IOSR Journal of Nursing and Health Science (IOSR-JNHS)
e-ISSN: 2320–1959.p- ISSN: 2320–1940 Volume 5, Issue 5 Ver. VII (Sep. - Oct. 2016), PP 31-43
www.iosrjournals.org

Effect of Implementing a Protocol of Nursing Care on Hemodialysis Patients ' Safety Outcomes

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Abstract:*Hemodialysis is a life saving treatment that can offer significant advantages for certain patients, but it can have serious risks if the patients and their caregivers didn't track and understand the concept of its safety. Safety is the condition of being protected against physical, social, spiritual, financial, political, occupational, psychological, educational or other types or consequences of failure, damage, error, accidents, harm or any other event which could be considered non-desirable. Keeping patients safe in the dialysis environment is a topic of great concern for patients and nurses.*

The study was aimed to*determine the effect of implementing a protocol of nursing care on hemodialysis patients ' safety outcomes. A quasi experimental, pre and post intervention design was followed on sixty adult patients who ever present and scheduled for maintenance hemodialysis and on fourteen nurses who were working in hemodialysis unit and provide the routine nursing care for the patients for whom the protocol of nursing care was applied to conduct the present study at hemodialysis unit in Gamal Abdel Naser Health Insurance Hospital at Alexandria, Egypt. Six tools were used by the researcher to collect the necessary data.*

Tool I: *Hemodialysis patient's assessment Schedule.*

Tool II: *Patient' satisfaction scale.*

Tool III:*Patients' anxiety assessment scale.*

Tool IV: *Hemodialysis Patients ' Safety Outcomes check list.*

Tool V: *Nurses' knowledge assessment.*

Tool VI: *Nurses' performance checklist for hemodialysis patients.*

The results of the study revealed that *there was a statistical significant difference between nurses' skills before and after nursing care training but not as much as compared to nurses' knowledge level. Also there was a decrease in the patients' level of anxiety and increased in patients' satisfaction level after the application of the protocol of nursing care.*

The study concluded that *the majority of patients had positive safety outcomes after the application of the protocol of nursing care.*

The study recommended that *all resources needed to provide competent nursing care for hemodialysis patients' should be available and accessible in hemodialysis units and reasonable nurse/patient ratio should be properly distributed in all shifts for maintaining good quality nursing care.*

Keywords:*Hemodialysis, End stage renal disease, Patient 'safety outcomes,Protocol of nursing care.*

I. Introduction

End stage renal disease (ESRD) is the complete or almost complete failure of the kidneys to function. The kidneys can no longer able to perform their functions; remove wastes, concentrate of urine, and regulate electrolytes [(1)]. End stage renal disease has reached an epidemic level, causing a foremost burden to health care resources, and it is a devasting medical, social, and economical problem for patients, and their families [(2).]

Patients with ESRD undergoes multipart treatment regimen including; a wide range of dietary restrictions, medications, and renal replacement therapy (RRT) i.e. hemodialysis (HD), peritoneal dialysis (PD), and kidney transplantation [(3)]. Definitely, hemodialysis is a life saving treatment that can offer significant advantages for certain patients, but it can have serious risks if the patients and their caregivers didn't track and understand the concept of its safety. Without attention to patient' safety and error prevention, even a well-established procedure like hemodialysis can result in an adverse event[(4)].Safety is the state of being "safe", the condition of being protected against physical, social, spiritual, financial, political, occupational, psychological, educational or other types or consequences of failure, damage, error, accidents, harm or any other event which could be considered non-desirable[(5)] .

Keeping patients safe in the dialysis environment is a topic of great concern for patients and nurses. Nurses are at the center of patients care and they are essential drivers of quality improvement. From the Institute of Medicine's reports, "patient safety remains one of the most critical issues facing health care today and that nurses are the health care professionals most likely to intercept errors and prevent harm to patients"[(6)]. On the

other hand, the most significant barrier to improve patients' safety is a lack of awareness of the extent to which errors occur daily in all health care settings [(5).]

Human error has been defined as; a failure of a planned action or a sequence of mental or physical actions to be completed as intended, or the use of a wrong plan to achieve an outcome. The focus on the responsibilities and influences of systems does not negate the challenge of understanding error and accepting the inevitability of many errors while concurrently increasing the quality of health care. Because safety is foundational to quality, one way to define quality is providing the right care, at the right time, for the right person, in the right way [(7).] In doing so, efforts to improve safety and quality need to address concerns with potential overuse, misuse, and underuse of health care services that can threaten the quality and safety of care delivered to patients. People make errors for a variety of reasons that have little to do with lack of good intention or knowledge. Humans have many intellectual strengths and limitations. Improving safety requires respecting human abilities by designing processes that recognize human strengths and weaknesses [(8)] .

Hemodialysis' units should create a dedicated safety team who improve patients' outcomes. Accordingly patient-specific outcome data that focus on performance criteria must address nurses' performance and patients' safety outcomes (9) .Consequently in order to ensure effective nurses performance, patients' safety outcomes should be measured against predetermined performance criteria express in specific and measurable/observable terms that are acceptable to safety outcomes. These terms includes specific measurable statements reflects the patients' physical and psychological parameters regarding adequacy of nursing care provided to them. Patients' physical parameters include; maintenance of patients' weight, stabilized vital signs and laboratory results ,absence of problems and complications' related to patients, machines and dialysate, intact vascular access, fall prevention and finally medication errors avoidance[(10)].

On the other hand, patients' psychological parameters include improvement in patients' satisfaction toward nursing care is essential as nurses play an important role in gaining patients' recovery. Patients' satisfaction measured against five dimensions consists of tangibility, reliability, responsiveness, assurance and empathy [(10)]. Reduction of patients' anxiety level is an important patient' safety outcomes because anxiety is the most common psychological adverse events encountered in HD patients. It is mainly related to uncertainty about the diagnosis, side effect of therapeutic maneuver, cost of treatment, progressive physical deterioration, and body image disturbance due to vascular access and risk of death, as well as lack of social or personal control [(11).]

The effective patients' outcomes include important characteristics as it should be scalable which denotes the applicability to patients across a broad range of units and hospitals. Also it must be feasible so its application does not pose undue burden on staff of participating units as the information is available from existing sources, such as the medical record or a quality improvement database, and can be collected in real time. Finally it should be valid and reliable as criteria measurement within and across participating sites is accurate and consistent over time [(12)].

Well-planned protocol of nursing care in the per-service or in-service training programs is indeed needed in order to improve nurses' performance in hemodialysis units and improving patients' safety outcomes. It surely will improve patients' mortality and morbidity rate and so it will decrease the economic burden on the hospital. That all will work in barrel process for the save of our patients and our nurses [(13).]

Aim of the study

This study aimed todetermine the effect of implementing a protocol of nursing care on hemodialysis patients ' safety outcomes.

II. Materials and Method

Materials

Research design

A quasi experimental, pre and post intervention design was followed to conduct the present study.

Setting

This study was carried out in the hemodialysis unit in Gamal Abdel Naser Health Insurance Hospital at Alexandria, Egypt.

Subjects

The subjects of the study comprised two groups:

a. ***patients***: A convenient sample of 60 adult patients who ever present and scheduled for maintenance hemodialysis in the above mentioned setting. The sample inclusion criteria wereadult patients (21-60 years old) who were scheduled for maintenance hemodialysis 3 times per week, free from comorbid conditions: cardiovascular disease, cancer, liver diseases, respiratory diseases, diabetes , and coagulation abnormalities.

b. ***Nurse***s: 14 nurses who were working in hemodialysis unit and provide the routine nursing care for the patients for whom the protocol of nursing care was applied wereincluded.

Tools of the study

Six tools were used by the researcher to collect the necessary data.

a. Patients ' tools:

Tool I: HemodialysisPatients AssessmentSchedule. This tool was developed by the researcher after review of related literature [14-16].It was used to assess the hemodialysis patients' health status before and after application of the protocol of nursing care for the patients, and to ensure the effectiveness of the protocol of nursing care .The tool consisted of six parts:

Part I: Bio-socio demographic data such as ; age, sex, marital status, level of education, occupation, and health related data included; hemodialysis access type, duration of hemodialysis that the patients passed, number of dialysis sessions \week, and associated diseases other than the comorbid conditionswith end stage renal disease.

Part II: Physical examinations and Machine assessment.

A. Physical examinations: as vital signs (temperature, pulse, respiration, and blood pressure), measuring body weight, height, and head to toe assessment. This part was performed by the researcher to evaluate patients' hemodynamic health status. Which included:-

- Inspection of patients' general appearance, edema in eye lid, feet, fingers, lower limbs and jugular vein distension.
- Auscultation of chest breath sounds examined by assessing absence or presence of normal/abnormal breathing sounds. The heart sounds were examined by assessing absence or presence of normal heart sound, S3, and S4.
- Palpationof the patients' abdomento check absence or presence ofabdominal distention. Skin turgor examined to checkskin elasticity.

B. Machine assessment: as ultrafiltration rate/hour, dialysate type, blood flow, fluid given and heparin dosage.

Part III: Vascular access's assessment.as inspection, palpation and auscultation of the vascular access arm to identify abnormal arterio-venous fistula changes.

Part IV:Nutritional assessment to determine patients' adherence to the given instructions related to therapeutic diet as;general appearance, hair, eyes, lips, gums, body weight and height.

Part V: List of patients' current medications**:** it was checked by the researcher through assessing patients' charts to determine nurses adherence to the medications' rights [17,18,19] as: Right patient name, medication name, dosage, route, time, documentation, patient education, right to refuse, assessment, and right evaluation.

Part VI:-List of patients' problems**:** was checked by the researcher to identify absence or presence of patients'problems before and after application of the protocol of nursing care for the patients [19-21]

Tool II: Patient satisfaction scale. This tool was developed by Chunlaka (2010) and it was modified by the researcher to measure patients' satisfaction with nursing care in hemodialysis unit before and after application of the protocol of nursing care [21]. It was composed of 20 items in form of statements grouped into 5 dimensions namely assurance, empathy, reliability, responsiveness, and tangibility. Each dimension contains 4 items. The score for each statement item was calculated as one for disagree, two for uncertain, three for agree. The highest total score was 60 and the lowest total score was 20. The total scores for each patient was calculated then converted to percent as follows: Lowest level of satisfaction 33>55%, Moderate level of satisfaction 55>77%, and highest level of satisfaction77-100%.

Tool III: Patients' anxiety assessment scale: This tool was developed by Hamilton (2008).It was used to measure patients' anxiety level about their health status [22]. It comprised 14 symptoms oriented statement. The score for each statement was calculated as zero for not present, one for mild, two for moderate, three for severe and four for very severe. According to this scoring system, the highest total score was 56 and the lowest total score was 14. The total scores for each patient were calculated then converted to percent as follows: Mild anxiety25> 50%, Moderate anxiety50>75% and Severe anxiety75-100%).

b. Nurses tool:

Tool IV:Hemodialysis Patients ' Safety Outcomes check list: It was developed by the researcher after review of related literature [23- 25]. It was used to assess the hemodialysis patients' safety outcomes in the previous mentioned dialysis unit for the patients before and after application of the protocol of nursing care. This tool composed of 9 items and 50 sub items grouped into 2 dimensions presented as physical and psychological parameters. The score for each was 100 and the lowest total score was 50.The total score for each patient was calculated then converted to percent as follows: Negative safety outcomes 50- 67%,Moderate level of positive safety outcomes 67>84%, Positive safety outcomes84>100%.

Tool V:Nurses' knowledge assessment schedule: This tool was developed by the researcher after review of related literature. It was used to obtain data about hemodialysis nurses' knowledge.

Tool VI:Nurses' performance checklist for hemodialysis patients:This tool was developed by the researcher after review of related literature. It was used to assess the hemodialysis nurses' performance in the dialysis unit. This tool composed of seven parts of performance checklistsabout setup/initiate dialysis, patient and equipment assessment, management of the patients' complications, machine alarmtroubleshooting procedures, and renal failure safety measures, discontinue dialysis, and infection control measures in dialysis unit. The observation

was done by the researcher until completion of all parts of the nurses' performance checklist.

Method:

1- An official approval to conduct the study was obtained after explanation of the purpose of the study.
2- The developed tools were tested for its content validity by 5 experts in the field of Medical Surgical Nursing, Faculty of Nursing, and Alexandria University.
3- A pilot study was carried out on 5 patients to test the clarity and the applicability of the tools and to identify the difficulties that may be faced during the application of the tools.
4- The researcher explained the purpose of the study to nurses and patients including in the study. Nurses' and patients' formal consent to participate in the study were obtained, and every nurse and patient were informed that confidentiality will be assured.
5- Four phases were followed to accomplish the purpose of the study:

a. Assessment phase:

- Hemodialysis patients assessment schedule,patient's satisfaction questionnaire,patient's anxiety assessment scale and hemodialysis patients' safety outcomes check list were used to assess the hemodialysis patients' health status before application of the protocol of nursing care; it took a period of 8 months.
- An assessment of nurses' knowledge was carried out for each nurse using Tool V. The assessment took a period of one month.
- Fourteen nurses were observed by the researcher for their performance skills regarding hemodialysis patients' routine care in the morning and evening shifts in hemodialysis unit by the researcher using tool VI. It took a period of 3months.

b. Planning phase:

- Hemodialysis nurses training were arranged by the researcher along 30 sessions for all nurses based on the results of the assessment phase, 10 sessions with different 10 topics for every nurse in a group of 5 nurses in relation to renal failure and hemodialysis process,setup/initiate dialysis, patient and equipment assessment, management of the patients' complications,machine alarm troubleshooting procedures , Renal failure safety measures, infection control measures, policies and procedures applied in hemodialysis unit, discontinue dialysis, hemodialysis patients teaching and home care.
- Each session lasted for 30 min.after ending the morning dialysis session in the break time before evening session; it took a period of one month.
- Discussion, and demonstration were utilized by the researcher in training; also the researcher used colored booklet, and videos to reinforce the information.

c. Implementation phase

- The protocol of nursing care was applied by the nurses who received training by the researcher about the protocol of nursing care for hemodialysis patients. Nurses used colored booklet to teach the patients about home care plan individually.
- The implementation phase took a period of one month.

d. Evaluation phase

- Hemodialysis patients were re-evaluated by the researcher using tools I, II, III and IV after completion of nurses implementation to the protocol of nursing care.
- Nurses were evaluated by the researcher using nurses' performance checklist and nurses' knowledge assessment schedule after one month.

6- Data were collected throughout the period of15 months (from November 2013 to March 2015).

Statistical analysis

Data were fed to the computer and analyzed using IBM SPSS software package version 20. The Wilcoxon signed ranked test was used for ordinal data to assess the effectiveness of nursing intervention before and after application of nursing care for hemodialysis patients. McNemar-Bowker was used for qualitative parameters to assess the effectiveness of nursing intervention before and after application of nursing care for hemodialysis patients. The level of significance for the study was $p \leq 0.05$.

III. Results

Table (I): Shows socio-demographic characteristics of the studied nurses. As regards age, the table showed that 64.3% were in the age group of >30, and57.2% were married. As for level of education, it was noted that the majority of nurses 71.4% had secondary education, while 28.6% had university education. Regarding Years of experiences in hemodialysis, the table showed an equal percentages of nurses 42.9% had 3-6,>6 years' of experiences in hemodialysis patients' careTable II: Illustrates the studied hemodialysis nurses' knowledge and skills before and after receiving nursing care training**.** The results revealed that there was a statistical significant difference between nurses' knowledge and skills before and after receiving training of the protocol of nursing care ($p = 0.001^{*}$). 85.7%of nurses had good knowledge level after receiving training of the protocol of nursing care, comparing to the percentages were 14.3% before receiving the training. On the other

hand,7.1% of nurses had good skills level after receiving training of the protocol of nursing, whereas, the percentage was 0% before receiving the training .Table III: Represents distribution of the studied patients according to their socio demographic data.As regards age, the table revealed that66.7% of the patients were in the age group of 50≤60, and76.7% of them were males. As for level of education, 53.2% of patients had secondary education, and 63.3% of them had no work. In relation to marital status, the majority of them 86.7% were married.

Table IV: Shows comparison between the studied patients before and after application of the protocol of nursing care according to their physical examination. It was observed that the majority of patients had normal pulse and blood pressure 93.3, 91.7% respectively after application of the protocol of nursing care as compared to 78.3%, 68.3% before application of the protocol of nursing care. The only statistical significant difference was found between the patients in relation to normal pulse and blood pressure before and after application of the protocol of nursing care ($p = 0.012^{*}, <0.001^{*}$) respectively. Table (V): Conveys the comparison between the studied patients before and after application of the protocol of nursing care according to their vascular access's assessment. Regarding pain, the table revealed that, 36.7% of patients suffer from pain before application of the protocol of nursing care, while this percentage was decreased to 5% after its application. There was statistical significant difference between before and after application of the protocol of nursing care ($p = <0.001^{*}$).Concerning abnormal sensation as numbness, 6.7% of the patients had numbness before application of the protocol of nursing care. On the other hand, the percentage decreased to (0 %) after its application. As for inspecting the access arm, the table revealed that, there was a statistical significant difference regarding color and swelling between before and after application of the protocol of nursing care ($p = <0.001^{*}$).

Table (VI): Represents a comparison between the studied patients before and after application of the protocol of nursing care according to their nutritional assessment. The table denoted that13.4% of the patients had abnormal skin condition, lips and gum (pale and dry skin)before application of the protocol of nursing care, whereas after its application the percentage became 1.7%. There was a statistical significant difference ($p = 0.016^{*}$) between before and after application of the protocol of nursing care.

Table (VII) : Regarding patients' complications the table denoted that 21.7 % of the patients had chest pain, 30% hypotension, 1.7% hypertension , 40% dyspnea ,38.3% nausea, 30% muscle cramps ,and 23.3% of them had pruritus before application of the protocol of nursing care for the patients, while after its application the percentage became 8.3% , 0%,8.3% , 25%,25% , 5% and 11.7% respectively. The differences were statistically significant between before and after application of the protocol of nursing care in all mentioned items where $p= 0.008^{*}$, $<0.001^{*}$, 0.004^{*}, 0.008^{*} , $<0.001^{*}$ and 0.039^{*} respectively.

Table (VIII): Regarding patients' satisfaction and anxiety levels before and after application of the protocol of nursing care. The table showed that 81.7%of the patients had moderate level of satisfaction before the application of the protocol of nursing care for the patients as compared with 91.7% after the application of the protocol of nursing care. As forpatient's anxiety level 56.7% of the patients had mild anxiety, while 41.7% of them had moderate anxiety before the application of the protocol of nursing care for the patients .The percentage increased 96.7%, 3.3% of the patients had mild and moderate anxiety level respectively after the application of the protocol of nursing care. There was a statistical significant difference ($^{WRST}p<0.001^{*}$) between before and after application of the protocol of nursing care. Table (IX): Represents a comparison between hemodialysis patients' safety outcomes levels before and after application of the protocol of nursing care. The table showed that 75.0%of hemodialysis patients had positive outcomes, 23.3% had moderate level of outcomes,1.7% had negative outcomes before application of the protocol of nursing care for the patients. After application of the protocol of nursing care the percentage were 96.7%, 3.3%, 0.0%respectively. There was a statistical significant difference (p = 0.001*).

Table (I): Socio-demographic characteristics of the studied nurses. (n = 14)

Socio-demographic data	No.	%
Age		
20 – 30	5	35.7
>30	9	64.3
Marital status		
Single	5	35.7
Widow	1	7.1
Married	8	57.2
Education		
Bachelor	4	28.6
High school	10	71.4
Years of experiences in hemodialysis		
<1	1	7.1
1 – 3	1	7.1
3 – 6	6	42.9
>6	6	42.9
Training program		
Yes	7	50.0

No	7	50.0
If yes when		
During working	7	50.0
No	7	50.0
Who was training you?		
Faculty of nursing staff members	3	21.4
Supervisor	4	28.6

Table (II): Studied hemodialysis nurses' knowledge and skills before and after one month receiving nursing care training (n= 14)

Nurses' knowledge and skills scores		**Before**		**After (one month)**		**p**
		No.	**%**	**No.**	**%**	
Knowledge	Poor	1	7.1	0	0	0.001*
	Fair	11	78.6	2	14.3	
	Good	2	14.3	12	85.7	
Skills	Poor	2	14.3	2	14.3	0.001*
	Fair	12	85.7	11	78.6	
	Good	0	0.0	1	7.1	

p: value for Wilcoxon signed ranks test for comparing between before and after
*: Statistically significant at $p \leq 0.05$

Table (III): Distribution of the studied patients according to their biosocio-demographic data (n = 60)

Patients biosocio-demographic data	**No.**	**%**
Age		
20<30	3	5
30<40	6	10
40<50	11	18.3
50≤60	40	66.7
Sex	46	76.7
Male		
Female	14	23.3
Education		
Illiterate	4	6.7
Read and write	4	6.7
Primary education	7	11.7
Secondary education	32	53.2
University	13	21.7
Occupation		
Professional	9	15
Manual	13	21.7
Not working	38	63.3
Marital status		
Single	2	3.3
Married	52	86.7
Widow	5	8.3
Divorced	1	1.7
Associated disease		
Endocrine disease	4	6.7
Bone disease	16	26.6
Free from associated disease	40	66.7
Duration of previous hemodialysis		
<1 year	4	6.7
1< 2 years	5	8.3
2<3 years	2	3.3
>3 years	49	81.7
Number of dialysis session \week		
3 sessions\week	60	100
Hemodialysis access type		
Arteriovenous fistula	60	100

Table (IV): Comparison between the studied patients before and after application of the protocol of nursing care according to their physical examination. (n = 60)

Physical examination of the patients		Before		After		p
		No.	%	No.	%	
Vital signs						
• Pulse	Normal(60-90 b\min)	47	78.3	56	93.3	0.012*
	Tachycardia (90b\min)	13	21.7	4	6.7	
• Temperature	Normal	60	100	60	100	-
• Respiration	Normal	60	100	60	100	-
• Blood pressure	Normal	41	68.3	55	91.7	<0.001*
	Hypertension	1	1.7	5	8.3	
	Hypotension	18	30	0	0	
Dialysis prescriptions						
• Body weight	Loss	60	100	60	100	-
• Ultrafiltration rate/hour	1-2	7	11.7	7	11.7	1.000
	2-3	53	88.3	53	88.3	
• Dialysate type	Bicarbonate	60	100	60	100	-
• Blood flow	150 ml\min	13	21.7	13	21.7	^{WRST}p = 1.000
	250 ml\min	32	53.3	32	53.3	
	300 ml\min	15	25	15	25	
• Fluid given	Normal saline	43	71.7	43	71.7	1.000
	Dextrose 5%	17	28.3	17	28.3	

p: value for McNemar test for comparing between before and after
^{WRST}p: p value for Wilcoxon signed ranks test for comparing between before and after
*: Statistically significant at $p \leq 0.05$

Table (V): Comparison between the studied patients before and after application of the protocol of nursing care according to their vascular access's assessment. (n = 60)

Vascular access's assessment		Before		After		P
		No.	%	No.	%	
Subjective data						
• Pain of the access arm	Present	22	36.7	3	5	<0.001*
	Absent	38	63.3	57	95	
• Abnormal sensation of the access arm	Present	4	6.7	0	0	0.125
	Absent	56	93.3	60	100	
Objective data						
Inspecting the access arm for						
• Color change accompanied by engorgement of superficial veins	Pallor	6	10	0	0	0.001*
	Cyanosis	1	1.7	0	0	
	Normal	53	88.3	60	100	
• Hematoma	Absent	60	100	60	100	-
• Swelling	Present	11	18.3	0	0	0.001*
	Absent	49	81.7	60	100	
• Discharge, or bleeding from incision	Present	3	5	0	0	0.250
	Absent	57	95	60	100	
• Ulceration of the involved extremity	Present	3	5	0	0	0.250
	Absent	57	95	60	100	
• Gangrene	Absent	60	100	60	100	-
***Palpation* of the access arm for**						
• Thrill	Present	60	100	60	100	-
• Change of temperature	Coldness	1	1.7	0	0	1.000
	Normal	59	98.3	60	100	
• Change in capillary refill	Immediate	60	100	60	100	-
• Distal pulses	Present	60	100	60	100	-
***Auscultation* of the access arm for**						
• The bruit	Present	60	100	60	100	-

p: value for McNemar test for comparing between before and after
*: Statistically significant at $p \leq 0.05$

Table (VI): Comparison between the studied patients before and after application of the protocol of nursing care according to their nutritional assessment. (n = 60)

Nutritional assessment parameters		Before		After		p
		No.	%	No.	%	
Skin condition	Normal	52	86.6	59	98.3	0.016*
	Abnormal	8	13.4	1	1.7	
Hair	Normal	59	98.3	60	100	1.000
	Abnormal	1	1.7	0	0	
Eyes	Normal	56	93.3	60	100	0.125

	Abnormal	4	6.7	0	0	
Lips	Normal	52	86.6	59	98.3	0.016*
	Abnormal	8	13.4	1	1.7	
Gums	Normal	52	86.6	59	98.3	0.016*
	Abnormal	8	13.4	1	1.7	
Anthropometric measurement	Normal	4	6.7	8	13.4	-
	Over weight	56	93.3	52	86.6	
24-Hour Diet Recall	Eat prescribed food	1	1.7	20	33.3	1.000
	Vegetarians	15	25.0	1	1.7	
	All food	44	73.3	39	65	

p: value for McNemar test for comparing between before and after
*: Statistically significant at $p \leq 0.05$

Table (VII):A Comparison between hemodialysis patients' safety outcomes physical parameters according to complications (for the patients) before and after application of the protocol of nursing care.**(n = 60)**

Hemodialysis patients' safety outcomes(physical parameters according to patients 'complications)		**Before**		**After**		p
		No.	%	No.	%	
Patients 'complications	Present	13	21.7	5	8.3	0.008*
Chest pain	Absent	47	78.3	55	91.7	
Arrhythmias	Absent	60	100	60	100	-
Cardiac arrest	Absent	60	100	60	100	-
Hypotension	Present	18	30	0	0	<0.001*
	Absent	42	70	60	60	
Hypertension	Present	1	1.7	5	8.3	<0.001*
	Absent	59	98.3	55	91.7	
Bleeding	Present	1	1.7	0	0	1.000
	Absent	59	98.3	60	100	
Hemolysis	Absent	60	100	60	100	-
dyspnea	Present	24	40	15	25	0.004*
	Absent	36	60	45	75	
Nausea	Present	23	38.3	15	25	0.008*
	Absent	37	61.7	45	75	
Vomiting	Present	15	25	13	21.7	0.125
	Absent	45	75	47	78.3	
Muscle cramps	Present	18	30	3	5	<0.001*
	Absent	42	70	57	95	
Seizure	Absent	60	100	60	100	-
Pyrogenic reaction	Present	0	0	1	1.7	1.000
	Absent	60	100	59	98.3	
Pruritus	Present	14	23.3	7	11.7	0.039*
	Absent	46	76.7	53	88.3	

p: value for McNemar test for comparing between before and after
*: Statistically significant at $p \leq 0.05$

Table(VIII) Comparison between hemodialysis patients' safety outcomes psychological parameters according to satisfaction and anxiety levels before and after application of the protocol of nursing care. (n = 60)

Patients' safety outcomes (psychological parameters)		**Before**		**After**		**p**
		No.	**%**	**No.**	**%**	
Patients satisfaction level	Lowest level of satisfaction	7	11.7	2	3.3	^{WRST}p = 0.206
	Moderate level of satisfaction	49	81.7	55	91.7	
	Highest level of satisfaction	4	6.7	3	5	
Patients anxiety level	Mild anxiety	34	56.7	58	96.7	^{WRST}p<0.001*
	Moderate anxiety	25	41.7	2	3.3	
	Severe anxiety	1	1.7	0	0	

p: value for McNemar test for comparing between before and after
^{WRST}p: p value for Wilcoxon signed ranks test for comparing between before and after
*: Statistically significant at $p \leq 0.05$

Table (IX): Comparison between hemodialysis patients' safety outcomeslevels before and after application of the protocol of nursing care. (n = 60)

Patients' safety outcomes	**Before**		**After**		**p**
	No.	**%**	**No.**	**%**	
Negative outcomes	1	1.7	0.0	0.0	0.001*
Moderatelevel of outcomes	14	23.3	2	3.3	
Positive outcomes	45	75.0	58	96.7	

p: value for Wilcoxon signed ranks test for comparing between before and after
*: Statistically significant at $p \leq 0.05$

IV. Discussion

End stage renal disease (ESRD) is the most serious consequence of kidney diseases; it occurs when the kidney functions are less than 10% normal. In that case renal replacement therapies as hemodialysis, peritoneal dialysis and renal transplant become necessary to sustain patients' life [(26).] Hemodialysis is a method of removing waste products such as creatinine and urea, as well as excess water from the blood when kidneys failed.

The present study revealed that, the majority of nursing staff were having a diploma qualification, and nearly half of them were in the age group more than 30 years and were had more than 6 years of experiences in hemodialysis unit. This come in line with Younes (2012), who studied knowledge and performance among nurses before and after receiving a training programme on patient' fall in hemodialysis unit, he found that the majority of nursing staff were having a diploma qualification [(27).] Also this finding was supported by Jawad (2015) who found that the majority of nursing staff age was more than 30 years [(28) .]

In relation to nurses' knowledge, the present results showed that, there was a notable statistical significant difference between nurses' knowledge before and after receiving nursing care training. This may be related to nurses' desire to improve their knowledge level as well as the simplicity of the received nursing care training. This finding was supported by Douglas (2012) and Shrestha, (2013) who noted that negative patient 'outcomes often were due to lack of trainingand direction from one that is responsible of nursing services. Moreover nursing training is moderating factor that affecting the patients 'safety[(29,30)] .In addition, the improvement in nurses' knowledge and clinical skills in relation to caring for hemodialysis patients after receiving training, and the implementation of the educational training programme improved patients' care and facilitated a better working environment.

Regarding nurses' skills, The present results pointed out that, there was a statistical significant difference between nurses' skills before and after receiving nursing care training but not as much as compared to nurses' knowledge level .This may be attributed to nurses need more periodical supervision after application of the nursing care training not only after month, increase nurse-patients ratio, and lack of the hemodialysis unit supplies that must be revised .This result was supported by Armistead(2011) who found that nursing staff inexperience and lack of training were directly contributed to 10 % of all adverse incidents reported for hemodialysis patients [(31)]. Also, Pageb (2014) emphasized that training of nursing staff has been identified in the literature as an important factor that influences patients' outcomes [(32).]

In relation to patients'sociodemographic data, the results of the present study demonstrated that, the majority of the patients were in the age group 50<60. This finding was supported by Mohamed (2010) and Holzer (2012) who reported that the patients between 50 and 60 years were frequently affected by ESRD more than other age groups [(33, 34).] In addition.Laudansk (2013) mentioned that the most common age groups of patients complaining from ESRD and undergoing AVF were ranging from 50 - 60 years old that may be due to age related changes[(35)] .

Several studies have reported a higher incidence rate of ESRD among men than in women [(36, 37)]. These were in line with the result of the present study which pointed that the majority of the studied patients were males. On the contrary, Abdallah (2010), and Sawako (2011) concluded that the incidence of ESRD among females was higher than males [(38,39)] .

Regarding marital status, the findings of this study indicated that the majority of patients were married. Similar finding was revealed by Ali (2014), and Gerogianni (2012) found that the majority of patients were married and some patients reported improvement in their sexual abilities with exercise training program [(37, 40).]On the other hand, Ayub (2014) revealed contradictory results, where the majority of patients were single and divorced because kidney disease affected their sexual function[(41)].

End stage renal disease's patients can compensate with their illness and continue their work if they had proper social and psychological support. Going with this context, the findings of this study in relation to patients' occupation revealed that, the majority of patients had no work. This result may be due to the effect of ESRD on the patients' daily living activities and limitations of the patients' ability to work as a result of hemodialysis sessions' burden. This is in line with Harold (2012) who mentioned that, ESRD and dialysis can result in work related problems [(42).]

The present results revealed that, concerning vital signs: it was observed that, the majority of patients had normal pulse and blood pressure during initiation phase of hemodialysis session after application of the protocol of nursing care as compared to low percentages before its application. This could be attributed to the application of the protocol of nursing care and patients' adherence to the prescribed dietary regimen, as well as nurses 'continuous blood pressure monitoring, and management of patients' problems [(43).]

Maintaining a healthy arteriovenous fistula forms a crucial part of dialysis nursing care to optimize dialysis [(44)]. Regarding vascular access's assessment of pain, the present study emphasized that more than quarter of the patients' had access's pain before the application of the protocol of nursing care as compared to very low percentage of the patients' suffer after application of the protocol of nursing care , that could be attributed to dialysis staff and patients adequately educated and trained in how to prevent access's pain, as proper needle puncture by well trained nurses , knowledge regarding how patients keep access arm elevated during dialysis

session and at home it should be cleaned and kept this place always dry, and the possibility of using prophylactic antibiotics, anti-edematous that are prescribed by a doctor if needed[45] ·In addition to avoid tight clothing, jewelry, bandages or blood pressure measuring on the access area. Moreover avoid carry heavy items across access arm, and sample taken from it, also had a role in decreasing access's pain [46]. In this context; Rushing (2010) wrotethat, patients should follow facility's policies and procedures and clinical tips to protect and preserve the vascular access and avoid complications [47].

The results of the present study illustrated that there were changes in access arm color as pallor, and cyanosis, swelling associated with decreased fistula blood flow due to inadequate inflow or prolonged compression of the fistula during sleep. On the other hand, it was observed that all patients had normal access appearance after the application of the protocol of nursing care. This was in agreement with Naushad(2013) who found that, proper nursing management including access arm exercises, elevation and applying measures that prevent compression on nerves and blood vessels, improve access arm blood supply and venous return [48].

Charlotte (2012) pointed out that, the majority of patients have a wrong concept about nutrition that patients can eat everything in any amount before dialysis session [49]. Eating the right foods in right type and amount can help them to improve dialysis outcome and health. As regards nutritional assessment, it was observed that, the minority of patients had abnormal skin condition, lips and gum as compared to more patients had those abnormalities before the application of the protocol of nursing care. This might be attributed to the patients' compliance to the prescribed dietary regimen in relation to careful regulation of protein intake, fluid intake, sodium intake, and some restriction of potassium. At the same time, adequate caloric intake and vitamin supplementation must be ensured to every patient undergoing hemodialysis.

Nursing interventions have a great impact on reducing risk for complications and promote ESRD patients health. Nursing interventions should be based on evidence based clinical practice guidelines [50] .As for patients' problems that any patient can be faced on dialysis unit, the study results concluded that, more than half of the patients had edema, muscles cramps, and access pain before the application of the protocol of nursing care. On the other hand these percentages were diminished after the application of the protocol of nursing care. That might be related to adherence to the prescribed treatment regimen. This was supported by Davenport, (2010) who stated that hemodialysis patients are vulnerable to complications before, during and after treatment [51]. Berns (2013) added that, preventive measures such as maintaining salt and fluid restrictions between dialysis sessions are considered to be more effective measures to help control muscle cramps [52].

Patients' satisfaction towards nurses' service quality was essential as nurses play an important role in gaining patients' recovery[53] .Regarding patients' satisfaction level, the present study showed that, there was increased in patients' satisfaction level after the application of the protocol of nursing care. This could be justified that given health education help patients to understand their condition and increase their self-care practices as well as improve their confidence satisfaction towards nurses' service. That result came in line with Ugurlu and Ali (2012) emphasized that, well informed patients with CRF are more likely to adjust to their condition and improve their quality of life than non-informed patients [54].

Not only hemodialysis patients exposed to physical problems but also they exposed to psychological problems concerning disease prognosis. Notably, anxiety is a common psychological problem that may emerge during the initial course of dialysis. As for anxiety level, the present results denoted that more than half of the patients had a mild level of anxiety, while the others had moderate level of anxiety before the application of the protocol of nursing care for the patients .on the other hand, the majority of the patients had mild level of anxiety after the application of the protocol of nursing care, that may be due to the nursing guidance to the patients in relation to the practices to reduce anxiety as listening to the Holy Quran and sermons, practiced deep breathing exercises, and spend some time to watch TV. In this context Besarab (2011) found that the incidence of anxiety increased over time in patients who were on hemodialysis and need special care to reduce it [55] .Also Mahdavi et al (2013) stressed that pharmacological anxiety control methods are costly and usually accompanied by complications, so relief must be focused on non-pharmacological techniques as deep breathing exercise which help to relieve anxiety [56] .

Hemodialysis patients' safety outcomes are closely linked to nurses who are the center of the patients' care, and they are the closest to the patients. They spend more time with patients than any other healthcare personnel, so they are concerned with maximizing patients' positive outcomes [57]. In relation to hemodialysis patients' safety outcomes at the ends of hemodialysis sessions, the study revealed that, the majority of patients had normal vital signs after application of the protocol of nursing care. That result was supported by the studyZager (2012) who concluded that hypotensive episodes continue to be a major problem for many patients receiving hemodialysis and nursing intervention is often required to overcome that problem [58].Aravind(2014) who found that, competent nursing care in vital signs monitoring associated with dialysis efficiency [59] .

In a conclusion of patients' safety outcomes, the results of the present study demonstrated that, the majority of patients had positive safety outcomes after the application of the protocol of nursing care. This may be attributed to nurses compliance with the instructions that positively had an effect on the patients' safety that include training the

hemodialysis nurses about competent patients' management that enables the nurse to identify basic information regarding dialysis, chronic renal failure, basic principles of hemodialysis. Moreover, the protocol of nursing care enables the nurse also to formulate comprehensive individualized home care plan for every hemodialysis patients, including personal hygiene, vascular access care, proper nutrition and exercises [(60)].

Additionally, the protocol of nursing care empowers nurses to identify causes that laps patients' safety and assume measures to prevent it, as prevention of clots in the hemodialysis circuit, avoidance of equipment and facility failure, medications errors prevention, needle dislodgement avoidance, and fall prevention. It also enhances the nurse to follow infection control measures as staff hand hygiene, vascular access safety, water treatment safety, immunizations for both nurses and patients, environmental and equipment cleaning/disinfection, and follow policies and procedures that applied in hemodialysis unit, in relation to employee health', patients' ambulation during entering or going out the unit, and isolation [(61)].

Finally, the results of the present study demonstrated that, nurses adherence to the protocol of nursing care were beneficial to both nurses and chronic hemodialysis patients. This finding was supported by Issa (2012)who mentioned that patient' outcomes were better improved after application of educational programs for the nurses staff [(62)] .Also Louise(2011) found an educational initiatives importance for multidisciplinary care team to attain successful patients vascular access outcomes. Exciting opportunities remain to be explored with online learning and the use of simulation to ensure that the knowledge and skills were gained about vascular access is translated into better patient outcomes [(63)].

Moreover, a study that was carried out by War (2014) who had a project best practice implementation in enhancing patient safety in hemodialysis unit, mentioned that, this project has made a significant improvement in establishing evidence-based practices for implementing standard hemodialysis care practice among the nurses. Audit results and feedback following completion of the project indicated that, the changes implemented were beneficial to both nurses and chronic hemodialysis patients [(64)].

Patient safety is an essential and vital component of quality care. Yet health care providers face many challenges in today's health care environment in trying to keep patients safe. Patient safety is fundamental to nursing care, nurses and their sound knowledge base enables them to play a critical role in chronic hemodialysis patients' safety [(65)]. The present results illustrated that the protocol of nursing care has benefited both patients and nursing staff. As for nursing staff, the protocol of nursing care enhance and develop nurses' knowledge and skills with regard caring for hemodialysis patients in dialysis unit and improve their job satisfaction level. Also they become more proficient and confident in dealing with hemodialysis patients' without avoidable delays and frustration [(66).]

Concerning hemodialysis patients, this protocol provided a stepping stone in the right direction and demonstrates staff commitment to listen and respond to patient needs, problems and improve the delivered care for them. On the other hand, patients felt more comfortable and had more confidence in nursing staff because care is now focused on the patient to ensure that treatment is delivered in a timely way, by nurses with the right knowledge and skills to do so. Lastly the protocol of nursing care is certainly needed in order to improve nurses' performance in hemodialysis units and improving hemodialysis patients' safety outcomes in relation to physical and psychological parameters [(67).]

V. Conclusion

It can be concluded from the present study that:

- Although the majority of nurses had good knowledge score, they had fair total performance score after nursing care training. Generally, there was a statistical significant difference between nurses' skills before and after nursing care training but not as much as compared to nurses' knowledge level
- There was a decrease in the patients' level of anxiety and increased in patients' satisfaction level after the application of the protocol of nursing care.
- The majority of patients had positive safety outcomes after the application of the protocol of nursing care

VI. Recommendations

Based on the results' findings of the present study, the following recommendations are suggested:

- Pre-service training program should be provided to the nurses before assuming independent responsibilities for hemodialysis patients' care.
- The developed competencies handout about care for hemodialysis patient should be available for all staff nurses working in hemodialysis units.
- Reasonable nurse/patient ratio should be properly distributed in all shifts for maintaining good quality nursing care.

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