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Correlates to extravasation among patient receiving chemotherapy at a university hospital

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Aim

The aim of this study was to examine correlates associated with the occurrence of extravasations among patients receiving chemotherapy at a university hospital.

Background

Extravasation injuries are a medical emergency that have the potential to cause serious disability, diminish the patient's quality of life, and leave nurses vulnerable to the risk of malpractice claims.

Methods

The study was conducted at a university Hospital in Cairo, Egypt. A convenience sample consisting of 300 adult male and female patients as well as all nurses working at the outpatient chemotherapy clinic (10 nurses) constituted the study sample. The following tools were used: (a) Patient Risk Factors Assessment Checklist for Extravasations, (b) Intravenous Administration of Chemotherapy via A peripheral Vein Checklist, and (c) Extravasations Recording Checklist.

Results

Only 11.4% of the participants had developed signs and/or symptoms of extravasations. The highest incidence rates of extravasations were among patients with age range between 18 and less than 30 years, among female patients, and among those who cannot read and write (17.24, 16.23, and 17.24%, respectively). Similarly, it was highest among those with uterine cancer, those with breast cancer, those with BMI less than 18.5, those having diabetes, those having hypertension, and those receiving nonirritant chemotherapy namely carboplatin (16, 15.3, 12.6, 12.2, 19.56, 14.29%.

Conclusion

Correlates to extravasations could be categorized as patients, chemotherapy, and environmental and nurses performance-related factors. Conducting periodic in-service training program for nurses and developing a standardized protocol of care in chemotherapy intravenous administration were strongly recommended.

Keywords:

chemotherapy, correlates, extravasations

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Introduction

Cancer is a large family of diseases that involve abnormal cell growth with the potential to invade or spread to other parts of the body (American Cancer Society, 2015). Recently, an article published in Al-Ahram National News Paper revealed that 120 000 new patients with cancer will be diagnosed in Egypt annually (Zayed, 2015). Chemotherapeutic drugs have been widely used to treat patients diagnosed with cancer; however, this can lead to various complications, of which the most devastating is extravasation. Extravasation is defined as an inadvertent leakage of chemotherapeutic agents from its intended vascular pathway (Dougherty, 2013; Gibson *et al.*, 2013). It is considered as a medical emergency that has the potential to cause serious disability, diminish the patient's quality of life, and leave nurses vulnerable to the risk of malpractice claims.

Nevertheless, the incidence of chemotherapy extravasations among adults as published in the literature varies widely, ranging from 6 to 22% (Bellin *et al.*, 2010; Al-Benna *et al.*, 2013).

Extravasation is manifested by a wide range of symptoms, and early effects include swelling at the infusion site, redness, and changes that may include a cold sensation, burning, stinging, or pain. In contrast, late effects include marked induration, dystrophy, and potential loss of function of the affected limb which might progress to blister formation and necrosis leading to amputation (Doellman *et al.*, 2009; Al-Benna *et al.*, 2013;

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Schulmeister, 2014). There are various potential factors that might contribute to the etiology of extravasation injuries including – though no limited to – (a) fragility of patients veins, (b) experience of personnel administering injections, (c) site of cannulation, (d) number of vein puncture attempt before establishing an operational intravenous line, (e) injection technique, and (f) chemotherapy characteristics (Upton *et al.*, 2009).

The nurse has an important role in assessing and managing many of the problems experienced by the patients undergoing chemotherapy because of the systemic effects on normal cells as well as malignant cells. More specifically, the nurse must undertake all safety precautions in prevention of extravasation including (a) identification of potential risk factors of extravasations, (b) assessment of patients who need a central access device and refer them to the appropriate service for placement, (c) ongoing vein assessments to determine if administration of chemotherapy is causing veins to become fragile, and (d) close monitoring throughout chemotherapy infusion (Kreidieh *et al.*, 2016). Identification of potential risk factors and carrying preventive measures definitely can reduce the risk of extravasation. Therefore, the present study is designed to examine correlates associated with extravasations among patients receiving chemotherapy.

Significance

Extravasations increases morbidity, as it leads to some undesirable events such as prolonged times of hospitalization, unnecessary diagnostic procedures and treatments, extra workload for healthcare team, and the economic loss as well as threatening the lives of patients. There are a scarce number of studies conducted in Egypt in relation to extravasations, so carrying out this research surely will add to the body of nursing knowledge in relation to this area as well as it will shed light on this problem in Egypt. Furthermore, understanding risk factors that might predispose to extravasations among patients receiving chemotherapy will certainly help in prevention of the adverse health effects caused by extravasations.

Research question

What are the correlates associated with the occurrence of extravasations among patients receiving chemotherapy at a university hospital?

Patients and methods

Research design

A descriptive correlation design was utilized in this study.

Sample

A convenient sample consisting of 300 adult male and female patients receiving chemotherapy in addition to all available nurses working in the designated chemotherapy outpatient clinic constituted the study sample. Requirements for potential patients were them being 18 years and older, receiving chemotherapy at outpatient clinic, and connected with peripheral catheter (cannula). Nevertheless, patients connected with port catheter or central lines were excluded from the study sample. Data were collected for consecutive 6 months starting in May 2016 and completed by the end of December 2016.

Setting

The study was conducted in chemotherapy outpatient clinics at a university hospital in Cairo, Egypt.

Tools for data collection

Three tools constructed by the research investigator were used. The first was the Patient Risk Factors Assessment Checklist for Extravasation. It consisted of three sections, the first section included questions related to patient personal and medical data such as age, sex, and level of education. The second section contained data to assess chemotherapy-related factors, such as type of chemotherapy and number of chemotherapy cycles. The final section covered environmental or work place-related factors such as presence of extravasation kit and portable lighting availability.

The second tool was Intravenous Administration of Chemotherapy via A peripheral Vein Checklist. It includes five sections. The first section contained personal and background data for nurses such as age, level of education, and years of experience in chemotherapy administration. The second section included items related to preinsertion nurses skills. In contrast, the third and fourth sections involved nurses skills related to peripheral catheter insertion and nurse's skills related to administration of chemotherapy. The final section involved nurses skills related to peripheral catheter site monitoring.

Scoring system for assessing the level of performance of participating nurses was categorized into four levels: first level indicates very low performance level (<25%), second level indicates low performance level (25 to <50%), the third level indicates moderate level of performance (50 to <75%), and the fourth level indicates high level of performance (>75%).

The third tool was Extravasations Recording Checklist. It was devoted to assess the patient signs

and symptoms of extravasations such as skin color, skin temperature, and edema at the site of cannula.

Tools validity and reliability

Developed tools were submitted to a panel of five experts in the field of Medical Surgical Nursing as well as Oncology and Nuclear Medicine to evaluate its content validity. Modifications were carried out according to expert's judgments on clarity of sentences and appropriateness of the contents. Reliability was established using Cronbach's α which showed a satisfactory level for the three tools as follows: 0.76, 0.75, and 0.85 for Patient Risk Factors Assessment Checklist for Extravasation, Intravenous Administration of Chemotherapy via A peripheral Vein Checklist, and Extravasations Recording Checklist, respectively.

Pilot study

A pilot study was conducted on 10% of the participants to test the feasibility of the study and the study tools, as well as to examine issues related to design, sample size, data collection procedures, data analysis approaches, time, cost, and availability of participants similar to the study. Hence, a few items were modified according to participant's responses; participants who participated in the pilot study were excluded from the study sample, though nurses were included in the study sample.

Ethical consideration

The research approval was obtained from the Research and Ethics Committee at the Faculty of Nursing, Cairo University. Moreover, an official permission was obtained from the selected outpatient clinics' administrators. At the initial interview, each potential participant was informed about the purpose, the procedure, and the benefits of the study, and a cover letter explaining the research project was also read to them. They were informed as well that participation in the study is completely voluntary and they have the right to withdraw from the study at any time without any penalty.

Procedure

Once permission was granted to proceed with the proposed study and upon receiving the formal approval from the Ethics and Research Committee at the Faculty of Nursing, Cairo University. The research investigator proceeded with the data collection in the following sequences. The nurses who were responsible for the administration of chemotherapy in the outpatient clinic were approached individually by the research investigator. At that time, the nature and purpose of the study were explained to each. Those who choose to participate in the

study were asked to sign the consent form. During the initial interview, the research investigator fulfilled the personal and background data form.

Regarding patients, a list of potential patients who met the criteria for possible inclusion in the study was obtained daily from the head nurse of the outpatient clinics. Before cannulation and/or starting chemotherapy session and while the patient was waiting in the waiting area, each patient was approached individually by the research investigator. At that time, the nature and purpose of the study were explained, as well as other ethical considerations mentioned previously were assured. Those who choose to participate in the study were asked to sign the consent form. At this point, the first tool (Patient Risk Factors Assessment Checklist for Extravasation) was completed.

Once the responsible nurse started preparation for the administration of chemotherapy to a patient, the research investigator shadowed/observed the nurse to complete the second tool (Intravenous Administration of Chemotherapy via A peripheral Vein Checklist/observation). This step was carried out every time the nurse participant administered chemotherapy for patients, summing ~40 observations for each nurse.

Statistical analysis

The collected data were scored, tabulated, and analyzed using statistical package for the social sciences program, version 20 (IBM Corporation 1989, 2011. USA). Number and percentage were used to assess risk factors of extravasations by calculating incidence rates for different variables. The one-tailed *t*-test for independent samples was used to test difference in nursing performance according to incidence of extravasations. Moreover, mean and SD for each nursing performance dimension were calculated. A probability level of 0.05 was adopted as the level of significance for answering research question.

Results

Table 1 revealed that only 11.4% of participated patients experienced some signs and/or symptoms of extravasations at the injection site in the form of swelling, burning, stinging pain, or any other acute change at the injection site. Nevertheless, none of the participated patients had experienced hematoma and only two participants experienced limitation of the affected extremity mobility.

In relation to patients' sociodemographic risk factors, Table 2 verified that the highest incidence rate of

extravasation was among participated patients whose ages ranged between 18 years and younger than 30 years, female patients, widowed, and illiterate (17.24, 16.23, 30, and 17.24%, respectively).

Regarding patients' medical risk factors, Table 3 showed that the highest incidence rate of extravasation was among participants with BMI below 18.5 (12.6%). Moreover, it was high among participated patients who had diabetes mellitus and hypertension (12.2%). Furthermore, the incidence rate of extravasation was high among lethargic and dysphasic patients who had thin and fibrosed veins combined with lymphedema and scars at the injection site (17.9, 12.4, 14.3, 13.4, and 14.3%, respectively). In contrast, the highest incidence rate of extravasation regarding cancer diagnoses was among participated patients who had uterine cancer and breast cancer (16 and 15.3%, respectively).

With reference to chemotherapy-related risk factors, Table 4 verified that the highest incidence rate of

extravasation was among participated patients who had received nonirritant chemotherapy, namely, carboplatin, and they had finished one to three chemotherapy cycles and their schedule for attending at chemotherapy outpatient clinics were one session per month (every 21 days) (19.56, 14.29, 13.19, and 11.97%, respectively).

Table 5 verified that the total number of participated nurses in the study were 10. Their age ranged between 31 and younger than 55 years, with a mean of 38.2 ± 3.6 years, and nine nurses fell in the age ranged between 31 and 44 years. In relation to the level of education, eight (80%) participated nurses had secondary school nursing diploma and only two (20%) had bachelor degree in nursing. Regarding current working position, 86% of participated nurses were staff nurse.

It was clear from Table 5 that nine of 10 participated nurses have been working in the administration of chemotherapy since they joined the nursing field and

Table 1 Frequency and percentage distribution of extravasation signs and/or symptoms among all participated patients (N=420)^a

Signs and/or symptoms	Yes [n (%)]	No [n (%)]
Swelling around the intravenous site	48 (11.4)	372 (88.6)
The patient complains of burning, stinging pain	48 (11.4)	372 (88.6)
Reduction and/or stopped in the flow rate of the infusion	48 (11.4)	372 (88.6)
Resistance on administration and no back flow of blood	48 (11.4)	372 (88.6)
Change in skin color (pink)	48 (11.4)	372 (88.6)
Change in skin temperature (hot)	48 (11.4)	372 (88.6)
Edema at site of cannula	48 (11.4)	372 (88.6)
Limitation of affected limb mobility	2 (0.4)	418 (99.6)
Hematoma formation	0 (0.0)	420 (100)

^aTotal is different from the number of participating patients as total number indicates number of observations (N=420).

Table 2 Incidence rate of extravasation according to patients' sociodemographic risk factors (n=48)

Risk factors	Category	Column 1 ^a	Column 2 ^b	Incidence rate ^c
Age	18 to <30	05	029	17.24
	30 to <43	04	024	16.67
	43 to <56	25	164	15.24
	56 to <69	12	071	16.90
	≥69	02	012	16.67
Sex	Male	17	109	15.60
	Female	31	191	16.23
Marital status	Married	35	210	16.66
	Single	03	040	07.5
	Widowed	06	020	30.0
	Divorced	04	030	13.3
Level of education	Cannot read and write	15	087	17.24
	Primary	18	114	15.79
	Preparatory	02	013	15.38
	Secondary	09	056	16.07
	University	04	030	13.33

^aColumn 1: n=48. ^bColumn 2: N=420. ^cIncidence rate (%)=number of participated patients with extravasations (n=48) (Column 1) divided by total number of all observations for participated patients (N=420) (Column 2) multiplied by 100. Bolded values mean, it is the highest incidence rate values in relation to other values within the same category.

had experiences that ranged between 18 and less than 23 years, with a mean of 19.4 ± 2.8 years. In relation to nurses-to-patients ratio, the majority of participated nurses (eight out of 10) were providing chemotherapy for 15 patients per shift. Moreover, all participated nurses reported that they did not receive any training courses regarding administration of chemotherapy.

Table 6 confirmed the significant relation between incidence of extravasations and nurses' performance in preinsertion assessment, as mean performance with extravasations is higher. There is also a significant relation between incidence of extravasations and nurses' peripheral catheter insertion performance, as mean performance without extravasations is higher. Moreover, there is a significant relation between the incidence of extravasations and nurses' administration of

chemotherapy performance, as mean performance without extravasations is higher. Furthermore, there is a significant relation between the incidence of extravasations and total nurses' performance, as mean performance without extravasations is higher. This indicates that extravasations are related to poor nurses' performance.

Discussion

The incidence of extravasation among participated patients was 11.4%. This result is synchronized with Schulmeister (2011) and Yarbrow *et al.* (2011), who stated that the incidence of chemotherapy extravasations among adults as published in the literature ranged from 6 to 22%. In contrast, this result is inconsistent with Rose *et al.* (2008), who

Table 3 Incidence rate of extravasation according to patients medical risk factors (n=48)

Risk factors	Category	Column 1	Column 2	Incidence rate
BMI	<18.5	3	24	12.6
	18.5 to <25	19	160	11.9
	25 to <30	20	169	11.8
	≥ 30	6	67	8.9
Comorbidities	Diabetes mellitus	12	104	11.6
	Hypertension	4	35	11.4
	Diabetes and hypertension	6	49	12.2
Level of consciousness speech	Alert	44	398	11.1
	Lethargic	04	022	17.9
	Dysphasia	04	032	12.4
	No speech disorders	44	388	11.3
Nature of patient veins	Thin	01	007	14.3
	Thin small	26	245	10.6
	Fragile	11	062	12.7
	Fibroses	02	087	14.3
	Patent	08	067	11.9
Local vascular problems	Lymphedema	12	090	13.4
	No	36	330	10.9
Scars at the injection site	No	44	329	11.2
	Yes	04	028	14.3

Bolded values mean, it is the highest incidence rate values in relation to other values within the same category.

Table 4 Incidence rate of extravasation according to chemotherapy-related risk factors (n=48)

Risk factors	Category	Column 1	Column 2	Incidence rate
Types of chemotherapy	Irritant	29	046	11.98
	Nonirritant	09	073	19.56
	Vesicant	09	245	06.82
Number of chemotherapy cycles	1–3	12	091	13.19
	4–6	26	261	12.04
	7–10	10	113	08.85
	Mean \pm SD	4.9 \pm 1.9		
Number of chemotherapy sessions	One	14	117	11.97
	Two	13	117	11.11
	Three	21	184	11.41

^an=48, number of patients with extravasation. Bolded values mean, it is the highest incidence rate values in relation to other values within the same category.

Table 5 Frequency and percentage distribution of personal and background characteristics among participated nurses (n=10)

Variables	Category	n (%)
Age	31 to <44	9 (90)
	44 to <55	1 (10)
	Mean±SD	38.2±3.6
Level of education	Secondary school nursing diploma	8 (80)
	Bachelor degree in nursing	2 (20)
Current position	Staff nurse	8 (80)
	Charge nurse	2 (20)
Years of experience as general	12 to <17	1 (10)
	18 to <23	9 (90)
	19.4±2.8	
Years working with chemotherapy administration	12 to <17	1 (10)
	18 to <23	9 (90)
	19.4±2.8	
Nurses-to-patients ratio	1 : 10	1 (10)
	1 : 15	8 (80)
	1 : 20	1 (10)
Training courses related to chemotherapy	Yes	0 (00)
	No	10 (100)

Table 6 Independent t-test relationship between nurses' performance and incidence of extravasation

Incidence of extravasation	No ^a		Yes ^b		t-Value	P-value
	Mean	SD	Mean	SD		
Nurses performance						
Preinsertion assessment	0.17	0.06	0.21	0.11	3.1	0.002*
Peripheral catheter insertion	0.54	0.08	0.50	0.14	2.9	0.003*
Administration of chemotherapy	0.81	0.05	0.53	0.18	24.5	0.0001*
Peripheral catheter site monitoring	0.20	0.01	0.22	0.26	1.3	0.19
Total	0.43	0.03	0.36	0.06	13.3	0.0001*

^aPatients without extravasation (n=372). ^bPatients with extravasation (n=48). *P<0.05, significant.

stated that incidence rate of extravasation ranged between 0.1 and 5% for chemotherapeutic agents. The variability of incidence rate could be explained as the published rate is likely to be underestimated, as many cases of extravasation go unreported and to the differences in the monitoring and notification systems for extravasation between hospitals.

In relation to patients' sociodemographic risk factors, it was found that extravasation occurred mostly between patients whose age ranged from 18 to less than 30 years. This result is supported by Schulmeister (2011), who reported that young patients are at more risk for the occurrence of extravasation. This could be explained by the fact that young participants were active and the majority of them were using their mobile phones during chemotherapy administration and they were very irritable. Based on literature review, patient movement is a well-described risk factor for extravasation (Pérez Fidalgo *et al.*, 2012). In contrast, Cassagnol and McBride (2009) indicated that patients 50 years or older are more at risk for exposure to extravasation. The latter author rationalized their statement by stating that the nature of veins for those patients is more fragile.

This interpretation is well supported by one of the study finding which revealed that patients with small and/or fragile veins are more at risk for the development of chemotherapy extravasation.

The fact that most participants in the study belong to female sex – the numbers of female participants in this study were double the number of male participants – and the commonest diagnoses were breast cancer and uterine cancer could provide a plausible explanation for the finding of the high incidence rate of extravasation among female patients in this study. This finding is in agreement with Camp-Sorrell (2010) and Una Cidon *et al.* (2011), who reported that most patients who developed extravasation in their studies were female. However, the findings of this study was inconsistent with Sauerland *et al.* (2006), who reported that fewer female patients than male patients had extravasation (female : male ratio=1 : 4.4). This discrepancy could be attributed to the sampling techniques used in these studies.

The incidence rate of extravasation happened to be higher among those patients who cannot read and write. This result is supported by Dougherty (2008), who reported

that uneducated and inexperienced personnel may pose a higher risk for extravasation, particularly during cytotoxic administration. This finding is congruent with Mohamed (2015), who found that half of their studied participants (50.9) who developed extravasation were illiterate. This result might be explained in light of the finding that most of the participated patients came from nearby rural areas where illiteracy is a common problem. Nevertheless, this result contradicts Pikó *et al.* (2011) who reported that the incidence of extravasation mostly occurs in highly educated personnel. Again, this discrepancy could be attributed to the sampling techniques used in these studies.

It is clear from the result of the current study that the incidence rate of extravasation was higher among participated patients whose BMI was below 18.5. This finding is congruent with Ahmed *et al.* (2011), who reported that extravasation injuries are more severe in patients with low muscular mass and atrophic subcutaneous tissue. This might be attributed to the fact that when the patients have low BMI, irritation from the peripheral catheter is very likely to cause mechanical phlebitis and possibly extravasation formation.

The current study revealed the occurrence of high incidence rate of extravasation among patients who had breast cancer. This result is supported by World Health Organization (2015) which declared that women diagnosed with breast, uterine, and colon cancers are more liable to develop extravasation. This result could be explained by the fact that the main protocol of care for patients diagnosed with breast cancer was adjuvant chemotherapy with four cycles followed by radiation therapy. Surely after four cycles their veins will be fragile. Moreover, most patients with breast cancer developed lymphedema, which is considered as one of the most important risk factors in the development of extravasation (Coyle *et al.*, 2014).

The current study findings denoted that the incidence rate of extravasation was higher among patients with lymphedema. The result of this study is in agreement with Ahmed *et al.* (2011), who reported that patients with lymphedema are less able to tolerate extravasation than those with a normal circulation. This finding is consistent also with Coyle *et al.* (2014) who reported that other problems from cancer or other diseases that might increase risk for extravasation include compromised circulation (e.g. lymphedema). This could be explained by the fact that patients with lymphedema had prior axillary lymph node dissection; hence, potential venous access sites are reduced.

Moreover, in most cases, venous access is limited to one arm only.

Regarding chemotherapy-related factors, the result of the current study depicted a high incidence rate of extravasation among patients who had received nonirritant chemotherapy. The result is congruent with Ahmed *et al.* (2011) and Sakaida *et al.* (2014) who reported that no relation between extravasation and types of chemotherapy. In contrast, the finding of the current study is an eye opener to Molas-Ferrer *et al.* (2015) statement that every 'patient who receives irritant and vesicant chemotherapy is at risk for extravasation' (p.2).

Carboplatin is chemotherapy of choice to treat a number of forms of cancer including ovarian, uterine, breast, lung, head, and neck cancers. Owing to the fact that most participated patients were diagnosed either with uterine or breast cancer and received carboplatin as a treatment of choice according to their diagnoses and to international cancer management protocols, the result of the current study affirmed the high incidence rate of extravasation among patients who had been receiving carboplatin. This study finding is congruent with the studies by Schulmeister (2011) and Revannasiddaiah *et al.* (2013), as they reported that chemotherapy drug with most frequently induced extravasation was carboplatin.

The finding of this study highlighted high incidence rate of extravasation with unfavorable environmental factors pertaining to high-level noise, distractions, and interruptions as well as unavailability of extravasation kits and/or portable lighting. This result may be logic in the presence of the increased number of patients receiving chemotherapy – up to 100 patients per day -- television set available for patients, and absence of a counter for preparation of chemotherapy.

The result of the current study revealed that there is a significant relationship between incidence of extravasations and level of nurses' performance. The higher the nurses performance, the lesser the incidence of extravasation, indicating that extravasations are strongly related to low nurses' performance. This current study finding is in harmony with Pikó *et al.* (2011) and Pluschnig *et al.* (2015) who listed 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

cannulas – particularly by inexperienced staff – may also increase the risk of extravasation. These findings could be explained by high workload, decreased patients–nurse ratio, and lack of training courses, as well as the unfavorable environmental circumstances.

Conclusion

Overall, 11% of participated patients developed signs and/or symptoms of extravasations. There are various potential factors that contributed to the etiology of extravasation, and these factors may be categorized as patients and/or physiological factors, chemotherapy and/or pharmacologic factors, environmental and/or work place factors, and nurses' performance-related and/or iatrogenic-related risk factors.

- (1) Patients-related correlates are age, sex, BMI, cancer diagnoses, presence of comorbidities, and thin, fibrosed veins, and scars at the injection site.
- (2) Chemotherapy-related correlates are patients receiving nonirritant therapy, namely carboplatin; had one to three cycles; and one session per month.
- (3) Nurses' performance-related correlates are the highest nurses' performance scores were during peripheral catheter insertion followed by administration of chemotherapy. However, the lowest performance scores were related to preinsertion assessment of peripheral cannula and peripheral catheter site monitoring.
- (4) Environmental-related correlates were the absence of extravasation kits, portable lighting, comfortable and sufficient place, and presence of high-noise and distractions/interruptions.

Implications and recommendations

- (1) Periodic in-service training programs for nurses working with chemotherapy intravenous administration should be provided.
- (2) Multidisciplinary clinical pathways to provide a standardized, comprehensive, and continuous patients care to those receiving chemotherapy should be developed.
- (3) The study on a larger probability sample selected from different geographical areas in Egypt should be replicated.

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Conflicts of interest

There are no conflicts of interest.

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