

**Effect of Implementing a Protocol of Nursing Care on Peripheral Venous Access
Complications for Patients Undergoing Chemotherapy**

⁽¹⁾ Alyaa W. El-seadi, ⁽²⁾Alaa M. Maria, ⁽³⁾ Rasha E. Ahmed and
⁽⁴⁾ Seham A. Abd El-Hay

⁽¹⁾ Demonstrator, Medical , Surgical Nursing, Tanta University,

⁽²⁾ Assist. Professor, Clinical Oncology Medicine, Faculty of Medicine, Tanta University ,

^(3,4) Assist. Professor , Medical , Surgical Nursing, Faculty of Nursing,
Tanta University, Egypt

Corresponding Author: drsehamahmed@yahoo.com

Abstract: Background: Cancer is a group of disease that is characterized by uncontrolled growth of abnormal cells. Chemotherapy is a vital treatment for cancer but in the same time it is associated with serious complications that are need standard of nursing care. **Aim of the study:** Evaluate the effect of implementing a protocol of nursing care on peripheral venous access complications for patients undergoing chemotherapy. **Design and Setting:** A quasi-experimental research design was used to collect data from Clinical Oncology and Nuclear Medicine Department of Tanta University Hospital. **Subjects:** A convenience sampling of (60) patients who were undergoing chemotherapy . They were divided into two equal groups; study and control; each group consisted of (30) patients. **Tools:** Three tools were used for data collection, Tool (I); Bio- socio-demographic and structured interview schedule evaluate patients' knowledge, Tool (II); Vein quality assessment to assess the quality of vein and Tool (III): Peripheral venous access complications assessment tool. **Results:** As a result of this study, it was determined that there was highly significant improvement in the total level of patients' knowledge, vein quality, visual infusion phlebitis and there was decrease in the incidence of extravasation among study group at 2nd month and post ending protocol of care compared to control group. **Conclusion and Recommendation:** Aprotocol of care has positive effect on reducing peripheral venous access complications among chemotherapeutic patients. So it was recommended that oncology nurses should follow protocol of nursing care while administrating chemotherapy for patients to decrease incidence of peripheral venous access complications.

Key words: Chemotherapy, peripheral venous access complications, Protocol of Nursing Care.

Introduction

Cancer is a group of disease that are characterized by uncontrolled growth of abnormal cells. It spreads directly to the surrounding tissue and to other body organs ^(1,2). The most common cancers that are estimated in 2018 are breast, lung and bronchus cancer, prostate cancer, colon and rectum cancer, bladder cancer, leukemia, pancreatic and liver cancer ⁽³⁾. The global cancer burden has been doubled in the last 30 years of the 20th century and will be doubled again by 2020 and nearly triple by 2030 worldwide and expected to increase three times more than by 2050 according to the National Plan for Cancer Control 2017-2020 ⁽⁴⁾. In 2018, it is estimated 1,735,350 new cases of cancer will be diagnosed in the United States and most of them will die from the disease ⁽³⁾. Cancer is a series of pathological events over a period of many years, during which frequent changes occur through a number of stages due to many risk factors ⁽⁵⁾. Early diagnosis of cancer is essential for effective treatment because every type of cancer requires a specific treatment regimen that encompasses one or more modalities of treatment ⁽⁶⁾. The goals of cancer treatment are to control the tumor progress and to improve patients' quality of life. Many treatment options for cancer

including; surgery, chemotherapy, radiation therapy, hormonal therapy and targeted therapy ⁽⁷⁾. Chemotherapy is one of the most commonly prescribed cancer treatment modality ⁽⁸⁾, it may be given for a purpose of curative intent or to palliate symptoms, chemotherapeutic agents act by killing cells that are dividing rapidly as one of the main properties of the most cancer cells ⁽⁹⁾.

Chemotherapy is the most widespread cancer treatment modality which is used to control cancer progress ⁽¹⁰⁾. Most chemotherapeutic drugs are administered directly into a vein by using a peripheral intravenous catheter, this allow drugs go directly to cancer cells ⁽¹¹⁾. Peripheral intravenous cannulas allows rapid administration of medication, but also they are associated with serious complications including; phlebitis, extravasation, infection, skin hyper pigmentation and hypersensitivity reactions ⁽¹²⁾. Phlebitis is defined as an inflammatory response to intravenously chemotherapeutic drugs ⁽¹³⁾, it may leads vein damage associated with pain, erythema and swelling ⁽¹⁴⁾. The incidence of phlebitis has been reported as 70% worldwide ⁽¹⁵⁾. Extravasation is leakage of intravenous drugs into surrounding perivascular tissue or subcutaneous spaces. It may cause severe

reactions as; tissue damage, pain, redness, swelling, tissue necrosis and permanent dysfunctional area of vein ^(16,17).

Other serious complications include; thrombosis of the veins which may occur due to local effect of chemotherapeutic agents on the endothelium ⁽¹⁸⁾.

Hypersensitivity reactions are also occur; the severity ranged from mild to life-threatening problem as fever, allergy, urticaria, swelling and flushing of the face ^(19, 20).

Cancer Patients who are receiving chemotherapy through peripheral vascular access devices need designed protocol of care to avoid these complications, oncology nurses are responsible for safe and timely administration of intravenous treatments to the patients through venous catheter and management of any possible complication ⁽²¹⁾. It is widely recognized that early detection and management of peripheral venous access complications are critical for prevention of potentially serious adverse outcomes for chemotherapeutic patients ⁽²²⁾.

Key elements of protocol of nursing care regarding prevention of the occurrence of peripheral venous access complications include re-evaluating of basic knowledge for nurse related to assessment, insertion, management ⁽²³⁾, ongoing monitoring of the venous access site after removal of the device help to reduce complications. Oncology nurse plays vital role in the

delivery of care, patient education about the importance of identifying and managing adverse reaction of chemotherapy treatment as; selection of the optimal device and site for cannula insertion; proper site preparation, management, and good removal of venous access which help in prevention of peripheral venous access complication ^(24,25). So this study will be done to evaluate the effect of implementing a protocol of nursing care on peripheral venous access complications for patients undergoing chemotherapy.

Significance of the study:-

Chemotherapy is one of the main cancer treatment modalities that provide cure for cancer patients ⁽²⁶⁾, which are given through intravenous catheter insertion that is performed in up to 70% - 80% of cancer patients ^(27,28). Chemotherapy drugs can have severe complications due to repeat exposure to IV cannulation; as phlebitis, extravasation, infection and hypersensitivity reactions ⁽¹³⁾. So the nurses should be able to understand these complications of chemotherapy and able to provide supportive care for these patients to control complications and allow more patients to benefit from receiving chemotherapy at full dose on schedule and improve quality of care⁽²⁹⁾. Hence there is urgent need to design protocol of nursing care to supply oncology nurses with the

chance to earn the necessary, knowledge and skills for safe chemotherapy administration.

Aim of the study

Evaluate the effect of implementing a protocol of nursing care on peripheral venous access complications for patients undergoing chemotherapy.

Research hypothesis

- 1- Post implementation of the protocol of nursing care, the study group exhibited improve in knowledge regarding chemotherapy, peripheral venous access complications, aseptic technique and hypersensitivity and infection than the control group.
- 2- Post implementation of the protocol of nursing care, the study group are expected to have minimal peripheral venous access complications than control group who received routine hospital care.

Research design:

A quasi-experimental research design was used in the present research.

Setting:

The study was conducted at the Clinical Oncology and Nuclear Medicine Department of Tanta Main University Hospital.

Subjects:

A convenience sampling of (60) patients who were undergoing chemotherapy in the

above previously mentioned settings. The sample size was calculated based on Epidemiological Information 7 statistical Program. The final acceptable sample size was estimated to be (60) patients. They were divided into two equal groups; each group consisted of (30) patients as following: **Study group**, Consisted of (30) patients who were managed with protocol of care that was designed and implemented by the researcher. **Control group**, Consisted of (30) patients who were managed with routine hospital care.

Inclusion criteria:

- Adult conscious cancer patients.
- Newly diagnosed patients.
- Planned to receive chemotherapy according to the following type; alkylating agents, anti metabolites, antitumor antibiotics and plant alkaloids.
- Duration of chemotherapy cycles ranged from 2-6 months.

Exclusion criteria:

Previous history of chemotherapy or hormonal treatment and previous venous complications.

Tools of the study:

Three tools were used to collect the data for this study. These tools aimed to evaluate the effect of implementing protocol of nursing care on peripheral venous access complications for patients

undergoing chemotherapy, which included the following:

Tool (I): Bio- socio-demographic and Structured Interview Schedule: It was developed by the researcher after reviewing of the related literatures ^(19,20,30).

It was comprised of three parts:-

Part (I): Socio- demographic data of the patients: which included; patient's code, age, sex, marital status, level of education, occupation and residence.

Part (II): patients' clinical data: which included; past medical history, current diagnosis, methods of treatment, duration of disease, duration of chemotherapy and the use of anti-inflammatory drugs.

Part (III): Patients' Knowledge Assessment Sheet: Include the the following:

- a- Knowledge about chemotherapy (10) questions which included; definition, preparation before administration, precautions, method of administration, types of drugs, side effect, drug preparation area, and specific intervention for veinless disorder and nursing care of cannula.
- b- Knowledge about peripheral venous access complications related to chemotherapy (9) questions which included; purpose of peripheral venous access cannula, signs and symptoms

and management of phlebitis, extravasations and infiltration.

- c- Knowledge about aseptic technique (7) questions which included; importance and components of infection control measures, early response to infection, preventive measures and care.

Scoring system of knowledge:

Correct and complete answer scored (2)

Correct and incomplete answer scored (1)

Don't know or incorrect answer scored (0)

The total scoring system of patients' knowledge was (26) classified as the following:

-Good → > 75% of the total score

-Fair → ≥ 60% - 75% of the total score

- Poor → < 60% of the total score

Tool (II): Vein Quality Assessment Tool:

Vein quality assessment tool was developed by **Jacobson 1999** ⁽³¹⁾ and **Lenhardt 2002** ⁽³²⁾ and was modified by the researcher after an extensive review of related literature ⁽³³⁾ to assess the quality of vein before and after application of peripheral venous access according to the following criteria:-

Vein quality	Scoring System	Vein character	vein puncture site	Management
Good	3	Vein is large, soft, easily visible and palpate when tourniquet is applied.	Forearm	Cannula inserted by the researcher.
		Vein is large, soft, resilient in hand and antecubital fossa, small and thin in forearm.	Hand	
Fair	2	Veins are small, thin, scarred or difficult to palpate in forearm –hand.	forearm	Cannula inserted by the researcher.
		Small, thin veins in hand, veins in forearm not palpable or visible.	Hand	
Poor	1	Vein unable to be seen or palpated, small, fragile veins easily rupture in hand and forearm.	Forearm	Cannula inserted by the researcher

Scoring system: - There are three categories of vein quality as following:- (3) indicated good vein quality, (2) indicated fair vein quality and (1) indicated poor vein quality.

Tool (III): Peripheral Venous Access Complications Assessment Tool:

It was comprised of three parts:

Part (I): Visual Infusion Phlebitis scale (VIP Scale):

It was developed by **Andrew Jackson (1998)** ⁽³⁴⁾, and evaluated by **Gallant and Schultz (2006)** ⁽³⁵⁾. It was used for indicating the first stages of phlebitis, when intravenous cannulas were to be replaced ⁽³⁶⁾.

This scale was consisted of 6 grades that ranged from (0-5) where (0) indicated no signs of phlebitis to (5) indicated advanced stage of thrombophlebitis. It was scored on a scale of 0–5 as following: -

Grade	Clinical Criteria to identify phlebitis
Grade (0) : No signs of phlebitis	IV site appears healthy
Grade (1) : Possibly first signs of phlebitis	<ul style="list-style-type: none"> ● Slight pain near IV site or ● Slight redness near IV site
Grade (2) : Early stage of phlebitis (Two signs are evident)	<ul style="list-style-type: none"> ● Pain at IV site ● Redness and swelling
Grade (3): Medium stage of phlebitis (All signs are evident)	<ul style="list-style-type: none"> ● Pain along path of cannula ● Redness around site and swelling
Grade (4): Advanced stage of phlebitis or start of thrombophlebitis (All signs are evident)	<ul style="list-style-type: none"> ● Pain along path of cannula ● Redness around site ● Swelling ● Palpable venous cord
Grade (5): Advanced stage of thrombophlebitis (All signs are evident)	<ul style="list-style-type: none"> ● Pain along path of cannula ● Redness around site and swelling ● Palpable venous cord

Part (II): Extravasation of Chemotherapeutic Agent scale:

It was adopted from British Columbia Cancer Agency, Approved By: Provincial Systemic Program Committee, first developed at 1997 and last revised at 2016 ^(37, 38, 39). It was used to assess the severity of extravasation at the time of detection, and determine the appropriate level of intervention.

Scoring system; It was consisted of 5 grades from (0-4) as following; (0) indicated no symptoms, (1) indicated mild symptoms, (2) indicated moderate symptoms, (3) indicated severe symptoms and (4) indicated worst symptoms

Grade	0	1	2	3	4
Color	Normal	Pink	Red	Blanched center surrounded by red	Blackened
Integrity	Unbroken	Blistered	Superficial skin loss	Tissue loss exposing s.c tissue	Tissue loss bone ,muscle with necrosis
Edema	Absent	Non pitting	Pitting	-	-
Skin temperature	Normal	Warm	Hot	-	-
Mobility	Full	Slightly limited	Very limited	Immobile	-
Pain	0	1-3	4-6	7-9	10
Fever	Normal	Elevated		-	-

Part (III): Hypersensitivity and infection Assessment sheet:

It was developed by the researcher after extensive review of related literature ⁽⁴⁰⁾ to detect the presence of chemotherapy related to S,S of infection and hypersensitivity. It included (10) questions.

Scoring system of knowledge: Correct and complete answer scored (2), correct and incomplete answer scored (1) and don't know or incorrect answer scored (0). Total scoring system of patients' knowledge was (10) classified as the following:

- Good → > 75% of the total score
- Fair → ≥ 60% - 75% of the total score
- Poor → < 60% of the total score

Ethical consideration:

The necessary official permission was obtained from the directors of the Clinical Oncology and Nuclear Medicine Department of Tanta Main University Hospital. Informed consent was taken from every patient after explanation aim of the study to participate in the study. Confidentiality and privacy was taken into consideration regarding data collection. A code number was used instead of name. The patient was informed the right to withdraw from the study at any time with no reason.

Methods of data collection:

1- All tools of the study were developed by the researcher after reviewing literature ⁽³²⁾ to collect data except tool (II); Vein Quality Assessment was developed by **Jacobson 1999** ⁽³¹⁾ and **Lenhardt 2002** ⁽³²⁾, and tool (III) part (I); Visual Infusion Phlebitis was first developed by **Andrew Jackson (1998)** ⁽³⁴⁾, Part (II); Extravasation of chemotherapeutic agent was adopted from British Columbia Cancer Agency, first developed at 1997 and last revised at 2016 ^(37, 38, 39).

2- All tools were reviewed for content validity by a panel of (5) expertise in the field of Oncology and Nuclear Medicine and Medical Surgical Nursing as well as protocol of nursing care, Their opinions were elicited regarding tools format and consistency, it was calculated and found to be = (98%).

3- All tools were tested for reliability using Cronbach's alpha test; it was 0.745 for tool (I) Part (III) and 0.628 for tool (II), 0.804 for tool (III) Part (I) and 0.712 for tool (III) Part (II).

4- Pilot study was conducted on (10%) of patients to test the feasibility, clarity, relevance and organization of the tools and to determine any obstacles that may be encountered during the period of data collection; needed modification was done.

The pilot study excluded from the study subjects.

5-A convenience sample of 60 patients was selected and divided equally into two equal groups; study group was received A protocol of nursing care, control group was received only routine hospital care.

6- The collection of the data for the present study was carried out within the period from October 2017 to the end of May 2018.

7- The present study was conducted through four phases (assessment, planning, implementation and evaluation) and it was continued for each **study patient** individually till the end of chemotherapy:-

Assessment phase;

Assessment of the baseline data for chemotherapeutic patients' was carried out by the researcher immediately once within admission to the department by using Tool (I), Tool II and Tool III to assess patients' knowledge, vein quality assessment and peripheral venous access complications for both control and study groups before implementation of the protocol of care for the studied patients. Each interview questionnaire took approximately one hour.

Planning phase;

Objectives of the study were prepared based on the needs of the patients. The protocol of care was designed by the

researcher based on the study subjects' assessment and extensive reviews of related literature ⁽⁴¹⁻⁴⁷⁾. An illustrative structured colored booklet was prepared and written in simple Arabic language supported by illustrative pictures as a guide for the study group and different methods were used as video, group discussion and power point and demonstration and re-demonstration for the practical part. A booklet was given to each patient during sessions to refresh their knowledge. The protocol of care was carried out through (4) sessions.

Implementation phase;

Study group; A protocol of nursing care was applied by the researcher from the date of admission throughout (4) basic sessions at the time of chemotherapy infusion for each patient until last chemotherapy session in the morning shifts as the following; *The First session;* The researcher met each participant individually in the chemotherapy administration ward to inform them regarding knowledge which included; chemotherapy definition, precautions, method of administration, types of drugs, how to deal with veinless disturbance, and peripheral venous access complications, take about 30 minutes and instruct them about any abnormal sensation during the

infusion to allow for prompt intervention, it took about 30 minutes.

The second session: was given to the patients regarding knowledge about care of cannula, aseptic technique precautions, management and preventive measures of infection, take about 30 minutes.

The third session: Venipuncture session:

This session aimed to protect vein during insertion of cannula in addition to decrease complications due to the chemotherapy infusion. It was implemented by the researcher, for about 10 minutes and included the following: assess patient's risk factors regarding occurrence of complications, teach the patient about relaxation techniques to relief stress, instructing patient to make exercise for hands with a rubber ball daily between treatments, moist heat was applied to the patient's arms for 5-10 minutes to dilate vein and local vein manipulation was used to aid dilation through; appropriate use of a tourniquet or blood pressure cuff to encourage pooling of venous blood, milking the veins from proximal to distal (elbow to hand), Gently striking the surface of the vein and proper care of the vascular access with chlorhexidine and flushing it with normal saline.

The fourth session: - Chemotherapy infusion session; -This session aimed to administer chemotherapy with minimal

complications. This session took about 2-4 hours to infuse the chemotherapy according to the ordered protocol for the patients. It was performed by the researcher with regard to the following: wear personal protective equipment, give premedication to the patient at least 20-30 minutes before chemotherapy, Dextrose 5% (D5W) or normal saline (NS) were commonly used to wash the vein prior to the actual administration of chemotherapy, chemotherapy agents were administered according to written policies and procedures in sequence of vesicant, irritant, non-irritant using proficient intravenous therapy skills and techniques, in the case of occurrence of any problem for the study group, the researcher firstly stopping the infusion then removing the cannula and applying warm compresses in case of phlebitis, while in case of extravasation the researcher was attaching 10 ml syringe and trying to aspirate the extravasated solution from under the skin then removing the syringe and injecting 10 ml NS into the cannula, then removing the cannula, covering the skin with sterile dressing, take about 2-4 hours.

- **Control group;** received the routine nursing care provided to the patients by oncology nurses. The routine nursing management in the Clinical Oncology and Nuclear Medicine Department at Tanta

University Hospital done by nurses includes the following: detect cannulation size (20-22) and insert it to patient. administer chemotherapy as doctor order and cold compresses in case of complications and discontinuation of chemotherapy.

Evaluation phase:-

- Evaluation was done for both study and control groups by using tool (I) part III to evaluate patients' knowledge regarding chemotherapy, peripheral venous access complications, aseptic technique and hypersensitivity and infection, once pre implementing, 2nd month and post completion of protocol of care. Tool (II) used to assess severity of extravasation at the time of detection, and determine the appropriate level of intervention, once pre implementing, 2nd month and post completion of protocol of care and Tool (III) used to assess peripheral venous access complications once pre implementing, 2nd month and post completion of protocol of care.

- Comparison was done between both groups to evaluate the effect of implementing a protocol of nursing care on peripheral venous access complications for patients undergoing chemotherapy.

Methods of data analysis: Data was collected then tabulated and statistically analyzed using Statistical Package for

Social Sciences (SPSS) version 25. Data expressed as number and percentage. t-test is used to determine significant for numeric variable. A probability level of p-value ≤ 0.01 was adopted as a level of significance for testing the research hypotheses.

Results:

Table (1) illustrated the distribution of the patients according to their Socio-demographic characteristics. As regard to age, it was observed that nearly one third (33.3%) from study group were in the age (50-60) year and more than one quarter (30%) from control group were in the age (30 < 40) year and (40 < 50) year respectively. Also the table revealed that (70%) and (56.7%) of the study and control groups were females respectively and nearly half (43.3%) of the study group had secondary education while (40 %) of the control group had both secondary and university education, also three quarters (73.3%) of both groups were married. In addition (56.7%) and (33.3%) of the study and control groups were house wives respectively.

Table (2) illustrated the distribution of the studied patients according to their clinical data. Concerning to the current diagnosis and method of treatment, it was found that the majority of the study and control groups were breast cancer and about

(100%) had undergone antimetabolites chemotherapy treatment. Regarding duration of chemotherapy, it was found that the mean duration of chemotherapy was (3.48 ± 0.636) , (3.63 ± 0.628) in the study , control groups respectively and (30%) and (53.3%) of the study and control groups' patients hadn't previously used anti-inflammatory drugs.

Table (3) illustrated the distribution of the studied patients according to their total level of knowledge about chemotherapy throughout all intervention periods of the study. **Concerning to the study group;** it was observed that, there was statistical significant improvement in the patients' total level of knowledge about chemotherapy pre , immediate implementation of protocol of care at p value < 0.001 and at immediate , post the protocol of care at p value 0.044. **In relation to control group;** there was no statistical significant difference in the patients' total level of knowledge.

Table (4) showed the distribution of the studied patients according to their total knowledge about peripheral venous access complications throughout all intervention periods of the study. **Concerning to the study group;** the table showed that, there was statistical significant improvement in the patients' total level of knowledge about peripheral venous access

complications pre , immediate implementation of protocol of care at p value < 0.001 and at immediate , post the protocol of care at p value 0.038. **In relation to control group;** there was no statistical significant difference in the patients' total level of knowledge.

Table (5) showed the distribution of the studied patients according to their total knowledge about aseptic technique throughout all intervention periods of the study. **Concerning to the study group;** it was observed that, there was statistical significant improvement in the patients' total level of knowledge about aseptic technique pre , immediate implementation of protocol of care at p value < 0.001 . **In relation to control group;** there was no statistical significant difference in the patients' total level of knowledge.

Table (6): showed the distribution of the studied patients according to their total knowledge about hypersensitivity and infection throughout all intervention periods of the study. **Concerning to the study group;** the table showed that, there was statistical significant improvement in the patients' total level of knowledge about hypersensitivity and infection pre , immediate implementation of protocol of care at p value < 0.001 and at immediate , post the protocol of care at p value 0.050. **In relation to control group;** there was

no statistical significant difference in the patients' total level of knowledge.

Table (7) showed the distribution of the studied patients according to vein quality assessment throughout all intervention periods of study. **Concerning to the study group;** the table showed that, there was a statistical significant improvement regarding vein quality assessment among the studied patients, where (63.3%) had good vein quality pre protocol of care, whereas about (93.3%, 100%) of the patients had good vein quality at the 2nd month and post the completion of the care respectively. **Concerning to the control group;** there was no significant difference in their vein quality where (76.7%) of the patients had good vein quality pre care, whereas about (50%) of the patients had good vein quality at the 2nd month and (43.3%) had fair vein quality post completion of care.

Table (8) showed the distribution of the studied patients according to visual infusion phlebitis throughout all intervention periods of the study. The table revealed that there was significant improvement in the study group after the completion of the protocol of care, on the other hand there were deterioration in the VIP scale among control group at the 2nd month of the care. Where the majority of the studied patients of both the study and

control groups had no signs of phlebitis (90%, 83.3%) respectively pre protocol of care. After 2 months of the protocol of care, there were about (70%) of the study group had no signs of phlebitis while in the control group nearly to half of the patients (46.7%) had developed possibly first signs of phlebitis. Post completion of the protocol of care, nearly all of the study group patients (96.7%) had no signs of phlebitis, while in the control group; about one third (33.3%) of the patients had developed medium stage of phlebitis and one quarter (20%) of them had developed early stage of phlebitis.

Table (9): showed the distribution of the studied patients according to extravasations of chemotherapeutic agent scale throughout all intervention periods of the study. **In relation to color,** all of the studied both groups had normal color prior to care. After 2 months and completion of the care, it was found that about (93.33, 100%) study group patients had normal color, while half of one third of control group had blanched center surrounded by red post routine care. **As regard to edema,** the majority of the studied patients of both the study and control groups didn't have edema (86.67%, 93.33%) prior to care. After 2 months and completion of the care, it was found that about (73.33, 93.33%) of the study patients didn't have edema,

while about (63.33%) of the control group patients had non pitting edema post routine care. There was significant improvement for study group. **According to skin temperature;** all the study group patients had normal skin temperature throughout all intervention period of study. Comparing to control patients where about (53.33 and 63.33%) of them had warm temperature after 2 months and post routine care respectively. **In relation to mobility;** there was a high statistical significant difference in the mobility of control group patients representing deterioration from full mobility post 2 month (96.67%) to (80%) post routine care respectively.

Table (10) showed correlation between socio demographic data of the studied patients and their total knowledge pre and post the protocol of care. **Concerning to the study group,** the table revealed that, there was a significant negative correlation between total knowledge score of the study group patients and their age post protocol of care, while there was a significant positive correlation between the

total knowledge of the study group and their educational level and being employees post protocol of care. **Comparing to the control group,** there was a significant positive correlation between the total knowledge of the control group and their educational level and being employees pre the routine care.

Table (1): Distribution of the patients according to their socio-demographic characteristics.

Characteristics	The studied patients (n=60)				χ^2 P
	Study group (n=30)		control group (n=30)		
	N	%	N	%	
Age (in years)					
▪ (21-<30) years	6	20.0	4	13.3	1.765 0.623
▪ (30-<40) years	5	16.7	9	30.0	
▪ (40-<50) year	9	30.0	9	30.0	
▪ (50-60) years	10	33.3	8	26.7	
Mean \pm SD	42.57 \pm 11.96		42.03 \pm 9.84		P=0.851
Sex					
▪ Male	9	30.0	13	43.3	FE 0.422
▪ Female	21	70.0	17	56.7	
Marital status					
▪ Married	22	73.3	22	73.3	1.067 0.587
▪ Single	2	6.7	4	13.3	
▪ Widow	6	20.0	4	13.3	
Educational level					
▪ Illiterate	6	20	5	16.7	1.067 0.587
▪ Read and write	3	10	1	3.30	
▪ Secondary education	13	43.3	12	40	
▪ University education	8	26.7	12	40	
Occupation					
▪ Not work	5	16.7	9	30.0	4.291 0.232
▪ Employee	6	20.0	10	33.3	
▪ Manual work	2	6.6	1	3.3	
▪ House wife	17	56.7	10	33.3	
Place of residence					
▪ Rural	24	80.0	27	90.0	FE 0.472
▪ Urban	6	20.0	3	10.0	

Table (2): Distribution of the studied patients according to their clinical data.

Clinical data	The studied patients (n=60)				χ^2 P
	Study group (n=30)		Control group (n=30)		
	N	%	N	%	
Current diagnosis					15.92 0.318
▪ Ovarian cancer	1	3.3	1	3.3	
▪ Lymphoma	3	10.0	1	3.3	
▪ Sinus tumor	2	6.7	2	6.7	
▪ Breast cancer	10	33.3	9	30.0	
▪ Lung cancer	4	13.3	2	6.7	
▪ Colon cancer	4	13.3	2	6.7	
▪ Testicular cancer	4	13.3	5	16.6	
▪ Anal cancer	2	6.6	7	23.4	
#Types of chemotherapy					9.210 0.353
▪ Alkylating agents	25	83.3	20	66.7	
▪ Antimetabolites	30	100	30	100.0	
▪ Antitumor antibiotics	15	50.0	16	53.3	
▪ Plant alkaloids	10	33.3	10	33.3	
Duration of chemotherapy (in months) Mean ± SD	3.48±0.636		3.63±0.628		t=0.918 P=0.362
Use of anti-inflammatory drugs					FE 0.288
▪ No	21	70.0	16	53.3	
▪ Yes	9	30.0	14	46.7	

#More answer was chosen.

FE: Fisher's Exact Test

Table (3): Distribution of the studied patients according to their total level of knowledge about chemotherapy throughout all intervention periods of the study

Knowledge about chemotherapy	Study group (n=30)						Control group (n=30)						
	Pre the protocol of care		At 2 nd month of the care		Post the completion of care		Pre the protocol of care		At 2 nd month of the care		Post the completion of care		
	N	%	N	%	N	%	N	%	N	%	N	%	
Poor (<60%)	16	53.3	0	0.0	0	0.0	15	50.0	12	40.0	9	30.0	
Fair (≥60% - 75%)	12	40.0	1	3.3	7	23.3	14	46.7	13	43.3	5	50.0	
Good (> 75%)	2	6.7	29	96.7	23	80.0	1	3.3	5	16.7	6	20.0	
Chi-square	X ²	48.824						3.037					
	P-value	<0.001**						0.219					
	X ²	4.043						0.662					
	P-value	0.044*						0.718					

*significant at p <0.05

**High significant at p <0.0

Table (4): Distribution of the studied patients according to their total knowledge about peripheral venous access complications related to chemotherapy throughout all intervention periods of the study.

Knowledge about chemotherapy			Study group (n=30)						Control group (n=30)					
			Pre the protocol of care		At 2 nd month of the care		Post the completion of care		Pre the protocol of care		At 2 nd month of the care		Post the completion of care	
			N	%	N	%	N	%	N	%	N	%	N	%
Poor (<60%)			12	40.0	0	0.0	0	0.0	16	53.4	13	43.3	14	46.7
Fair (≥60% - 75%)			17	56.7	2	6.7	8	26.7	13	43.3	15	50	14	46.6
Good (> 75%)			1	3.3	28	93.3	2	73.3	1	3.3	2	6.7	2	6.7
Chi-square	X ²	Pre , Immediate	48.980						0.787					
	P-value		<0.001**						0.675					
	X ²	Immediate , Post	4.320						0.072					
	P-value		0.038*						0.965					

Table (5): Distribution of the studied patients according to their total knowledge about

Knowledge about chemotherapy			Study group (n=30)						Control group (n=30)					
			Pre the protocol of care		At 2 nd month of the care		Post the completion of care		Pre the protocol of care		At 2 nd month of the care		Post the completion of care	
			N	%	N	%	N	%	N	%	N	%	N	%
Poor (<60%)			1	43.3	0	0.0	0	0.0	1	40.0	10	33.3	1	36.7
Fair (≥60% - 75%)			1	56.7	0	0.0	2	6.7	1	43.3	15	50.0	1	46.7
Good (> 75%)			0	0.0	30	100.0	28	93.3	5	16.7	5	16.7	5	16.7
Chi-square	X ²	Pre , Immediate	60.00						0.325					
	P-value		<0.001**						0.850					
	X ²	Immediate , Post	2.069						0.082					
	P-value		0.150						0.960					

aseptic technique throughout all intervention periods of the study. .

*significant at p <0.05

**High significant at p <0.01

Table (6): Distribution of the studied patients according to their total knowledge about hypersensitivity and infection throughout all intervention periods of the study.

Knowledge about chemotherapy			Study group (n=30)						Control group (n=30)					
			Pre the protocol of care		At 2 nd month of the care		Post the completion of care		Pre the protocol of care		At 2 nd month of the care		Post the completion of care	
			N	%	N	%	N	%	N	%	N	%	N	%
Poor (<60%)			17	56.7	1	3.3	0	0.0	16	53.3	15	50.0	14	46.7
Fair (≥60% - 75%)			13	43.3	1	3.3	7	23.3	9	30.0	6	40.0	11	36.6
Good (> 75%)			0	0.0	28	93.4	23	76.7	5	16.7	2	10.0	5	16.7
Chi-square	X ²	Pre , Immediate	52.508						0.961					
	P-value		<0.001**						0.619					
	X ²	Immediate , Post	5.990						0.578					
	P-value		0.050*						0.749					

*significant at p <0.05.

**High significant at p <0.01

Table (7): Distribution of the studied patients according to Vein Quality Assessment throughout all intervention periods of study.

Vein Quality Assessment (VQA)			Study group (n=30)						Control group (n=30)					
			Pre the protocol of care		At 2 nd month of the care		Post the completion of care		Pre the protocol of care		At 2 nd month of the care		Post the completion of care	
			N	%	N	%	N	%	N	%	N	%	N	%
• Good			19	63.3	28	93.3	30	100.0	23	76.7	15	50.0	9	30.0
• Fair			10	33.3	1	3.3	0	0.0	5	16.7	11	36.7	13	43.3
• Poor			1	3.3	1	3.3	0	0.0	2	6.7	4	13.3	8	26.7
Chi-square	X ²		9.087		2.069			4.601		3.000				
	P-value		0.011*		0.355			0.100		0.223				

* Significant at P < 0.05

Table (8): Distribution of the studied patients according to Visual Infusion Phlebitis (VIP scale) throughout all intervention periods of the study.

Visual Infusion Phlebitis (VIP)	Study group (n=30)						Control group (n=30)					
	Pre the protocol of care		At 2nd month of the care		Post the completion of care		Pre the protocol of care		At 2nd month of the care		Post the completion of care	
	N	%	N	%	N	%	N	%	N	%	N	%
No signs of phlebitis	27	90	21	70	29	96.7	25	83.3	6	20.0	3	10.0
Possibly first signs of phlebitis	3	10	9	30	1	3.3	5	16.7	14	46.7	5	16.7
Early stage of phlebitis	0	0	0	0	0	0.0	0	0.0	6	20.0	8	26.7
Medium stage of phlebitis	0	0	0	0	0	0	0	0.0	4	13.3	10	33.3
Start of thrombophlebitis	0	0	0	0	0	0	0	0.0	0	0.0	4	13.3
Advanced stage of thrombophlebitis	0	0	0	0	0	0	0	0.0	0	0.0	0	0.0
Chi-square	X2		3.795		7.680				21.640		4.565	
	P-value		0.048*		0.006**				<0.001**		0.335	

* Significant at P < 0.05

**high significant at p<0.001

Table (9): Distribution of the studied patients according to extravasations of chemotherapeutic agent scale (ECA scale) throughout all intervention periods of the study

ECA items	The studied patients (n=60)													
	Study group (n=30)						χ^2 P	Control group (n=30)						χ^2 P
	Pre the protocol of care		At 2nd month of the care		Post the completion of care			Pre the protocol of care		At 2nd month of the care		Post the completion of care		
	N	%	N	%	N	%		N	%	N	%	%		
1. Color														
▪ Normal	30	100	28	93.33	30	100	4.09 0.129	30	100	16	53.33	16.67	36.52 0.00*	
▪ Pink	0	0.00	2	6.67	0	0.00		0	0.00	7	23.33	26.67		
▪ Red	0	0.00	0	0.00	0	0.00		0	0.00	6	20.00	16.67		
▪ Blanched red	0	0.00	0	0.00	0	0.00		0	0.00	0	0.00	33.33		
▪ Blackened	0	0.00	0	0.00	0	0.00		0	0.00	1	3.33	6.67		
2. Integrity														
▪ Unbroken	30	100	30	100	30	100	-	30	100	29	96.67	90.00	3.663	
▪ Blistered	0	0.00	0	0.00	0	0.00		0	0.00	1	3.33	10.00	0.160	
3. Edema														
▪ Absent	26	86.67	22	73.33	28	93.33	10.63 0.005*	28	93.33	14	46.67	26.67	37.79 0.00*	
▪ Non pitting	4	13.33	9	30.00	2	6.67		2	6.66	16	53.33	63.33		
▪ Pitting	0	0.00	0	0.00	0	0.00		0	0.00	0	0.00	10.00		
4. Skin temperature														
▪ Normal	30	100.0	30	100.0	30	100.0	-	30	100.0	14	46.67	36.67	29.27 0.00*	
▪ Warm	0	0.00	0	0.00	0	0.00		0	0.00	16	53.33	63.33		
5. Mobility														
▪ Full	30	100.0	29	96.67	29	96.67	1.02 0.60	30	100.0	29	96.67	80.00	9.604 0.008*	
▪ Slightly limited	0	0.00	1	3.33	1	3.33		0	0.00	1	3.33	20.00		
6. Pain														
▪ (0)	24	80.00	20	66.66	28	93.33	8.14 0.017*	30	100.0	15	50.00	20.00	41.78 0.00*	
▪ (1-3)	6	20.00	10	33.34	2	6.67		0	0.00	15	50.00	73.33		
▪ (4-6)	0	0.00	0	0.00	0	0.00		0	0.00	0	0.00	6.67		
7. Fever														
▪ Normal	30	100.0	30	100.0	30	100.0	-	30	100.0	30	100.0	96.67	2.022 0.364	
▪ Elevated	0	0.00	0	0.00	0	0.00		0	0.00	0	0.00	3.33		

* Significant at P < 0.05

Table (10): Correlation between socio-demographic characteristics of the studied patients and their total knowledge score pre and post protocol of care.

Characteristics	Total knowledge score of the studied patients							
	Study group (n=30)				Control group (n=30)			
	Pre protocol of care		Post protocol of care		Pre routine care		Post routine care	
	r	P	r	P	r	P	r	P
Age (in years)	-0.291	0.119	-0.574	0.042*	-0.249	0.185	0.040	0.835
Sex								
▪ Male	0.249	0.184	0.358	0.169	0.327	0.078	0.288	0.123
▪ Female	-0.249		-0.358		-0.327		-0.288	
Marital status								
▪ Single	0.132	0.487	0.147	0.437	-0.057	0.766	-0.074	0.699
▪ Married	-0.061	0.748	0.109	0.565	0.170	0.369	0.196	0.299
▪ Widow	-0.160	0.400	-0.203	0.281	-0.165	0.385	-0.181	0.337
Educational level	0.128	0.500	0.396	0.030*	0.365	0.047*	-0.153	0.419
Occupation								
▪ Not work						0.171		0.055
▪ Employee	-0.119	0.530	-0.130	0.494	-0.257	0.038*	-0.353	0.169
▪ Manual work	0.247	0.188	0.392	0.032*	0.381	0.427	0.258	0.094
▪ House wife	-0.178	0.346	0.078	0.683	0.151	0.319	0.311	0.864
	-0.137	0.472	-0.141	0.458	-0.188		-0.033	

* Significant at P < 0.05

Discussion:

The patients undergoing administration of intravenous chemotherapy are susceptible for the occurrence of many types of peripheral venous access complications as phlebitis, extravasation, skin hypersensitivity and infection. These complications arise mainly if the nurse does not adhere firstly to the basic guidelines of cannulation and vein selection. So, the oncology nurse should maintain high standard of knowledge and protocol of care related to the prevention of these complications^(48,49). So this study aimed to evaluate the effect of implementing a protocol of nursing care on peripheral venous access complications for patients undergoing chemotherapy.

Concerning to sociodemographic data of the patients, the current study results revealed that nearly two thirds of the studied patients were in the age group between (50-60 years) and (40- 50 years) and nearly three quarters in the study group and more than half of the control group were females. Also approximately three quarters of the studied patients of both groups were married and nearly half of them were secondary education. Concerning to occupation and place of residence, more than half and one third of the study and control patients were house wives. These results were in line with

Kurian et al, (2018)⁽⁵⁰⁾ who reported in their study about chemotherapy that the majority of age group (85%) among breast cancer patients' was ≥ 50 years old.

Also these results were supported by **Chan , Ismail (2014)**⁽⁵¹⁾ who reported that the majority of cancer patients in Malaysian general hospital (73.3%) were in the age range of 45-64 years. Moreover these results were supported by **Chagani et al, (2017)**⁽⁵²⁾ who mentioned that (66%) of the adult cancer patients undergoing chemotherapy treatment in the Pakistan were females. Moreover, the educational level result was supported by **Chan , Ismail (2014)**⁽⁵¹⁾ who reported that (40%) of the studied cancer patients were secondary education. Also it was supported by **Üstündağ , Demir (2015)**⁽⁵³⁾ who reported that nearly half of the cancer patients undergoing chemotherapy in his study were house wives. Moreover, the place of residence result was in line with **Choenyi et al, (2016)**⁽⁵⁴⁾ who stated that most of the cancer patients (58%) belonged to rural area, while (42%) were from urban area.

Concerning to clinical data, the study results revealed that one third of the patients of both groups were diagnosed with breast cancer and all patients of both groups were treated with antimetabolites chemotherapy and nearly half of the them

had duration of disease more than six month, moreover duration of chemotherapy ranged from three to five months and number of cycles ranged from five to ten cycles for both groups. This findings were in the same line with **Pearce et al, (2017)** ⁽⁵⁵⁾ who reported that more than half of the studied chemotherapeutic patients were diagnosed with breast cancer. Moreover, **Kim et al, (2006)** ⁽⁵⁶⁾ reported that more than two thirds (68.5%) of the studied patients were undergone chemotherapy treatment pre surgical treatment. Also **Wakiuchi et al, (2015)** ⁽⁵⁷⁾ reported that more than half of the studied patients (55.3%) had duration of disease more than six months. And **Singh et al, (2014)** ⁽⁵⁸⁾ who reported that half of the patients (50%) had duration of chemotherapy less than six months

Regarding to levels of knowledge throughout all intervention periods of the study, the study results revealed that there was a high significant improvement in the **study patients'** levels of knowledge concerning to chemotherapy, peripheral venous access complications, hypersensitivity and infection from pre implementation until post the completion of the protocol of care. This may be attributed to insufficient information related to chemotherapy and peripheral venous complications and lack of

continuous education and in-service training programs among patients, **comparing to the control group** there was no significant improvement in their total levels of knowledge from pre implementation until post the completion of the protocol of care.

These findings were supported by **Barakat (2016)** ⁽⁵⁹⁾ who reported that 90% of chemotherapeutic patients had poor level of knowledge about chemotherapy, complications, prevention of infection in pretest, while (100%, 96%) of the patients had good level of knowledge post 1 month posttest respectively. Also these results were in the same line with **Abd-Allah et al, (2000)** ⁽⁶⁰⁾ who reported that the in-service training program has a beneficial effect in the improving knowledge for the patients regarding caring of peripheral venous access complications and infections control measures. Also, they were supported by **Traeger et al, 2012** ⁽⁶¹⁾ who mentioned that "It is crucial that patients must be educated about chemotherapy and management of complications prior and during subsequent cycles of treatment.

These findings also are in the agreement with **Bouvier et al. (2013)** ⁽⁶²⁾ who mentioned that in their study, it is necessary to optimize specific guidelines and translating this knowledge into

practical recommendations which allow for the patients to identify chemotherapy complication. Also **Shinde , Babu, 2014** ⁽⁶³⁾ showed that (15%) of cancer patients undergoing chemotherapy during pre-test were having poor knowledge about chemotherapy and its complications, (82.5%) of patients were having average knowledge while the majority of patients during post-test were having good knowledge post educational guidelines.

In relation to Vein Quality Assessment, the study results revealed that there was a statistically significant improvement regarding vein quality assessment among the **study group** patients throughout all periods of intervention **comparing to the control group**, where there was no statistically significant improvement in their vein quality throughout all periods of intervention. The improvement in the study group can be attributed to the effectiveness of the designed protocol of care that helped to improve the quality of the veins for its visibility and palpability which are leading to facilitation of peripheral vein cannulation.

This finding was in the same line with **Kaur et.al (2011)** ⁽⁶⁴⁾ ,who reported that after implementation of the protocol of care about (73%) of chemotherapeutic patients had developed good vein quality, while (26%) of these patients had

developed fair vein quality. Also, the results were supported by **Simarpreet et al, (2018)** ⁽⁶⁵⁾ who mentioned that after intervention for chemotherapeutic patients such as (moist heat therapy application and hand exercises), there was (78%) of the patients had good vein quality that enhances the visibility and palpability of the veins facilitating peripheral cannulation and reducing the number of pricks, while (84%) of the control group patients had developed fair vein quality after the routine care.

Concerning to Visual Infusion Phlebitis, the study results revealed that there was a high significant improvement regarding visual infusion phlebitis among **study group** patients after the completion of the protocol of care comparing to **control group**, where the study results revealed that there was a high significant difference in the control group representing deterioration in the VIP scale at the 2nd month of the care. The improvement in the study group can be due to the effectiveness of the designed protocol of care to prevent the occurrence of phlebitis and to effectively manage the presented conditions hence reducing its incidence among the studied chemotherapy patients as a peripheral venous access complication related to the infused chemotherapy.

This finding was in the same line with **Uslusoy , Mete (2008)** ⁽⁶⁶⁾ who reported that phlebitis has been linked with inappropriate catheter insertion sites and inappropriate catheter usage during chemotherapy administration. Also, **Martinho , Rodrigues (2008)** ⁽⁶⁷⁾ had reported that mechanical phlebitis often occurs when the size of the cannula is too big for the selected vein. Moreover, **Macklin (2003)** ⁽⁶⁸⁾ suggested that the placement of a cannula near a joint or venous valve will increase the risk of mechanical phlebitis due to irritation of the vessel wall by the tip of the cannula .In addition, a poor standard of infection control has a part to play and infection control and hygiene standards are essential in the treatment and prevention of the condition.

Regarding to extravasation of chemotherapeutic agent, the study results revealed that the incidence of extravasation signs and symptoms among **study group** patients was (2.3%) post the completion of the protocol of care comparing to **control group** where the incidence rate of extravasation was higher than 40%. This finding may be attributed to the effectiveness of the planned protocol of care provided to the study group patients by the researcher to avoid the occurrence and limit the incidence of extravasation

due to the infused chemotherapeutic agent among the participants.

This study finding was in the same line with **Rose et al, (2008)** ⁽⁶⁹⁾, who reported that the incidence rate of extravasation ranged between (0.1 and 5%) for chemotherapeutic agents. Also, the current study finding was in harmony with **Pikó et al, (2011)** ⁽⁷⁰⁾ and **Pluschnig et al, (2015)** ⁽⁷¹⁾ who listed that insufficient training of the staff, poor technique in cannula insertion, and administration of chemotherapy as the common risk factors related to nurses performance. Iatrogenic causes of extravasation such as poor puncture technique or inappropriate placement of indwelling cannula particularly by inexperienced staff may also increase the risk of extravasation.

In relation to correlation between socio demographic data of **studied patients** and their total knowledge score pre and post the protocol of care. The study results revealed that, there was a significant positive correlation between total knowledge of the study patients and their educational level and being employees post protocol of care. In addition, there was a significant negative correlation between the total knowledge of the study group patients and their age in years. Comparing to **control group**, where there was a significant positive correlation

between the total knowledge of patients and educational level and being employees pre the routine care.

This study result was in the same line with **Mohammed et al, (2016)⁽⁷²⁾** who reported that there was significant association between overall Knowledge of the breast cancer patients regarding complications of chemotherapy, occupational status of the patient, and also the educational level. Also, this finding was supported with **Samir et al, (2014)⁽⁷³⁾** who reported that there was statistical significant correlation between breast cancer patient knowledge and socio demographic data as age, education and occupation.

Conclusion

In the light of the current study, it can be concluded that: implementation of protocol of nursing care had significant effect on improving level of chemotherapeutic patients' level of knowledge about chemotherapy, peripheral venous access complications, infection and hypersensitivity. Also it had an obvious effect on maintaining vein quality and reducing peripheral venous access complications as phlebitis and extravasation.

Recommendations

Based on the results of the present study recommendation are suggested that;

- 1- Oncology patients should be encouraged to attend training teaching program about chemotherapy and its PVAC complications
- 2- Oncology patients should be informed about the importance of follow up and periodical check-up for early detection of any deterioration of vein condition.
- 3- Cooperating with other institutions to improve nursing staff behavior and identify the barrier against application of protocol of care for patients undergoing chemotherapy sessions.

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