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Tool Development to Assess Nausea and Vomiting Among Patients Receiving Chemotherapy

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Abstract

The purpose of this study was to develop a psychometrically valid and reliable tool to assess nausea and vomiting among patients with cancer who receive chemotherapy treatment. Nausea and vomiting are considered the most common side effects for chemotherapy treatment. Several tools are available in the literature to assess nausea and vomiting, but it lacks the thorough measure of these symptoms. This has led to the development of a new tool, which combined all important assessment elements for nausea and vomiting. Standardized steps for developing the tool were followed, which include; explicating the objectives, blueprinting, and tool construction. The constructed tool has 24 items in which captures all the characteristics of nausea and vomiting. Cronbach's alpha for this tool is 0.97. The content validity index is 0.88. The concurrent validity with Rhodes Index of Nausea, Vomiting, and Retching (INVR) was established

Keywords: Tool development; Nausea & Vomiting; Cancer; Chemotherapy

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Introduction

Nausea and vomiting are considered common and distressing side effects of cancer treatment[1,2]. If not controlled, nausea and vomiting can cause serious complications such as electrolyte imbalances, anorexia, weight loss, dehydration, and deterioration of the general condition of the patient[3,4].The severity of nausea and vomiting may lead to lowering the administered doses of chemotherapy. In addition, uncontrolled vomiting can cause patients to refuse or abandon treatment, which signifies that nausea and vomiting are still problems for patients with cancer receiving treatment[5].

Recent studies demonstrated that nausea and vomiting significantly affect social activities, work-related aspects, and daily activities domains of quality of life[6,7]. Reducing the length and severity of chemotherapy-induced nausea and vomiting helps patients retain their ability to maintain normal life functions, including caring for themselves and sustaining their relationships with others[8].

According to Rhodes and McDaniel (2001), nausea is defined as "an unpleasant sensation experienced in the back of the throat and the epigastrium that may or may not result in the expulsion of material from the stomach" and vomiting involves the actual forceful upward expulsion of contents from the stomach[9,10].

The Rhodes Index for nausea, vomiting and retching (INVR), developed by Rhodes & McDaniel (1999), has a total of eight items, using a 5-point Likert scale, capturing nausea, vomiting and retching (NVR), and the components (frequency/amount, duration, severity, distress) of each symptom in the previous 12 hours. Spearman Correlation Coefficient for this tool is 0.87, Split-half reliability is 0.90, and Cronbach's Alpha is 0.98[11]. The defect in this tool is that the items are not linked to the timing of chemotherapy administration so it will be difficult to assess whether this is an anticipatory, acute or delayed nausea and vomiting. Therefore, it is very important to link the questions on the characteristics of nausea and vomiting with the time that the treatment received by the patient.

There is another tool developed later by the Multinational Association of Supportive Care in Cancer (MASCC) for the assessment of nausea and vomiting after cancer treatments, the MASCC Antiemesis Tool (MAT). The MAT was designed to be a short self-administered tool that can be easily used in clinical practice to measure both acute and delayed nausea and vomiting. The major advantage of the MAT over other nausea and vomiting scales is that the MAT is completed once per cycle of chemotherapy, thereby avoiding repeated daily assessments and minimizing both patient and clinician burden[12]. This tool has a total of eight items, asking about the occurrence, frequency, and severity of both acute (within the first 24 hours of chemotherapy treatment) and delayed nausea and vomiting (after 24 hours of treatment to 4 days after chemotherapy treatment). Internal consistency Cronbach's alpha is 0.77 - 0.82 and the concurrent validity with INVR tool r = 0.86. This tool does not include items about the duration of nausea and vomiting and the amount of the vomiting. In addition, the tool does not have any items related to the anticipatory nausea and vomiting.

We notice that each one of the three tools does not fully capture the full characteristics of nausea and vomiting experience, so there is a need to develop a tool to be comprehensive in the assessment of nausea and vomiting. Therefore, the purpose of this study was to develop a valid and reliable tool to assess nausea and vomiting for patients with cancer receiving chemotherapy. With the consideration of being easy to use, parsimonious, capture all the periods of nausea and vomiting, and anticipatory for acute and chronic episodes of nausea and vomiting. Furthermore, to assess the psychometric properties of the new tool with a group of patients with cancer who are receiving chemotherapy treatment?

Designing a Norm-Referenced Measures

According to Waltz, Strickland, and Lenz in their measurement textbook for nursing and health research, they delineated certain steps to be followed in designing a norm-referenced measure[13]. These steps include: deciding the conceptual model, explication of objectives, development of a blueprint; and construction of the measure.

Conceptual Framework: Nausea and vomiting are caused by a complex interaction of nerve impulses between the brain and stomach. Progress has been made in understanding the neurophysiologic mechanisms that control nausea and vomiting (emesis) (N&V). Both are controlled or mediated by the central nervous system but by different mechanisms. Nausea is mediated through the autonomic nervous system. Vomiting results from the stimulation of a complex reflex that is coordinated by a putative true vomiting center, which may be located in the dorsolateral reticular formation near the medullary respiratory centers. The vomiting center presumably receives convergent afferent stimulation from several central neurologic pathways, including the following[14].

The chemoreceptor trigger zone (CTZ) is located in the area postrema, one of the circum ventricular regions of the brain on the dorsal surface of the medulla oblongata. Unlike vasculature within the blood-brain diffusion barrier, the area postrema is highly vascularized with fenestrated blood vessels, which lack tight junctions between capillary endothelial cells. The CTZ is anatomically specialized to readily sample elements present in the circulating blood and cerebrospinal fluid[15,16].

Currently, evidence indicates that acute emesis following chemotherapy is initiated by the release of neurotransmitters from cells that are susceptible to the presence of toxic substances in the blood or CSF. Area postrema cells in the CTZ and entero chromaffin cells within the intestinal mucosa are implicated in initiating and propagating afferent stimuli that ultimately converge on central structures corresponding to a vomiting center. The relative contribution from these multiple pathways culminating in nausea and vomiting symptoms is complex and is postulated to account for the variable emetogenicity (intrinsic emetogenicity and mitigating factors (dosage, administration route, and exposure duration) and emetogenic profile (i.e., time to onset, symptom severity, and duration) of agents.

Explicating the objectives: The second step in developing a tool is explicating the objective. The behavioral objectives of the tool are stated by using Tyler and Kibler's approach, where the objective is composed of three components: (1) a description of the respondents; (2) delineation of the kind of behavior the respondent will exhibit to demonstrate accomplishment of the objective; and (3) a statement of the kind of content to which behavior relates[16,17]. The objective of this tool is to measure three kinds of nausea and vomiting (anticipatory, acute, and delayed) for patients with cancer receiving chemotherapy.

Blueprinting

The blueprint of the study is presented in Table 1

Table 1: Blueprint for a Measure to assess nausea and vomiting in patients with cancer receiving chemotherapy treatment

Objective	Content		
	Anticipatory N & V	Acute N & V	Delayed N & V
To assess the presence, duration, intensity & frequency of N & V among patients with cancer receiving chemotherapy	8	8	8
Total items	24		

Tool Construction

Administration: This tool is intended to be used with any patient with cancer, who is receiving chemotherapy and are at risk of having nausea and vomiting for better assessment and thus better management of those two distressing symptoms. The purpose of the study, direction how to fill the questionnaire was explained. Participants were assured that their anonymity and confidentiality will be maintained. Pilot testing of the tool will be conducted to assess the clarity of items, and the psychometric properties of the tool (Reliability and Validity).

Items: This tool has a total of 24 items, 8 items asking about the experience anticipatory nausea and vomiting, 8 items asking about the experience of acute nausea and vomiting, and the last 8 items asking about the experience of delayed nausea and vomiting. The items capture all the characteristics of nausea and vomiting that are needed in the assessment, including the occurrence

of the symptom, duration, frequency, severity, and the amount.

Translation: The original tools are available in English language except the (MAT) which has an Arabic version. Therefore, the English tools were translated, following a standardized method, into Arabic while maintaining the meaning of the items. Then, the tool was back translated by bilingual experts into the original language which resulted in an equivalent form.

Scoring: For the questions that have "yes" or "no" answer, "yes" will be assigned a value of "1", and " no" will be assigned a value of "0."

1. For questions asking about the duration of nausea, if the duration is less than one hour, the score is "1", if the duration is more than one hour, the score is "2."
2. For the questions asking about the severity of nausea and vomiting, mild will be assigned a value of "1", moderate will be assigned a value of "2", severe will be assigned a value of "3", and intolerable will be assigned a value of "4."
3. For the questions asking about the frequency of nausea and vomiting, "once" will be assigned a value of "1", "twice" will be assigned a value of "2" and so on.
4. For the questions asking about the estimation of the amount of vomiting, "small amount" will be assigned a value of "1", "moderate amount" will be assigned a value of "2", and "large amount" will be assigned a value of "3."

Methods

Design: This is a cross-sectional pilot study to assess the psychometric properties of the modified tool assessing nausea and vomiting among patients who receive chemotherapy treatment for cancer.

Sample: Convenience samples of 30 patients who have a diagnosis with cancer, and were receiving chemotherapy were included in this pilot study. Inclusion criteria also include patient's ability to read, not acutely ill, and willing to participate in this pilot study.

Setting: The study was conducted in a specialized cancer hospital in Jordan. The hospital has established programs that focus on all stages of comprehensive cancer care; from prevention and early detection, through diagnosis and treatment, to palliative care.

Ethical Consideration: The Institution Review Board in the hospital approved the study. The participation was voluntary to patients, and those who agreed to participate where included in the study.

Psychometric Analysis and Validation

Reliability: The attributes of reliability assessed with this tool is internal consistency(Cronbach's alpha coefficient), which is equal in value to the mean of the distribution of all possible split-half coefficients associated with a specific set of items. Cronbach's alpha was calculated using SPSS version 21, Cronbach's alpha for this tool is 0.97 which is considered high[18,19]. There was no much change in the reliability result if any of the items were deleted.

Validity

The attributes of validity assessed with this tool are content validity by two experts in the field (CVI). The concurrent validity with the INVR (Rhodes Index of Nausea, Vomiting & Retching) which is developed by Rhodes & McDaniel (1999).

Content Validity Index (CVI): The tool was given to two experts in the field of oncology to rate the relevance of the items to the objective on a 4-point Likert scale: (1) not relevant, (2) somewhat relevant, (3) quite relevant, and (4) very relevant. There was agreement about 21 items that are quite/very relevant, and 3 items somewhat relevant (items asking about the duration of nausea). The Content Validity Index (CVI) is defined as the proportion of items given a rating of quite relevant /very relevant by both raters involved[16]. The results are displayed in Table 2. For this tool, the CVI = 21/24 or 0.88 which is considered an acceptable level of CVI[13].

Table 2: Content Validity for the 24 items of the tool judged by two experts

	Judge 1		
Judge 2	**(1 or 2) not/somewhat relevant**	**(3 or 4) quite/very relevant**	**Total**
(1 or 2) not/ somewhat relevant	3	0	3
(3 or 4) quite/ very relevant	0	21	21
Total	3	21	24

Concurrent Validity: Concurrent validity is defined as the degree of correlation of two scales of the same concept administered at the same time. The concurrent validity of this tool was done with Rhodes Index of Nausea, Vomiting, and Retching (INVR). INVR is an eight-item scale measuring nausea, vomiting, and retching experience. Each item is measured on a five-point Likert scale, and subjects are asked to report their symptoms over the past 12 hours. Each response is assigned a number based on a predefined scoring algorithm. Cronbach's Alpha is 0.98[11,20].

Participants' were asked to answer the (INVR) after filling the modified tool in this project. The total score was calculated for each participant after reverse coding of items 1, 3, 6, and 7 in the INVR. Then Pearsons' correlation was calculated ($r = 0.94$, $P < 0.01$) which indicates that the concurrent validity of the modified tool with the INVR is high (Appendix I).

Appendix I: The Nausea and Vomiting Tool for Patients with Cancer Receiving Chemotherapy

A	Anticipatory Nausea and Vomiting
	1. Did you experience NAUSEA before your last chemotherapy treatment? a. Yes b. No (if no, please skip to question #5)
	2. How long did the NAUSEA last?--------- hours
	3. How would you describe the NAUSEA at its worst? a. Mild b. Moderate c. Severe d. Intolerable
	4. How many times you felt nauseated? ----------
	5. Did you experience VOMITING before your last chemotherapy treatment? a. Yes b. No (if no, skip to next part of the questionnaire).
	6. How would you describe the VOMITING at its worst before treatment? a. Mild b. Moderate c. Severe d. Intolerable
	7. How many times you vomited before treatment? ----------
	8. Estimate the amount of the vomiting before treatment. a. Small amount b. Moderate amount c. Large amount
B	Acute Nausea and Vomiting
	1. Did you experience NAUSEA during or within 24 hours of your last chemotherapy treatment? a. Yes b. No (if no, please skip to question #5)
	2. How long did the NAUSEA last? ---------- hours.
	3. How would you describe the NAUSEA at its worst? a. Mild b. Moderate c. Severe d. Intolerable
	4. How many times you felt nauseated? ----------
	5. Did you experience VOMITING during or within 24 hours of your last treatment? a. Yes b. No (if no, please skip to next part of the questionnaire).
	6. How would you describe the VOMITING at its worst? a. Mild b. Moderate c. Severe d. Intolerable
	7. How many times you vomited during or within 24 hours of treatment? -----
	8. Estimate the amount of the vomiting: a. Small amount b. Moderate amount c. Large amount
C	Delayed Nausea and Vomiting
	1. Did you experience NAUSEA 24 hour or more of your last chemotherapy treatment? a. Yes b. No (if no, please skip to question #5)
	2. How long did the NAUSEA last? ---------- hours.
	3. How long did the NAUSEA last? ---------- hours. a. Mild b. Moderate c. Severe d. Intolerable
	4. How many times you felt nauseated? ----------
	5. Did you experience VOMITING 24 hour or more of your last treatment? a. Yes b. No (if no, there is no need to answer the rest of the questions).
	6. How would you describe the VOMITING at its worst? a. Mild b. Moderate c. Severe d. Intolerable
	7. How many times you vomited 24 hour or more of treatment? ----------
	8. Estimate the amount of the vomiting: a. Small amount b. Moderate amount c. Large amount

Discussion

The main purpose for this study was to develop a psychometrically valid and reliable tool to assess nausea and vomiting among patients with cancer who receive chemotherapy treatment. The existing tools that measure nausea and vomiting has several limitations such as lacking questions regarding the frequency of nausea and vomiting, quantity of vomiting, not linked with the timing of chemotherapy administration, and not including items about the duration of nausea and vomiting[19,21,22].

The developed tool in this study has a total of 24 items divided into three subscales. A) The experience anticipatory nausea with 8; B) the experience of acute nausea and vomiting with 8 items; and C) the experience of delayed nausea and vomiting with 8 items. The developed tool is considered holistic and multidimensional in capturing all the characteristics of nausea and vomiting. Furthermore, it is considered easy to use, parsimonious, and captures all the periods of nausea and vomiting.

Conclusion

The developed tool combined all important assessment elements for nausea and vomiting. The researchers have followed a standardized approach for developing the tool. The validity and reliability of the new tool are established. However, it is recommended to assess the psychometric properties of the tool with a larger group of patients with cancer who are receiving chemotherapy treatment.

Conflicts of Interest: None

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