients undergoing hemodialysis treatment experience. Muscle cramp is aggravating for the patient and often forces the nurses to separate the patients from the dialysis machine sooner than required that affect the quality of the dialysis for the patients, reduces their quality of life and also increase mortality rate ( Mohmadi, Shahgholian,Valiani &Mardanparvar, 2016). Moist heat and cold therapy are considered part of the standard of care for acute musculoskeletal pain which include muscle cramp. In spite of, most recommendations for use heat and cold therapy in muscle cramps are based on empirical experience or unconfirmed information because the evidence base supporting the efficacy of these modalities is quite limited. So it was relevant to examine the effect of moist heat versus cold therapy on leg muscle cramp among patients on hemodialysis to improve quality of patients care and establish evidence based data that can promote nursing practice.

Apparently the following discussion represented in three main sections. Section (I) denoted the demographic characteristics of the study sample, and description of the hemodialysis induced cramp of the control and the two intervention groups. Section (II) Highlighted the comparison of mean scores of pain among the control and the two intervention groups along the

study period. Section (III) Emphasized the comparison of mean scores of muscle cramp intensity among the control and the two intervention groups along the study period.

**Section I) Description of the study samples' demographic characteristics, hemodialysis related information, and description of the hemodialysis induced cramp of the control and the two intervention groups.**

The current study revealed that more than one third of the control, moist heat and cold therapy groups had age ranged from 45 to less than 60 years, more than half of them were male and the majority of them were married, educated and didn't work. The researchers pointed out that higher percentage of educated patients in the study had a positive effect to teach the patients proper technique and instructions regarding moist heat or cold therapy administration. Additionally, there was no statistically significant difference among the three study groups regarding demographic variables. These results were matched with study done by Salem & Elhadary, (2017) on 60 patients on hemodialysis revealed that more than half of patients were from 40 - 60 years old. Other study congruent with the study findings reported that around one half of their patients on hemodialysis were in age range of 39-62 years (50.2±15.4), males, married, unemployed but they were illiterate not educated in contrast with our study finding(Atashpeikar, Jalilazar & Heidarzadeh, 2011). The researchers clarified that patients receiving hemodialysis experienced most changes in their everyday lives and also affect the continuation of work or studies and change life plans, therefore, the higher percentage of the sample didn't have work. Other study didn't match with the study findings reported that highest percentage of patients were within the age group of 30- 40 years and were self-employed, and had family income of Rs 5000 – 10,000/month (Thomas & Silva, 2015).

The researchers pointed out that gender differences in renal failure are influenced by various risk factors such as hypertension, hyperglycemia, albuminuria, body mass index, lifestyle factors, and renal structure and sex hormones which keep male or female at high risk factor for renal failure. In this study, the percentage of males were higher than females which was matched with Chang et, al. (2016) who demonstrated that African-American men have a higher risk of renal failure progression than African-American women do because of the poorly controlled hypertension, presence of albuminuria and also decrease glomerular- filtration rate might be greater among men than women. The present study found that around one half of patients were on hemodialysis for less than 5 years, and majority of them had hemodialysis session for 4 hours. Additionally, there was no statistically significant difference among the control group and the two intervention groups regarding hemodialysis related information. On the same line, these findings were supported by (Atashpeikar, Jalilazar & Heidarzadeh, 2011) and (Salem & Elhadary, 2017) as they reported that more than half of their patients had undergone hemodialysis for 1-6 years, underwent dialysis 3 times a week and hemodialysis session for 4 hours according to the hospital policy and patient's condition.

Regarding calcium level, the results concluded that around two third of the sample groups had hypocalcemia which was matches with other study done by (Jean, Souberbielle & Chazot, 2017) which titled as "Vitamin D in Chronic Kidney Disease and Dialysis Patients" denoted that with decreased renal functions, hormone which called $1,25(OH)_2D$ decrease and result in

hypocalcemia which are the main causes of secondary osteoporosis. Other authors (Frazão, Sá, Medeiros, Fernandes, Lira & Lopes, 2014) more clarified that the reduction of calcium ions, poor intestinal absorption of calcium result of shortage of vitamin D and chelating effect of the phosphorus are predisposing factors for developing hypocalcemia. In the light of this fact, the researchers pointed out that measuring of the calcium level have to be routine in patients undergoing hemodialysis with any type of vascular access to avoid complications which could even be fatal.

Painful muscle cramps, usually in the lower extremities are common in patients receiving HD which interfere with the delivery of the hemodialysis treatment according to their recent two survey studies, found that more than three quarters of the patients during the first survey and more than half during the second survey reported having muscle cramps within the previous month, cramps frequently occur at the end of the dialysis sessions and majority of the two surveys requested that fluid removal to be decreased (Lynch, Abate, Suh, & Wadhwa, 2014). Other authors (Isaac & Jacob, 2016) added muscle cramps are a common complication of hemodialysis treatment, occurring in more than three quarters of patients; they often result in the early termination of hemodialysis session changes in plasma osmolality and/or extracellular fluid volume have been implicated. In fact, the current study results are consistent with a recent survey and study of HD patients revealed that around one half of the study sample had muscle cramp for 2 times per week, in the morning. In addition, the majority of them suffers from muscle cramp during dialysis session and reported that the best method used to treat cramp was decreased fluid removal.

Regarding the impact of the leg muscle cramp, the study results concluded that almost all the study sample suffer from severe restriction of the daily living activities as a consequence of leg muscle cramp. The researchers pointed out that intolerance to activity, one of the main symptoms of chronic renal failure, is evidenced by fatigue and a difficulty in undertaking activities of daily living. A study done under the title of "A Promising Approach to Effectively Reduce Cramp Susceptibility in Human Muscles: A Randomized, Controlled Clinical Trial" mentioned that the calf muscles rank among the most common affected muscle groups that had cramp and can substantially reduce activity of daily living as well as the quality of life (Behringer, Moser, McCourt, Montag & Mester, 2014). Other authors added that patients on hemodialysis had a significant reduction in quality of life, in particular in physical activity and in everyday activities (García-Llana , Remor & Selgas,2013). Patients receiving hemodialysis more often experienced worse quality of sleep, chronic fatigue, pain, and chronic weakness (Turkmen, Erdur & Guney, 2012). Moreover, recent study reported that the most common complications among the hemodialysis patients were muscle spasms, back pain, headache, and increased blood pressure, all of these signs and symptoms restrict the activity of daily living and affect quality of patient's life (Bender, Dykowska, Żuk, Milewska, & Staniszewska, 2018).

**Section II) Comparison of mean scores of pain among the control and the two intervention groups along the study period.**

Nonpharmacological treatment strategies for acute musculoskeletal injury revolve around pain reduction and promotion of healing in order to facilitate a return to normal function and activity. Heat and cold therapy modalities are often used to facilitate this outcome despite

prevalent confusion about which modality (heat vs cold) to use and when to use it. (Malanga, Yan & Stark, 2015).

The current study revealed that no statistically significant difference among the three study groups in the pre intervention time in relation to pain intensity score. While, There was statistically significant difference among the three study groups regarding pain intensity score by the end of the 1st and 2nd weeks, whereas, intervention groups who received either moist heat or cold therapy had lower mean pain intensity score than the control group who received the routine hospital care. Moreover, the study findings concluded that moist heat therapy has lower mean pain intensity score than the cold therapy group, which may indicated that moist heat was effective to reduce intensity of pain in patients on hemodialysis more than cold therapy. The researches may explain this finding that warm water produce relaxation to muscle as well as overall body and this relaxation may contribute to pain reduction. Accordingly, the study findings support ($H_1$) and ($H_3$) which stated that the intervention groups who received either moist heat or cold therapy will have a significant lower mean pain intensity score compared to the control group who received routine hospital care ($H_1$) and, there will be a difference between applying moist heat versus cold therapy on mean pain intensity score among the intervention groups ($H_3$).

The study findings was supported by (Malanga, Yan & Stark, 2015) who clarified that the physiological effects of cold therapy include reductions in pain, blood flow, edema, inflammation, muscle spasm, and metabolic demand. There is limited evidence from randomized clinical trials (RCTs) supporting the use of cold therapy following acute musculoskeletal pain. While, the physiological effects of heat therapy include pain relief and increases in blood flow, metabolism, and elasticity of connective tissues provides short term reductions in pain and disability greater than cold therapy according to RCTs.

Kafkia , Julkunen and Krepia (2014) on the same line reported that intensity of pain reduced among the majority of patients on hemodialysis who use warm towel, according to their study which titled as" Assessment and management of pain in hemodialysis patients". They also explained that heat application causes vasodilatation resulting in increased blood flow and reduced pain levels, so nurses can apply heat through the use of warm blankets or electric heating pads, and by assisting the patient to bathe before or after HD session to reduce pain intensity. Another study done by Dehghan & Farahbod (2014) under the title of "the efficacy of thermotherapy and cryotherapy on pain relief in patients with acute low back pain, A clinical trial study" concluded that application of either thermotherapy or ice therapy relive low back pain when compared to control group, on the other hand, application of thermotherapy was found to be more effective than ice in relieving pain. In contrast, another randomized control trail done by (Garra, Singer, Leno, 2010) compared the analgesic efficacy of 30 minutes of heat or cold therapy in 60 patients presenting to an emergency department for acute back and neck strains. The study reported that no significant differences in pain scores were observed between the heat and cold groups after a single 30-minute treatment.

**Section III) Comparison of mean scores of muscle cramp intensity among the control and the two intervention groups along the study period.**

The current study denoted that no statistically significant difference among the three study groups in the pre intervention reading in relation to leg muscle cramp mean intensity score. While, There was statistically significant difference among the three study groups regarding leg muscle cramp mean intensity score by the end of the 1st week as well as 2nd week, whereas, intervention groups who received either moist heat or cold therapy had lower leg muscle cramp mean intensity score than the control group who received the routine hospital care. Moreover, the study findings concluded that moist heat therapy has lower leg muscle cramp mean intensity score than the cold therapy group, which may indicated that moist heat was effective to reduce intensity of leg muscle cramp in patients on hemodialysis more than cold therapy. The researchers reported that relaxation of muscles and reduction of pain intensity level may contribute to decrease mean muscle cramp intensity scores. In general, it is known that applying warm water particularly to legs and feet provide sense of comfort, relaxation and relief pain as well as, decrease leg muscle spasm or tension. So, the study findings support ($H_2$) and ($H_4$) that revealed the intervention groups who received either moist heat or cold therapy will have a significant lower mean muscle cramps intensity score compared to the control group who received routine hospital care ($H_2$). There will be a difference between applying moist heat versus cold therapy on mean muscle cramps intensity score among the intervention groups ($H_4$).

The current study finding was in agreement with a study done under the title of "say yes to warm for remove harm: Amazing wonders of two stages of water" reported that warm water sooth nerve pain, relief joint pain, muscle cramp and muscle pain. The researchers added that warm water can be used in the form of bath or warm water bags (Patel, Patel, Patel, Sen, 2015). In a recent systematic review done by Ellapen, Hammill, Swanepoel & Strydom (2018) reported that warm water was effective in reducing muscle spasm as evidenced by reduced dosage of oral baclofen (skeletal muscle relaxant) for such patients receiving warm water application. Additionally, a meta-analysis study results added that there was no statistical effect of cold water on muscle soreness (pain) and spasm, on the other hand, comparison of the effect of contrast water therapy (alternating cold and warm water immersion) versus warm water was investigated, as there was significant lower pain and muscle damage in contrast water therapy group when compared to warm water group (Bieuzen, Bleakley, Costello, 2013).

Finally, the researchers pointed out that the current result disclosed that patients in the study group who received moist heat or cold therapy in addition to their hospital care have been improved more than the control group who received the hospital care only. This gave optimistic results for patients with renal failure on hemodialysis; that heat or cold therapy improved the intensity of muscle cramp pain in the study groups. Hopefully the result of the current study could act as an additional corner stone in nursing evidence practice related to patients with renal failure on hemodialysis suffering from muscle cramps.

**Conclusion**

Muscle cramps in renal failure patients on hemodialysis are very common and lead to non adherence to hemodialysis treatment. Application of heat or cold therapy had been a significant effect in reduction of both pain and leg muscle cramps among patients on hemodialysis and effectiveness of heat therapy to reduce muscle spasm was greater than cold therapy. As well, the four research hypotheses were supported.

**Recommendations**

1. The application of moist heat therapy is recommended to be endorsed as a nursing practice for patients who are scheduled on hemodialysis.
2. Further studies are required to explicate the effectiveness of heat vs cold therapy on leg muscle cramp among hemodialysis patients.
3. The study can be replicated including larger sample size for better generalization.
4. Further studies can be conducted on patients on peritoneal dialysis.

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**Implications for nursing practice**

A nurse is the health staff member who is in contact with the patients on hemodialysis along the session time. Patients on hemodialysis suffer from tremendous complications such as leg muscle cramp. Therefore, the nurse must act as a pro-active member to support such patients by empowering them to use self-management methods to reduce pain and leg muscle cramp, as well as quality of life. Considering nursing implications for practice, endorsement of moist heat compresses may contribute to improve quality of nursing care for such patients. As for implications for nursing education, application of moist heat therapy would provide a reference framework to be taught in basic and continuing education programs as a practice for the health professionals. This study may provide a practice framework for the future development of other nursing evidence based practice. Finally application of moist heat is safe, cost effective, can be done independently anywhere and anytime, which increases their applicability.

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