Efficacy of Applying a Structured Checklist on Safety Outcomes of Hemodialysis Patients

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Abstract

Background: Hemodialysis is a technically complex procedure, that more likely to develop adverse events. Such events expose the patient to harm, lower dialysis quality, and result in life-threatening conditions. The use of checklists is an important strategy for ensuring that procedures are performed safely and reduce treatment-associated morbidity in the hemodialysis unit. **Aim:** To evaluate the efficacy of applying a structured checklist on safety outcomes of hemodialysis patients. **Design**: A quasi-experimental one-group (pre- and post-test) design was used. **Setting**: Hemodialysis unit at Mansoura Main University Hospital. **Subjects:** A convenient sample composed of 48 hemodialysis patients and 30 nurses. **Tools**: The researchers used three tools to collect the data: Structured interview questionnaire, it divided into two parts for assessing patient' demographic and medical data in addition to assessing nurses' demographic and professional data, Audit tool and checklists of dialysis safety, and Patients' safety outcomes assessment tool. **Results:** There was a statistically significant difference in the mean scores of total patients' safety outcomes during hemodialysis phases (sign in, time out, sign out), as well as nurses performance before and after applying the patient safety checklist ($P \leq 0.001$). Moreover, there was a statistically significant decrease in the adverse events score ($t = 8.167$, $p \leq 0.001$). **Conclusion:** As a result of applying the checklist, patients' safety outcomes improved, the frequency of adverse events decreased. **Recommendations:** A structured checklist can be routinely applied to reduce adverse events and promote a safety culture in hemodialysis units.

Key words: Hemodialysis, Structured Checklist, Safety Outcomes.

Introduction

Hemodialysis (HD) is a standardized life-saving treatment for more than 800,000 people worldwide who have end-stage renal disease (ESRD). It is the most common form of kidney replacement therapy in the world, accounting for approximately 69% of all kidney replacement therapies and 89% of all dialysis therapy types **(Bello et al., 2022)**. In Egypt, the annual incidence of ESRD is about 74 per million, and the prevalence of patients on dialysis is 264 per million population **(Farag & El-Sayed, 2022).**

Dialysis units are complex departments that apply advanced technology for caring the patients with chronic renal failure. As technology becomes more complex in dialysis facilities, the possibility for errors increases and potential risks must be identified and prioritized **(Aghakhani, Mobaraki, Ahmadzadeh & Ahmadzadeh, 2020).**

Several risk factors including, invasive procedures, using complex equipment, water treatment, critical patients, high patient turnover, and the administration of potentially harmful drugs like heparin, set up HD units as places where adverse events (AEs) could be life-threatening and are one of the top ten global causes of death and disability brought on by medical care **(Bowman & Rosner, 2023).**

It was demonstrated that, 98,000 patients died annually from medical errors in the US,

Canada, Australia, and England, emphasizing the importance of maintaining patient safety in dialysis settings **(Ahamed& Sallam, 2018).** To maintain safety for HD patients, the dialysis units require advanced medical care utilizing technology, staff training, safe environment, infection control, avoiding medication errors, and maintaining patient safety parameters **(New et al., 2021).**

Patient safety is characterized as lowering to an acceptable level the risk of unwarranted harm connected with medical care. Patient safety focuses on reducing the risks associated with the medical care in order to prevent AEs, which are accidents that happen during medical treatment leading to physical, social, and psychological harm **(World Health Organization, 2019).**

To lower patient harm risks, prevent or lessen errors, and to improve the standard of care, HD units must promote a culture of safety. The Agency for Healthcare Research and Quality (2019) emphasizes the need for all organizational levels to reduce AEs of a patient during complex and potentially dangerous procedures like HD treatments **(Jennifer Dillon, 2020)**.

High-quality care must include patient safety as a key element. High-quality institutions with a strong safety culture equip professionals to handle AEs at all levels of the organization by anticipating them. Therefore, they provide tools so that experts can learn how to convert such AEs into better system resistance. Hospitals can detect and address pertinent safety risks in their everyday work by conducting patient safety assessments in the future **(Thomas et al., 2016& Walton et al., 2022).**

Guidelines, protocols, checklists, and care bundles are strategies used to encourage the consistent delivery of high-quality care, but for these to be effective, they must be suited for the task at hand and applied correctly. Even when such strategies are supported by strong data, adoption and long-term adherence must be ensured through individual and organizational appreciation of worth and effectiveness based on constructive communication and performance feedback (**Rocha, 2022).**

Checklist is a method used in high-risk contexts where proper execution of technical activities is required. It has just lately been applied in healthcare **(Chemweno & Pintelon, 2020).** Checklists are considered useful instruments for enhancing patient safety, adherence to rules and regulations, communication, teamwork, and procedure uniformity. Moreover, checklists are a crucial tool for ensuring that procedures are carried out properly since they make it possible to identify and prevent the occurrence of avoidable harm and its repetition **(Silver et al., 2015).**

Significance of the study

Adverse events and errors during HD sessions are very common. To decrease these AEs and ensuring application of patient safety measures, the extracorporeal blood circulation system must be controlled, the dialyzer and other equipment must be prepared, blood must be accessed, the patient must be monitored to avoid complications and to ensure hemodynamic stability for safe care practices, and there must be adequate structure and qualified professionals who provide standard care **(Rich et al, 2017 & Albreiki et al., 2023).**

Checklist is considered a useful patient safety tool that have improved care among medical field **(Rocha, 2022).** So, it is necessary to develop measures to provide standardized care and improve nurses' performance in HD units by using checklists for multistep HD treatment, promoting collaboration and communication between patients and nursing staff to ensure compliance with protocols in addition to maintaining patient safety.

Aim of the study

The aim of this study was to evaluate the efficacy of applying a structured checklist on safety outcomes of hemodialysis patients.

Research hypothesis

H1: Applying HD safety checklist improves patients' safety parameters.

H2: Applying HD safety checklist decreases the frequency of AEs for patients.

Operational definitions:

A structured hemodialysis checklist: It is a safety a checklist that standardize HD procedures, developed by **Silver et al., (2015).** Afterward it was tested for its feasibility by **Thomas et al., (2016)**. The HD safety checklist contains safety parameters items regarding procedures applied by the nurses for patients undergoing HD.

Safety outcomes of HD patients: It involves evaluating patient safety parameters and addressing the AEs that occur during the provision of health care and that result in harm to the patient. It was evaluated by using Tool III (part I& II).

Subjects and method

Research design:

A quasi experimental, one group (pre and posttest) design was used for implementing this study.

Setting:

The current study was conducted at HD unit at Mansoura Main University Hospital. The HD unit includes two large halls, with a number of 25 HD machines.

Subjects and sampling:

There were two types of studied sample included in this study as the following:

A) Studied Patients:

A convenient sample of 48 patients scheduled for maintenance HD were included based on the following sample size calculation: Using data from the literature **(Dhule & Jacob, 2020)**, considering level of significance of 5%, and power of study of 80%, the sample size was calculated using the following formula: n = $\frac{2(Z\alpha/2 + Z\beta)^2 \times p\,(1-p)}{(d)^2}$ where, p = pooled proportion obtained from previous study; d = expected difference in proportion of events; Zα/2 =1.96 (for 5% level of significance) and Zβ = 0.84 (for 80% power of study). Therefore, n = $\frac{2(1.96 + 0.84)^2 \times 0.40\,(1-0.40)}{(0.28)^2}$ = 48. Accordingly, the sample size required is 48.

B) Studied Nurses

A convenient sample of 30 nurses who are working in HD unit, from both genders with different ages and level of education, who provide direct routine nursing care for the studied patients for whom the checklist was applied and who accepted to participate voluntary in the current study.

Tools of data collection:

The researchers used three tools for data collection. Tool 1 (part 1 and part II) was developed by the researchers after reviewing the relevant literatures (**Ahmed et al., 2021& Osman, 2021**), while tool II and tool III (part I) were adopted by the researchers as the following:

Tool I: Structure interview questionnaire

This tool included two parts:

Part I: Demographic characteristics and medical data of the studied patients

The researchers used this part to assess patient' demographic characteristics and medical data such as age, gender, level of education, occupation, causes of renal failure, HD access type, duration of HD that the patients passed, and associated comorbid diseases.

Part II: Demographic characteristics and professional data of the studied nurses

The researchers used this part to assess nurses' demographic characteristics and professional data such as age, gender, level of education, years of experience and attendance of training workshops about patient safety.

Tool II: Audit tool and checklists of dialysis safety

The researchers adopted this tool from **Center for Disease Control and Prevention, (2019)** to assess the nurses' performance at HD unit. It consists of five parts related to dialysis safety procedures as the following:

1.Catheter care (10 items).
2.Catheter exit site care (10 items)
3.Arterio-venous fistula & graft cannulation and decannulation (20 items)
4.Dialysis station disinfection (9 items)

5.Injection safety: medication preparation and administration (14 items).

Scoring system

One mark awarded for each item that correctly done and zero for incorrect or not completely done item. The total performance score ranged from 0 to 63. Nurses' performance was categorized into two levels: Unsatisfactory < 75% of total scores & Satisfactory ≥ 75% of total scores **(Idris Sagiron & Abdalla Jarelnape, 2022).**

Tool III: Patients' safety outcomes assessment tool:

The researchers used this tool to evaluate the efficacy of applying a structured checklist on safety outcomes of HD patients and included two parts as the following:

Part 1: Patient safety parameters assessment checklist:

The researchers adopted this checklist from **Thomas et al., (2016)** to assess nurse's adherence regarding patient safety parameters. The checklist containing 31 items divided into three parts as follows:

1.Sign-in (pre-dialysis session) included 7 items; Confirming patient identification, pre-dialysis weight, allergies checked, doctor's orders noted and transcribed, medications correctly administered, treatment plan reviewed with patient, and patient asked about health concerns.

2.Time-out (session initiation) included 14 items; Hand washing, pre-dialysis blood pressure, easy cannulation, correct needle insertion, pain-free cannulation, secured dialysis needles, correct dialyzer, correct dialysis solution, correct machine setting, no circuit clotting, blood pump speed at the prescribed rate, blood samples collected, blood specimens correctly labeled, dialysis treatment for complete duration.

3.Sign-out (post-session) included 10 items regarding; Blood loss, blood clotting after dialysis, evidence of access infection, post-dialysis blood pressure, post-dialysis weight, patient falls, needle stick injuries, medical errors reported if witnessed, management support for incident reporting, and adherence to HD procedures.

Scoring system:

One mark awarded for each item that done or checked and zero for not done or not checked one. The total score was summed before and after applying checklist. If the total means score was less than 50%, it was considered low safety. If it was between 50% and 70%, it was considered average. If it was more than 70% ،the safety status of patients considered high **(El-Hady et al., 2016)**.

Part II: Hemodialysis related AEs assessment sheet:

The researchers developed this tool after reviewing literatures **(Arenas Jiménez, Ferre & Álvarez-Ude, 2017& Faria Rocha & Moura Pinho, 2019).** It included (13) items of most common AEs as hypotension, cramps, arterial hypertension, central chest pain, altered heart rhythm, nausea and vomiting, vascular access-related infection, AVF acute complications.

Validity and reliability

Data collection tools, as tool II and Tool III (Part I) were adopted by the researchers. On the other hand, a structured HD checklist was adopted from **(Silver et al., 2015),** it was the final version of HD safety checklist that accepted and approved by Delphi panel process, the researchers translated the final English version of checklist and tool I (part II) into Arabic language, then the back-translation technique was created for the checklist and the tool. The experts reviewed the Arabic version of the checklist and the tool and tested for face, and content validity by a panel of five experts: nephrologist, medical-surgical nursing, administration nursing, community health nursing, and medical biostatistics. The experts revised the tools for comprehensiveness clarity, relevancy, simplicity, and applicability. All suggested modifications were done, and the final format of the tools was prepared.

Reliability of tools: The researchers used Cronbach's Alpha to test reliability of the study tools, which is an international measure of

reliability, its maximum value is 1.0 which indicates the highest reliability, and the minimum accepted value is 0,65, below this value indicates an unreliable tool. The Cronbach's alpha value of the patient safety parameters was **0.901**, and of the AEs frequency was **0.897**, and nurses' checklist was **0.895**.

Pilot study

The researchers carried out the pilot study on 10% (five patients) and (three nurses) to evaluate clarity, and applicability of the developed tools and make any necessary modifications before conducting the main study, as well as to estimate the required time needed for completing the questionnaire. Participants included in the pilot study were excluded from the target sample size sample.

Ethical Considerations:

The researchers get the approval Ethical Committee for Scientific Research of the Faculty of Nursing, Mansoura University, Egypt, approved the study **(IRP: Ref. no. P.0447),** the official permission before conducting the current study from the Mansoura Main University Hospital administrator was obtained after explaining the nature and purpose of the study. Then obtained the informed consent from both studied patients and nurses who accepted to voluntary participate after clarifying the aim, and nature of the current study. Withdraw from the study at any time, and the patients' rights to refuse to participate in the study without adverse effects on their care were assured. Privacy was absolutely ascertained, and data confidentiality was secured by coding data, and the researchers confirmed that data will be used only for research purpose.

Field work and data collection

Data collection lasted four months from the beginning of April 2023 to the end of July 2023. Fieldwork is accomplished through five phases which are consecutively commenced in order to achieve the aim of the current study.

Phase I: Preparatory phase

The researchers obtained written approval from the relevant authorities to conduct the study before commencing data collection. The study process was coordinated with healthcare providers, including nursing staff, after providing a clear explanation of the aim and nature of the study. In addition, during this phase, the study tools and the structured checklist were prepared by the researchers.

Phase II: Assessment phase (Pre-test)

In this phase, the researchers collected the initial data to assess demographic characteristics and medical data of studied patients using **Tool I (Part 1**). Also, patient records were reviewed for frequency of AEs during HD sessions through the previous two months.

- On the other hand, the researchers interviewed each studied nurse individually according to their work schedule at the HD unit after introducing themselves and giving the studied nurses a brief idea about the aim and nature of the study. Afterward data collection was carried out to assess studied nurses' demographic characteristics and professional data using **Tool I (part II).** The studied nurses filled out the questionnaire within 15-20 minutes.

- Afterward, the researchers assessed the nurses' performance regarding HD safety procedures at HD unit using **Tool II**. Finally the researchers assessed the nurses adherence regarding patient' safety parameters for the studied patients using **Tool III part (1)**.

- These data of assessment phase were collected through a period of two months.

Phase III: Planning phase (Preparing the structured checklist)

- Based on initial data collection, the researchers considered the pre-test data in relation to nurses' demographic and professional characteristics, nurses' performance of HD procedures, and nurse's adherence or compliance regarding patient safety parameters in the preparing of the structured checklist.

- The researchers addressed variety of the teaching materials and methods to address the structures HD safety checklist in the form of simple colored handouts, PowerPoint presentation. The interactive presentation and hand out of structured checklist were a simplified for the studied nurses aimed to develop knowledge, and support nurses in implementing safety practices regarding HD procedure.

Phase IV: Implementation phase (Applying the structured checklist)

- Before implementing the structured HD safety checklist by the studied nurses on the studied patients, first the researchers started to prepare the studied nurses by acquiring them knowledge and practices through providing educational sessions using Power point presentation related to catheter care procedure, catheter exit site care, AVF & graft cannulation and decannulation, dialysis station disinfection, and injection safety procedures.

- This was achieved by conducting three sessions per week and lasted for two weeks in the morning, afternoon and evening shifts according to studied nurses' available time, using the variety of the teaching materials and methods.

- Then, the studied nurses were trained about HD safety checklist and how to apply during HD sessions using printed colored checklist. All studied nurses were trained in the administration of the checklist.

- The researchers presented the structured safety checklist content in three sessions at different intervals regarding caring of HD patients at sign in time (before the patient assigned to HD hall), time out (prior to cannulation and HD initiation), and sign out (after HD completion), as the following :

First session:

This session presented knowledge and safety practices for the studied nurses at the time before the patient assigned to HD hall to start his/ her HD session including; HD patient' identity is verified, patient concerns are reviewed, along with the dialysis access including the infection control and cannulation strategy.

Second session:

It presented knowledge and safety practices regarding the care of HD patients at the time of beginning of HD session including; reviewing of the dialysate prescription, the treatment strategy (including blood pressure, the target weight, the duration of the treatment, and any potential problems), and any access issues such as needle size and failed cannulation attempts.

Third session:

It presented knowledge and safety practices regarding the care of HD patients at the time of post HD session including; evaluation of vital signs, blood loss, difficulties with the dialysis access, target weight, and duration of HD. At this session the studied nurses had a conversation with the patients and the studied patients also had the chance to clarify any misunderstandings or inaccuracies by asking questions regarding their treatment plan.

Phase V: Evaluation phase (Post-test)

- In this phase, the studied nurses' performance was evaluated by the researchers after two months of initial assessment using Tool II (audit tool and checklists of HD safety)

- Evaluation of patient safety outcomes was done using (Tool III) to assess patients' safety parameters after applying the checklist.

- Patients' records were monitored over a period of two months through 24 dialysis session for the frequency of incidence of AEs during the evaluation phase.

Statistical analysis:

Statistical analyses were performed after data collection using SPSS for windows version 20.0 (SPSS, Chicago, IL). Continuous data were normally distributed and were expressed in mean ±standard deviation (SD). Categorical data were expressed in number and percentage. Chi-square test (or fisher's exact test when applicable) was used for comparison of variables with categorical data. The paired groups (pre and post intervention) were compared by paired t test. The study data were tested for normality by the Kolmogorov-Smirnov test. For normally distributed variables. The reliability (internal consistency) test for the questionnaires used in the study was calculate. Statistical significance was set at $p<0.05$.

Results:

Table 1: shows that the mean age of studied patients was 41.3 ±5.9 years with 47.9% aged 40 to less than 50 years, and 58.3% being male. Regarding educational level, it was noticed that 25.0% of the studied patients had secondary education and 77.1% didn't work.

Table 2: Reveals that, 62.5% of the studied patients had diabetic nephropathy as a leading cause of renal failure as a result of diabetic nephropathy. Regarding associated diseases, it was found that 36.6%, 36.6%, 39.0%, and 41.5% of them had diabetes, coronary artery disease, congestive heart failure, and peripheral vascular disease respectively. In addition, 85.4% of the studied patients had AVF as a vascular access, and 45.8% of them have been on HD from 1 to less than 5 years, with a mean of 5.2 ±1.8.

Table 3: shows that the mean age of nurses was 32.4 ±6.1 years, with 50.0% aged 20 to less than 30 years, 56.7% being female. Regarding educational level and years of experience, it was noticed that 46.7% the studied nurses had technical institute and less than 5 years of experience. The majority of the studied nurses (80.0%) did not receive any training workshops about patient safety.

Table (4) illustrates that 63.3%, 80.0%, 66.7%, 63.3%, and 70.0% of the studied nurses showed satisfactory performance levels regarding (catheter care, catheter exit site care, AVF, graft cannulation and decannulation, and injection safety) respectively after applying of the structure safety checklist. Overall, the total performance score revealed that 76.7% of the studied nurses showed unsatisfactory performance level with a mean of 49.0 ±4.8 marks before applying of the patient safety checklist in relation to catheter care, catheter exit site care, AVF, graft cannulation and decannulation, and injection safety. However, 63.3% of them showed satisfactory performance levels with a mean of 57.3 ±2.9 marks after applying of patient the safety checklist. The difference was significant ($t = 8.039$, $p \leq 0.001$) between pre- and post-applying the checklist regarding the previous item.

Table 5: reveals that there were statistically significant variations in mean scores of patient safety parameters during HD phases (sign in, time out, sign out), as well as total patients' safety outcomes before and after applying the patient safety checklist ($P \leq 0.001$). According to the results of the paired t-test, the mean scores of patient safety parameters during sign-in phase (pre-dialysis session) significantly increased from 2.6 ±1.1 before the applying the checklist to 4.5 ±2.0 after check list application. Moreover, it was found that the mean score of patient safety parameters during the time out phase (session initiation) was significantly increased from 7.3 ±3.3 before applying the checklist to 9.1 ±3.7 after the application. Additionally, the table shows

the mean score of patient safety parameters during the sign-out phase (post-session) was significantly improved from 5.4 ±2.6 pre checklist to 7.9 ±2.4 post checklist. Lastly, the mean score of total patients' safety outcomes was 15.4 ±6.6 before applying patient safety checklist compared to 21.5 ±7.1 after the application ($t = 4.375$, $p \leq 0.001$).

Table 6: it is noteworthy that, there was a significant decrease in frequency of AEs after the patient safety checklist application. Furthermore, the table shows a statistically significant decrease in the total mean score of AEs frequency pre-checklist 21.8 ±2.3 compared to 18.0 ±2.2 post checklist ($t = 8.167$, $p \leq 0.001$).

Table 1. Demographic characteristics of the studied patients N = (48)

Items	N	%
Age (Years)		
20- < 30	4	8.3
30- < 40	8	16.7
40- < 50	23	47.9
50 – 60	13	27.1
Mean ± SD	**41.3 ±5.9**	
Gender		
Male	28	58.3
Female	20	41.7
Educational Level		
Non educated	9	18.8
Read and write	21	43.8
Secondary education	12	25.0
University education	6	12.5
Occupation		
Working	11	22.9
Not working	37	77.1

Table 2. Medical data of the studied patients N = (48)

Items	N	%
Causes of renal failure		
Glomerulonephritis	9	18.8
Diabetic nephropathy	30	62.5
Cystic kidney disease	9	18.8
Suffering from associated diseases	41	85.4
Diabetes	15	36.6
Coronary artery disease	15	36.6
Congestive heart failure	16	39.0
Peripheral vascular disease	17	41.5
Chronic pulmonary disease	12	29.3
Type of vascular access		
Arteriovenous Fistula (AVF)	41	85.4
Arteriovenous Graft (AVG)	5	10.4
Central venous catheter (CVC)	2	4.2
Time on HD (years)		
< 1 year	10	20.8
1 - < 5 years	22	45.8
5 - < 10 years	16	33.3
Mean ±SD	**5.2 ±1.8**	

Table 3. Demographic characteristics and professional data of the studied nurses (N= 30)

Items	N	%
Age (Years)		
20- < 30	15	50.0
30 -< 40	8	26.7
40 and more	7	23.3
Mean ±SD	32.4 ±6.1	
Gender		
Male	13	43.3
Female	17	56.7
Educational Level		
Secondary school	5	16.7
Technical institute	14	46.7
Bachelor's degree	11	36.7
Experience (Years)		
< 5	14	46.7
5- < 10	10	33.3
10 and more	6	20.0
Mean ±SD	5.9 ±2.3	
Attendance of training workshops about patient safety	6	20.0

Table 4. Comparison of the Nurses' performance and their total performance score before and after applying a structure safety checklist N = (30)

	Pre – checklist		Post- checklist			
Nurses' performance level	**N**	**%**	**N**	**%**	**Test of significance**	**P value**
Catheter care						
Unsatisfactory	25	83.3	11	36.7		
					$\mathbf{X^2}$ =13.611	<0.001**
Satisfactory	5	16.7	19	63.3		
Mean ±SD	7.1 ±1.2		8.9 ±0.8		**t** =6.660	<0.001**
Catheter exit site care						
Unsatisfactory	23	76.7	6	20.0	$\mathbf{X^2}$ =19.288	<0.001**
Satisfactory	7	23.3	24	80.0		
Mean ±SD	7.9 ±0.8		8.9 ±0.5		**t** =5.853	<0.001**
AVF& graft cannulation and decannulation						
Unsatisfactory	26	86.7	10	33.3	$\mathbf{X^2}$ =17.778	<0.001**
Satisfactory	4	13.3	20	66.7		
Mean ±SD	15.5 ±1.5		17.8 ±0.7		**t**=7.881	<0.001**
Dialysis station disinfection					$\mathbf{X^2}$ =15.864	<0.001**
Unsatisfactory	26	86.7	11	36.7		
Satisfactory	4	13.3	19	63.3		
Mean ±SD	7.1 ±1.0		8.6 ±0.5		**t**=7.137	<0.001**
Injection safety					$\mathbf{X^2}$ =15.152	<0.001**
Unsatisfactory	24	80.0	9	30.0		
Satisfactory	6	20.0	21	70.0		
Mean ±SD	11.4 ±1.1		13.1 ±0.8		**t**=6.772	<0.001**
Total performance					$\mathbf{X^2}$ =9.774	0.002*
Unsatisfactory	23	76.7	11	36.7		
Satisfactory	7	23.3	19	63.3		
Mean ±SD	49.0 ±4.8		57.3 ±2.9		**t**=8.039	<0.001**

t Paired T test $\mathbf{X^2}$ chi square P (significance) * Significant (p< 0.001)

Table 5. Comparison of the safety parameters and total safety outcomes score before and after applying a structure safety checklist N = (48)

Items	Pre – checklist		Post- checklist		Test of significance	P value
	N	%	N	%		
Sign In (pre dialysis session)					X^2 = 19.309	<0.001**
Low Safety	30	62.5	12	25.0		
Average Safety	14	29.2	15	31.3		
High Safety	4	8.3	21	43.8		
Mean ±SD	2.6 ±1.1		4.5 ±2.0		t = 5.767	<0.001**
Time Out (session initiation)					X^2 =10.203	0.006*
Low Safety	19	39.6	9	18.8		
Average Safety	17	35.4	12	25.0		
High Safety	12	25.0	27	56.3		
Mean ±SD	7.3 ±3.3		9.1 ±3.7		t = 2.515	0.013*
Sign Out (post session)					X^2 =26.392	<0.001**
Low Safety	15	31.3	6	12.5		
Average Safety	24	50.0	8	16.7		
High Safety	9	18.8	34	70.8		
Mean ±SD	5.4 ±2.6		7.9 ±2.4		t = 4.753	<0.001**
Total Patients' safety outcomes						
High Safety	6	12.5	26	54.2	X^2 =19.750	<0.001**
Mean ±SD	15.4 ±6.6		21.5 ±7.1		t = 4.375	<0.001**

t paired T test X2 chi square P (significance) * Significant (p< 0.001)

Table 6. Comparison of AEs frequency before and after applying patient safety checklist N = (48)

Items	Pre – checklist		Post - checklist		Test of significance	
	N	%	N	%	X^2	P
Frequency						
Hypotension	32	66.7	18	37.5	8.181	0.004*
Cramps	36	75.0	22	45.8	8.537	0.003*
Arterial hypertension	34	70.8	15	31.3	15.048	<0.001**
Central chest pain	26	54.2	15	31.3	5.151	0.023*
Altered heart rhythm	34	70.8	18	37.5	10.741	<0.001**
Nausea and vomiting	36	75.0	31	64.6	1.235	0.266
Vascular access-related infection	36	75.0	23	47.9	7.432	0.006*
Venous extravasation or bruising	24	50.0	15	31.3	3.498	0.061
AVF acute complications	36	75.0	33	68.8	0.464	0.496
Catheter rupture or dysfunction	36	75.0	18	37.5	13.714	<0.001**
Needles coming out	14	29.2	3	6.3	8.649	0.003*
Clotting of the system	36	75.0	21	43.8	9.717	0.002*
Allergic reactions	42	87.5	9	18.8	45.553	<0.001**
Mean ±SD	**21.8 ±2.3**		**18.0 ±2.2**		**t =8.167**	**<0.001****

Discussion

Hemodialysis is a hospital sector with a high risk of AEs. Strategies must be used to limit the occurrence of AEs, thereby ensuring the quality of dialysis and, consequently, the quality of life of HD patients **(Rocha, 2022).** Furthermore, one patient safety method that may improve safety culture is the use of checklists in the HD unit, which promotes communication, teamwork, and consistency of care through standardization of protocols and procedures. **(CNS-BC & Morin, 2020; Albreiki et al., 2023).** As a result, the current study investigated the efficacy of applying a structured checklist on safety outcomes of HD patients.

Regarding the medical data of the studied patients, the current result illustrated that about two-thirds of the studied patients had renal failure as a result of diabetic nephropathy. These results agree with the study of **Maguire et al. (2022)**, who stated that diabetes was the primary cause of ESRD. Conversely, **Sobh et**

al. (2019) & ElSharkawy et al. (2018) reported that the main known cause of end stage renal disease was hypertension. In Egyptian governorates, hypertension and diabetic nephropathy were the most frequent causes of ESRD, while glomerulonephritis had a lower rate, according to a recent data registry by **Hassaballa et al. (2022**). However, due to the rapid increase in the prevalence of obesity and diabetes, it is well established that diabetic nephropathy is now the leading cause of kidney failure in developed countries, along with hypertension nephropathy. Furthermore, results showed that less than half of the studied sample were suffering from peripheral vascular disease, which contradicts the findings of **Moustafa Abdallah Elpasiony et al. (2022**), who discovered that more than half of the HD patients under study had chronic health problems, particularly anemia.

The current study displayed that, the majority of the studied patients had AVF as a vascular access, and less than half of them had been on HD from 1 to less than 5 years, with a mean of 5.2 ±1.8 years. This came in line with **Maguire et al. (2022) and Moustafa Abdallah Elpasiony et al. (2022),** who observed most HD patients had AVF as the most current vascular access used, and **Abozead et al. (2018)**, who recorded more than half of patients started HD within 1 year to less than 5 years. While the study of **Rocha (2022)** disagrees with the current finding, which indicated that central venous catheter are the predominant type of vascular access in patients undergoing HD in Brazil.

Studying the main socio-demographic characteristics of the participant nurses showed that nearly half of the nurses had a technical institute and one third had a bachelor's degree this may be explained as families prefer technical institutes due to their shorter time and lower cost influenced by the economic conditions in their study area. The results agreed with **Sobh et al. (2019**) study who revealed that more than half of HD nurses were nursing institute graduates, and one third graduated with a bachelor's degree. The present results disagree with the study of **Ahamed & Sallam (2018)**, who observed that more than half of nurses in HD units had a bachelor's degree. As well as **Jeesh et al. (2021)**, who reported that the majority of the studied nurses have a diploma degree. The study's differences may be attributed to factors like education, which may be influenced by social or cultural differences within the Egyptian community.

In relation to years of experience, results illustrated that less than half of nurses had less than 5 years of experience, with a mean SD = 5.9 ±2.3 years, which agrees with **Mrayyan (2022) and Shahdadi & Rahnama (2018)** results who found approximately similar years of experience in HD units, while disagreeing with the study of **Abdo et al. (2020)**, who recorded that more than half of dialysis nurses had work experience ranging from 6 to 10 years.

Findings of the present study indicate that the majority of the studied nurses did not receive training workshops about patient safety. This may be explained as a shortness of nursing time due to a preoccupation with providing nursing care for HD patients. These findings are similar to those of **Ahamed & Sallam (2018)**, who found that more than two-thirds of nurses in HD units did not attain any training program.

Results displayed that more than three-quarters of nurses exhibited unsatisfactory performance levels before implementing a patient safety checklist, while nearly two-thirds showed satisfactory performance levels after the checklist was applied. This may be explained by nurses' need to improve their performance as well as the simplicity, feasibility, and acceptable safety checklist for use among their study participants in the HD unit. **Saleh, Ali, and Afifi (2018)** supported these results and reflected that only one-third of nurses had satisfactory performance pre-intervention, while most achieved very good or excellent improvement in overall performance post-intervention. In the same respect, a study by **Younis et al. (2022)** stated that the majority of the studied nurses had an unsatisfactory practice level compared with most of them having a satisfactory level of practice after their educational program.

The study found significant variations in patient safety parameters and total scores during HD phases and overall patient safety outcomes

before and after using a patient safety checklist. These findings agree with results obtained by **Mrayyan (2022)**, who reported significant differences in the total score of patient safety culture outcomes; these differences highlight additional aspects that hospitals and nursing leaders must consider when addressing patient safety. As well as the study of **Ali Mohamed Ismail & Zayed Mohamed Ismail (2020)**, who recorded a highly statistically significant difference between pre- and post-applying of patient safety guidelines ($p \leq 0.001$) In contrast, results obtained by **Atashzadeh-Shoorideh (2022)** indicated that there is no significant difference in the level of adherence to patient safety guidelines at two university-affiliated hospitals.

Furthermore, **Albreiki et al. (2023)**, demonstrated that implementing practices like HD treatment technology training, risk detection tools, root cause analysis, dialysis nurses using HD checklists, and effective communication between employees and leadership can enhance safety culture in HD settings. From the researchers' point of view, improving hospital performance and service quality requires increasing patient safety practices and culture. Prioritizing safety-focused practices and using checklists can enhance patient safety culture and clinical outcomes.

The results show that, the patient safety checklist significantly reduced the total mean score of AEs for patients before and after application, with a statistically significant decrease. Results obtained came in the same vein as those of **Liu et al. (2022**), who showed that the AEs in the experimental group were significantly lower than those in the control group. Also, this result was consistent with the study of **Connolly et al. (2021)**, who examined the effectiveness of the patient safety initiative "In Safe Hands" and reported the initiative was successful in decreasing overall adverse event rates. Conversely, the study conducted by **Rocha (2019)** who observed that HD is a health care sector with high potential for the occurrence of AEs, and the most frequent AEs related to vascular access for HD are bleeding, double lumen catheter secretion, inadequate blood flow, and infection or signs of vascular access infection.

Moreover, the study of **Rocha (2022)** suggested that the importance of continuing education for human resource training and development in preventing AEs in dialysis units. Strategies include effective communication, medication error reduction, correct dialysis, equipment preparation, infection control, and checklist use. In summary, the study highlights applying a structured checklist in the HD unit to promote safety outcomes and the need for a more sensitive and verified patient safety measurement tool, as well as a series of interventions to promote safety culture.

Conclusion

According to the findings of the current study, the researchers concluded that the use of structured checklists is an effective safety strategy to decrease the frequency of AEs at HD units. It was evident that the use of safety checklists had led to significant improvements in patients' safety outcomes.

Recommendations

- A structured checklist can be routinely applied to prevent AEs and promote the patient safety culture in HD units.
- Providing training programs to orient health team personnel about the importance and elements of patients' safety strategies.
- Follow up on nurses' and other health team members' suggestions for AEs prevention and inclusion in the HD units' safety plans.
- Ongoing evaluation of nurses regarding adherence to standard nursing care and their compliance to safety parameters at HD units.

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