RESEARCH ARTICLE

Development and Psychometric Evaluation of the Patient Safety Violation Scale in Medical Oncology Units in Iran

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Abstract

Background: Patient safety is one of the key components of nursing care for cancer cases. Valid and reliable context-based instruments are necessary for accurate evaluation of patient safety in oncology units. The aim of the present study was to develop and evaluate the psychometric properties of the Patient Safety Violation Scale in medical oncology units in Iran. Materials and Methods: In this methodological study, a pool of 58 items was generated through reviewing the existing literature. The validity of the 58-item scale was assessed through calculating impact score, content validity ratio, and content validity index for its items as well as conducting exploratory factor analysis. The reliability of the scale was evaluated by assessing its internal consistency and test-retest stability. Study sample consisted of 300 oncology nurses who were recruited from thirteen teaching hospitals affiliated to Tehran University of Medical Sciences, Tehran, Iran. Results: Sixteen items were excluded from the scale due to having low impact scores, content validity ratios, or content validity indices. In exploratory factor analysis, the remaining 42 items were loaded on five factors including patient fall, verification of patientidentity, harm during care delivery, delay in care delivery, and medication errors. These five factors explained 62% of the total variance. The Cronbach's alpha of the scale and the test-retest interclass correlation coefficient were equal to 0.933 and 0.92, respectively. Conclusions: The 42-item Patient Safety Violation Scale is a simple and short scale which has acceptable validity and reliability. Consequently, it can be used for assessing patient safety in clinical settings such as medical oncology units and for research projects.

Keywords: Patient safety - instrument development - psychometric evaluation - oncology - nursing

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Introduction

Healthcare providers have embarked on a longstanding task to provide the best possible care to patients diagnosed with various types of cancer (Charalambous et al., 2009). Nonetheless, clients are occasionally injured in these systems which seriously affect patient safety (Kuzel et al., 2004). Patient safety has been defined differently. The simplest definition is: protecting clients and patients from unwanted errors and injuries (Who, 2015). Patient safety is one of the vital aspects of quality care delivery and a determining factor in clients' health. It is considered as a high priority of healthcare systems in developed countries (Aspden et al., 2004). According to the World Health Organization's definition, patient safety is: decreasing the risk of injuries to patients in healthcare settings (Runciman et al., 2009). Moreover, patient safety has been defined as identifying, analyzing, and managing medical errors in order to minimize errors and provide safer care.

Approximately 10% of all patients is in some way harmed by the health care system. Risk factors have been identified and patients with cancer are at high risk due to the seriousness of the disease, co-morbidity, often old age, high risk treatments such as chemo and radiotherapy. Therefore, a closer look on safety for patients undergoing chemotherapy is needed (Kullberga et al., 2013). Currently, patient safety is a matter of paramount importance. oncology is an ever-advancing, complex, technologically based specialty that has been thrust into the public spotlight because of recent reports of serious treatment delivery errors that have impacted the Safety of patient care (Chera et al., 2012).

The contribution of the nurses has been acknowledged throughout the earlier times when the aim was to attain quality care to the later ones where the focus was shifted to retaining the high levels of care (Charalambous et al., 2009). As nursing is an interpersonal event (Rooyen et al., 2008), the context of oncology nursing relies on an intricate matrix of therapeutic, collegial, and professional relationships. Several articles described the therapeutic relationship established between oncology nurses and cancer patients as ''unique'' (Bakker et al., 2006) and

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''unlike the relationship with any other patient.'' (Rooyen et al., 2008). The nurse-patient relationship is intense and of long duration and includes connecting with and navigating patients and families through their cancer journey from diagnosis through to death or survivorship (Bakker et al., 2013).

All countries which are members of the World Health Organization have been required to prioritize patient safety and develop policies and strategies for enhancing it (Who, 2015, Iom, 2000). However, evidence shows that medical errors and patient safety violation are among the most serious health-related concerns. The World Health Organization's reports show that one tenth of hospitalized patients suffer from the negative outcomes of medical errors. The Institute of Medicine also reported that 44000-98000 Americans have died so far due to medical errors (IOM, 2000). Medical errors in other countries are as common as 2.9-16.6%-most of which being preventable (Thomas et al., 2000, Brennan et al., 2004). However, there are limited data on the prevalence of medical errors and patient safety in medical oncology wards in developing countries (Bates et al., 2009). and hence, it is necessary to conduct further studies for measuring patient safety in these countries. McLoughlin et al. (2006) and Bottle and Aylin (2009) highlighted the necessity for further studies in all countries for creating patient safety indices (Mcloughlin et al., 2006, Bottle and Aylin, 2009).

The ongoing evolution of safety challenges in oncology requires corresponding evolution in caring programs to ensure the Safety of patient care. Patient safety and medical errors are measured through assessing documented events and errors despite the fact that not all events and errors are documented or reported accurately (Elfering et al., 2006). In many instances, patient safety data are obtained from nurses' verbal reports as well as their subjective perceptions. Consequently, developing effective systems and valid instruments for assessing medical errors and patient safety seems crucial. The aim of this study was to develop and evaluate the psychometric properties of the Patient Safety Violation Scale (PSVS) in medical oncology wards.

Background in Iran

The Iranian Ministry of Health and Medical Education has recently established the Clinical Governance System for improving care quality and patient safety. Nonetheless, only few studies have been conducted on patient safety in Iran and hence, limited data exist on patient safety and patients' complaints (Moghaddasi et al., 2007). The results of a local study in Iran showed that patients' complaints of medical errors have increased (Jafarian et al., 2009). A significant factor contributing to poor error reporting may be lack of valid instruments for evaluating medical errors and patient safety.

Materials and Methods

This methodological study was conducted in a number of hospitals associatated with the Tehran University of Medical Sciences, Iran, in 2011. The PSVS was developed using the Schwab's Approach (Schwab, 1980).

Item generation

We conducted a literature review for generating the preliminary items of the PSVS. Accordingly, the databases of Ovid, PubMed, Science Direct, and ProQuest were searched by using the key terms of 'psychometric evaluation', 'patient safety', 'instrument', oncology and 'nurse'. The results of this review revealed that none of the existing instruments comprehensively assess instances of patient safety violation. Moreover, this literature review helped us determine the domains of patient safety and generate a preliminary item pool for developing the PSVS. Items were arranged in a scale format. The primary PSVS contained 58 items.

Psychometric evaluation

Face validity assessment: The face validity of the PSVS was evaluated both qualitatively and quantitatively. For qualitative face validity assessment, ten oncology nurses were invited to comment on the difficulty, relevancy, and ambiguity of each PSVS item. The quantitative face validity was assessed by calculating the impact score of the items. Accordingly, the same ten oncology nurses were asked to rate the importance of each PSVS item on a five-point scale from 1 ('Unimportant') to 5 ('Completely important'). Then, the impact score of each item was calculated by employing the following formula, Impact score = Frequency (%) × Importance (Lang et al., 2004).

Content validity determines the relationship between the content of a measure and the intended construct (Cook and Beckman, 2006).

The content validity of the PSVS was also evaluated both qualitatively and quantitatively. Qualitative content validity assessment was done by asking ten experts in instrument development to determine the simplicity, clarity, and relevancy of the PSVS items. On the other hand, quantitative content validity of the scale was assessed by calculating the Content Validity Ratio (CVR) and the Content Validity Index (CVI) of the items. The CVRs of the PSVS items were calculated by asking a panel of seven experts in instrument development to rate each item on a three-point scale: 'Essential', 'Useful but not essential', and 'Not essential'. Then, the following formula was used for calculating the CVR of each item, CVR = (ne - N/2) / (N/2), (Rungtusanatham, 1998) where ne is the number of experts who rate the item as 'Essential' while N is the total number of experts. Both CVR_{strict} and $CVR_{relaxed}$ were calculated for each item. CVR values can range from -1 to +1. Items with a CVR_{strict} value of 0-0.62 and a mean score of 0.5 or higher were preserved in the scale (Lawshe, 1975).

Five experts in instrument development were invited to determine the relevance of the PSVS items on a four-point scale. Then, the CVI of each item was calculated through Moreover dividing the number of experts who had rated the item as 3 or 4 by the total number of experts. According to Polit and Beck (2006), when the number of experts is equal to 5, a CVI of 0.72 or greater is acceptable (Polit and Beck, 2006).

Construct validity assessment: The construct validity of the scale was assessed by conducting exploratory factor

analysis. The necessary sample size for factor analysis is equal to 5-10 times more than the number of items (Knapp and Brown, 1995).

Therefore, we recruited a stratified sample of 300 oncology nurses. The process of sampling was initiated by selecting thirteen hospitals from all 27 teaching hospitals with oncology units affiliated to Tehran University of Medical Sciences, Tehran, Iran. Then, a list of all nurses working in oncology units in each of these thirteen hospitals was created and sampling was done accordingly. The number of nurses which had to be recruited from each hospital was calculated through dividing the total number of nurses working in that hospital by the total number of nurses working in all thirteen hospitals and dividing the result by 300. The inclusion criteria were having an associate degree or higher in nursing, having physical and mental health, and having a work experience of more than one year in nursing in oncology units. Study participants were asked to complete the PSVS and a demographic questionnaire. The demographic questionnaire contained items on age, gender, marriage, employment status, educational status, working shift, work experience in nursing, and work experience in current position in oncology units. Thereafter, principal component exploratory factor analysis with orthogonal or varimax rotation was performed. The Kaiser-Meyer-Olkin (KMO) and the Bartlett's tests were conducted for evaluating sampling adequacy and factor analysis appropriateness, respectively. The number of factors was determined by using the scree plot and eigenvalues (Peterson et al., 2007).

Table 1. Participant Details

Demographic characteristics		Mean/%
Age		32±6.14 years
Gender	Male	13.3
	Female	86.7
Marital status	Single	36
	Married	64
Employment status	Official/permanent	26.7
	Official/provisional	56.7
	Post-graduation service	12.7
	Contract employment	4
Educational degree	Associate diploma	1.7
	Bachelor's	96.3
	Master's or higher	2
Working shift	Morning	20
	Evening	3.3
	Night	2.3
	Rotational	74.3
Work experience in nursing		7±6.034 years

Factors with an eigenvalue of 1 or greater remained in the factor structure of the PSVS. Moreover, factor loadings of 0.3 or higher were considered as acceptable (Hinkin, 1995).

Reliability assessment

The reliability of the PSVS was evaluated by using both the internal consistency and the test-retest stability approaches. Accordingly, 30 oncology units nurses were asked to complete the PSVS twice. The time interval between the test and the retest measurements was two weeks. Then, the Cronbach's alpha and the Interclass Correlation Coefficient (ICC) were calculated. ICC values of greater than 0.4 were considered as acceptable (Govender and Schlebusch, 2012).

Ethical considerations

This study was corroborated by the Ethics Committee of Tehran University of Medical Sciences. The confidentiality of participants' personal information was guaranteed and verbal informed consent was obtained from all of them.

Results

In total, 300 oncology nurses participated in this study. Table 1 shows participants' demographic characteristics.

In the face validity assessment phase, six items obtained an impact score of less than 1.5 and hence, were excluded from the scale. On the other hand, six more items were also excluded in the content validity assessment phase due to obtaining a CVR_{strict} of less than zero or higher than 0.62 or a mean score of less than 0.5. Accordingly, the number of items was reduced from 58 to 52 and then to 46. Then, CVI values were calculated for the 46-item PSVS. The CVI values of four items were less than 0.72. These items were also excluded from the scale. The final version of the PSVS which was used for construct validity assessment included 42 items.

The KMO test value was equal to 0.901, confirming that the study sample was adequate for factor analysis. Moreover, the Bartlett's test value was 519.69 with a P value of less than 0.0001, indicating the appropriateness of factor analysis. The scree plot showed that the PSVS contained five main factors (Diagram 1). Principal component analysis with orthogonal or varimax rotation revealed that the same five factors had eigenvalues of higher than 1. This five-factor structure was accountable for 62% of the total variance (Table 2). Factors were labeled according to their items and contents. Table 3 shows the factor structure of the PSVS and the factor loadings of the items.

Table 2. The total variance explained by the extracted factors before and after rotation

Component	Initial Eigen Values[a]			Extraction Sums of Squared Loadings			Rotation Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	7.492	36.686	36.686	7.492	36.686	36.686	1.943	9.514	9.514
2	2.36	11.555	48.242	2.36	11.555	48.242	6.822	33.409	42.923
3	1.349	6.608	54.85	1.349	6.608	54.85	1.236	6.051	48.973
4	1. 671	5.828	60.678	1.19	5.828	60.678	1.542	7.549	56.522
5	1.19	3.286	63.964	0.671	3.286	63.964	1.028	5.036	61.559

Table 3. The factor structure of the PSVS and the factor loadings of its items

Rotated Component Matrixa	1	2	3	4	5
Patient fall (% of Variance: 27.686)					
Fall while taking a break at bed	0.538	0.378	0.183	-0.288	0.217
Fall while transferring patient from bed to wheelchair/stretcher or vice versa	0.587	0.455		-0.209	
Fall while walking	0.52	0.282	0.105	-0.133	0.326
Fall while being in toilet	0.515	0.369			0.389
Fall from a wheelchair	0.543	0.416		-0.101	0.353
Verifying patient's identity (% of Variance: 15.53)					
Failure to verify patient's identity before conducting laboratory studies	0.379	0.542		-0.272	
Failure to verify patient's identity before performing diagnostic imaging studies	0.378	0.541	-0.286	-0.147	0.252
Administrating drugs without verifying patient's identity	0.334	0.586	-0.349	0.129	
Transferring a patient to operating room without verifying his/her identity	0.404	0.59	-0.417	0.112	
Transferring a patient to operating room without attaching an identity card to his/her hand	0.26	0.57	-0.289		
Inaccurate introduction of a patient to the nutrition unit and hence, administrating a wrong dietary regimen for him/her	0.257	0.542			-0.102
Failure to cross-check patient's identity with specifications printed on blood products	0.382	0.628	-0.405	0.132	
Discharging and delivering a patient (infant, elderly, etc.) to a wrong family	0.236	-0.497	0.304	0.128	
Harming patient during care delivery (% of Variance: 7.05)					
Harming patient while providing care (e.g. cutting his/her skin while shaving)	0.337	0.299	-0.565	0.274	-0.183
Causing burn while providing care (e.g. during cauterization or while applying a hot bag)		0.38	0.518	-0.234	-0.274
The occurrence or development of pressure ulcer(s) during hospitalization	0.209	0.249	0.468		0.227
Failure to control medical equipments and harming patients due to using faulty equipments (such as a faulty electroshock or suctioning device)	0.156	0.363	0.559		0.166
Delays in care delivery (% of Variance: 4.36)					
Checking and following physicians' orders	-0.398	-0.32	0.404	0.464	-0.117
Implementing cardiopulmonary resuscitation	-0.234	-0.286	0.142	0.548	-0.143
Referring to patient and fulfilling his/her needs when he/she rings call bell		-0.452	0.13	0.537	-0.205
Reporting a new hospitalization or a newly-developed acute condition to the attending physician	0.63			-0.632	-0.134
Sending samples to laboratories and reporting laboratory results to the attending physician	0.542			-0.658	
Responding to the alarms of equipments attached to patient	0.548			-0.643	
Performing diagnostic imaging studies	0.567			-0.588	
Administrating analgesics and relieving patient's pain		-0.549	0.125	0.618	
Managing patient's fever		-0.588		0.61	
Providing care while a patient experiences a hypersensitivity reaction		-0.528	-0.125	0.631	0.117
Transferring a critically-ill patient to critical care unit		-0.506	-0.152	0.524	0.238
Preparing a bed for admitting a new patient	0.529		-0.117	-0.531	0.147
Managing an active bleeding		-0.508	-0.213	0.643	
Managing a patient with chest pain		-0.404	-0.172	0.689	
Medication errors (% of Variance: 3.48)					
Early or late drug administration (administration time)	0.272	0.178	-0.125		0.692
Administration of a drug in a wrong time (either before or after meal)	0.317		-0.106	0.269	0.639
Failure to monitor patient while administrating drugs which need special attention (such as pulse rate or blood pressure monitoring)	0.35		0.39	-0.143	0.471
Mixing two or more drugs in an infusion set without considering probable drug interactions		0.302	0.348	0.133	0.495
Rapid infusion of a drug which should be infused at a slow rate	-0.153	0.326	0.312	0.144	0.448
Administrating several oral drugs simultaneously	0.214		0.422	0.323	0.515
Wrong administration route (intramuscular instead of intravenous or vice versa and intravenous instead of subcutaneous or vice versa)	-0.351	0.277	-0.217	0.129	0.567
Asking a patient to swallow a chewing or a sublingual drug	-0.397	0.155	-0.122		0.549
Administrating a drug without knowing its accurate administration route	-0.187	0.341	-0.216	0.113	0.6
Administrating a non-prescribed analgesic	0.35	0.197	0.229		0.447
Administrating a drug at doses higher or lower than the prescribed dose	-0.217	0.3	-0.131	0.235	0.51

*Extraction Method: Principal Component Analysis, [a]5 components extracted

Factor 1 encompassed five items relating to patient fall. The highest and the lowest factor loadings in this factor were related to the item of 'Fall while transferring patient from bed to wheelchair/stretcher or vice versa' and 'Fall while being in toilet'. The total variances explained by this factor before and after rotation were 36.686% and 9.514%, respectively.

The number of items falling into factor 2 was equal to eight. This factor dealt with verifying patient's identity. The highest and the lowest factor loadings in this factor

Table 4. The Cronbach's alpha values of the PSVS

Domains	Number of items	Cronbach's alpha (N = 300)	ICC
Patient fall	5	0.841	-
Verification of patient's identity	8	0.869	-
Harming patient during care delivery	4	0.526	0/52
Delays in care delivery	14	0.949	-
Medication errors	11	0.293	0/75
Total PSVS	42	0.933	-

were related respectively to the items of 'Failure to cross-check patient's identity with specifications printed on blood products' and 'Failure to verify patient's identity before performing diagnostic imaging studies'. The pre- and post-rotation variances explained by this factor were equal to 11.555% and 33.409%, respectively.

Factor 3 contained four items. All items falling into this factor were related to inflicting harm to patient during care delivery. The items of 'Harming patient while providing care (e.g. cutting his/her skin while shaving)' and 'The occurrence or development of pressure ulcer (s) during hospitalization' obtained respectively the highest and the lowest factor loadings. This factor was accountable for 6.608% (before rotation) and 6.051% (after rotation) of the total variance.

Factor 4 consisted of fourteen items in the area of delays in care delivery. The highest and the lowest factor loadings in this factor were related to the items of 'Managing a patient with chest pain' and 'Checking and following physicians' orders', respectively. The pre- and the post-rotation variances explained by this factor were respectively equal to 5.828% and 7.549%.

Finally, factor 5 contained eleven items in the area of medication errors. The items of 'Early or late drug administration (administration time)' and 'Administrating a non-prescribed analgesic' obtained the highest and the lowest factor loadings, respectively. The amounts of variance explained by this factor before and after rotation were respectively equal to 3.286% and 5.036%.

After construct validity assessment, we evaluated the reliability of the PSVS. The Cronbach's alpha of the scale was equal to 0.933, indicating a satisfactory internal consistency. The Cronbach's alpha values of factors 4 and 5 were less than 0.7. Consequently, we calculated a mean Cronbach's alpha value for these two items through summing the Cronbach's alpha values of all items in each these factors and dividing the result by the number of items in that factor. Finally, the mean Cronbach's alpha values of these two items were 0.52 and 0.75, confirming an acceptable internal consistency (Table 4). The pretest-posttest ICC of the total PSVS was 0.92 and the ICC values of the PSVS factors ranged from 0.63 to 0.91, confirming the stability of the scale over time.

The final version of the PSVS contained 42 items. Items were scored on a four-point Likert scale from 1 to 4 as follows, 1: Never; 2: 1-5 times; 3: 6-10 times; and 4: more than 10 times. Accordingly, the total score of the scale would be 42-168. Higher scores reflect lower patient safety.

Discussion

We conducted this study for developing the PSVS and evaluating its psychometric properties in medical oncology units. Study findings revealed that the 42-item PSVS had satisfactory psychometric properties and therefore.

The content validity of the PSVS was assessed both quantitatively and qualitatively. During content validity assessment, sixteen items were excluded from the scale. Finally, study findings revealed that the scale had acceptable content validity. Moreover, exploratory factor analysis was performed for construct validity assessment. The KMO test value was equal to 0.901. KMO values of higher than 0.80 indicate that the sample size is adequate for conducting factor analysis (Munro, 2005).

The results of exploratory factor analysis revealed a five-factor structure for the PSVS which explained 62% of the total variance. The five factors or domains of the scale included patient fall, verification of patient's identity, harming patient during care delivery, delays in care delivery, and medication errors. Teng et al. (2010) also reported that patient safety is a multidimensional phenomenon (Teng et al., 2010). Factor 1 contained five items in the area of patient fall. Patient fall is among the most prevalent nursing errors (Backer et al., 2007). The eight items of factor 2 were related to violating patient's identity verification. According to Staehl et al. (2010), verifying patients' identity before and during implementing medical and nursing procedures has a pivotal role in preventing medical and nursing errors (Stahel et al., 2010). The third factor contained four items relating to harming patients during care delivery. Hsu and Hsieh (2013) noted that careful care delivery can help prevent patients from harms and injuries (Hsu and Hsieh, 2013). The fourteen-item factor 4 was related to delays in care delivery. When care is delivered with delays, some aspect of patient care may be missed and the quality of care is significantly reduced (Rutebemrwa et al., 2009). Finally, factor five included eleven items and dealt with medication errors. Medication errors are also among the most common nursing errors and can seriously threaten patients' lives (Stetina et al., 2005).

Study findings also revealed that the Cronbach's alpha of the PSVS was 0.933. Cronbach's alpha values of greater than 0.7 reflect acceptable internal consistency (Gliem and Gliem, 2003). Moreover, the pretest-posttest ICC was equal to 0.92 which confirmed acceptable stability of the scale. According to Terwee et al. (2007), ICC values which are higher than 0.4 represent satisfactory stability (Terwee et al., 2007). A reliable instrument can help detect significant correlations and differences.

In conclusion, As the population ages, the number of people with or at risk for cancer will also grow, placing increased demands for oncology nursing care. Thus, recruitment and retention of nurses with specialized knowledge and skill in the care of cancer patients and their families will continue to be a major health human resource issue over the next decades. To achieve quality cancer

care, healthcare administrators need to better understand the contextual attributes and forces that can be modified to both improve the context of oncology nursing and effectively meet the care needs of cancer patients and their families. Study findings indicate that the 42-item PSVS is a valid and reliable scale for assessing instances of patient safety violation. The PSVS is a simple and short scale whose items were worded succinctly. Consequently, this scale can be used for assessing patient safety in oncology units and research projects.

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