Original article

The validation of a newly developed Arabic scale to assess patient-reported side-effects of antineoplastic agents

Reem Alhaider [a], Yazed AlRuthia [a,*], Ghadah Almuaythir [b], Wejdan Alsharif [b], Hala Alrasheed [b], Shatha Asiri [b], Bushra Alghamdi [b], Khalid Alsaleh [c], Fahad D. Alosaimi [d], Sultan Alghadeer [a], Azher Arafah [a]

[a] Department of Clinical Pharmacy, College of Pharmacy, King Saud University, Riyadh, Saudi Arabia
[b] College of Pharmacy, King Saud University, Riyadh, Saudi Arabia
[c] Department of Hematology/Oncology, College of Medicine, King Saud University, Riyadh, Saudi Arabia
[d] Department of Psychiatry, College of Medicine, King Saud University, Riyadh, Saudi Arabia

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ABSTRACT

Background: Multiple scales in different languages were developed to measure patient-reported side effects of antineoplastics. However, these scales vary in their coverage of antineoplastics' side effects, and none of them address both the severity and impact of antineoplastics' side effects on patient quality of life. Hence, there is a need to develop a comprehensive, concise, and general scale to assess patients' perceptions of both severity and impact of the commonly reported side effects of antineoplastics on patients' activities of daily living and make it available in Arabic.

Objectives: To develop and validate a new scale in Arabic to assess patient-reported antineoplastics' side-effects among Arabic-speaking patients undergoing chemotherapy.

Methods: A new scale was developed in Arabic that addresses 40 different emotional, cognitive, and physical side-effects of antineoplastics. The Antineoplastic Side effects Scale (ASES) contained three sub-scales focused on the side effects frequency, severity, and interference with patients' activities of daily living. Seventy-eight patients with different cancer types were recruited from the oncology clinics of a university-affiliated tertiary care hospital in Riyadh, Saudi Arabia. The reliability of the questionnaire was examined using Cronbach's alpha method. The construct validity was examined using principal component analysis with varimax rotation. The association between the scores of ASES subscales and various patient medical and sociodemographic characteristics were also examined.

Results: The mean age of participants was 53.8 (12.5) years and most of them were female (65.3%) and married (84.6%). The ASES demonstrated good internal consistency (Cronbach's alpha = 0.91). The severity of the perceived side effects and their impact on activities of daily living were positively associated with female gender.

Conclusion: The newly developed ASES demonstrated good validity and reliability. This tool will hopefully help healthcare providers and patients to identify commonly reported antineoplastic side effects.

1. Introduction

Cancer is one of the leading causes of morbidity and mortality globally. The World Health Organization (WHO) estimated that cancer led to 9.6 million deaths worldwide in 2018, indicating that 1 in 6 deaths was due to cancer (World Health Organization, 2018). According to the International Agency for Research on Cancer, the number of newly diagnosed cases of cancer is expected to increase by 70% over the next two decades (Stewart and Wild, 2014). In Saudi Arabia, the number of newly diagnosed cancer cases in 2014 was 15,807. Among them, 76% were Saudi citizens, and women represented 52.8% of the cases (Cancer Incidence Report Saudi Arabia, 2014).

Despite the recent advances in molecular biology and immunology of cancer, chemotherapy remains the most commonly used therapeutic modality (DeVita and Chu, 2008). Several studies have

proven the efficacy of chemotherapy in improving the survival rates among patients with different types of cancer (Miller et al., 2016). However, chemotherapeutic agents cause a broad spectrum of adverse drug reactions that are both physical and psychological in nature (Griffin et al., 1996; Oh, 2017). The antineoplastics' side effects range from mild, such as nausea and vomiting (Kayl and Meyers, 2006; Kamen et al., 2014), and hair loss (Chon et al., 2012), to severe adverse drug reactions, such as cardiac (Tamargo et al., 2015), vascular (Cameron et al., 2016), neurologic (Dropcho, 2010), cognitive (Evenden, 2013), renal (Jhaveri et al., 2014), hepatic (Aloia and Fahy, 2010), and gastrointestinal disorders (Gibson and Keefe, 2006). These side effects can lead to treatment interruption or discontinuation (Casadei Gardini et al., 2016). Therefore, the assessment of antineoplastic drugs' side effects is essential not only to improve patient quality of life, but also to maintain a high quality of patient care (Martin, 1992; Martin, 1996; Stam and Challis, 1989; Lindley et al., 1999; Williams et al., 2016; Sotelo et al., 2014; Badger et al., 2001).

Several tools have been developed and used to assess patients' perception of chemotherapy side effects. They include the Visual Analogue Scale (VAS) (Grunberg et al., 1996), and Time Trade-off (TTO) (McNeil et al., 1981), which were used to identify nausea and vomiting as the most bothersome side effects reported by ovarian cancer patients (Sun et al., 2002). Similar conclusions were reached among this group of patients using the VAS and Memorial Symptom Assessment Scale (MSAS) (Sun et al., 2005). The negative impact of nausea and vomiting on cancer patients' quality of life has also been documented using different patient reported measures such as the Morrow Assessment of Nausea and Emesis (MANE) (Morrow, 1992). In another study that assessed the chemotherapy side effects using a 5-point Likert-type scale, hair loss, nausea and vomiting, and changes in taste and smell perception were identified as the most frequently reported aggravating side effects of chemotherapy (Lindley et al., 1999). In general, questionnaires using a Likert-type scale are the most frequently used for the evaluation of antineoplastics' side effects (Macquart-Moulin et al., 1997; Robison and Smith, 2016). The M.D. Anderson Symptom Inventory (MDASI) is one of these widely used tools for the severity assessment of 13 different side effects among cancer patients undergoing chemotherapy (Mendoza et al., 1999; Cleeland et al., 2000). It is mainly focused on the extent to which antineoplastics' side effects interfere with patients' activities of daily living using an 11-point rating scale from 0 to 10, where zero indicates the absence of a side effect and 10 means that the side effect is as bad as the patient can imagine (Reilly et al., 2013). It was the intention of the authors of MDASI to generate an antineoplastics' side effects assessment tool that is easy to translate into other languages (Cleeland and Ryan, 1994). In fact, the MDASI has been translated into different languages including the Arabic language (Nejmi et al., 2010). Although it remains the only available Arabic-language tool for the assessment of antineoplastics' side effects, its validity among different Arabic-speaking populations other than the Moroccan cancer patient population in which the MDASI was validated in was not examined (Nejmi et al., 2010). Furthermore, the MDASI only covers 13 cancer-related symptoms over the last 24 hours, and includes six items that assess the interference of these symptoms with the patients' activities of daily living. Another scale that was developed almost 15 years ago is the Functional Assessment of Cancer Therapy General (FACT-G). The scale consists of 33 items assessing the impact of different antineoplastics' side effects on the patient physical, emotional, social/family, and functional well-being. Also, the FACT-G assesses the patient-physician relationship. However, the FACT-G scale does not list different antineoplastics' side effects, but rather focuses on the impact of these side effects on the patient well-being (Cella et al., 1993). Therefore, it was complemented with another scale to rank the top most bothersome antineoplastics' side effects among cancer and non-cancer patients (Lindley et al., 1999). There are also other scales that showed both high validity and reliability in assessing antineoplastics' side effects among cancer patients. However, these scales are specific to certain types of cancer (Sun et al., 2005; Kim et al., 2012; Beisecker et al., 1997). The Memorial Symptom Assessment Scale (MSAS) is one of these scales that was validated among ovarian cancer patients and assesses 27 health states associated with chemotherapy (Sun et al., 2005). Other scales focus on few side effects such as the Marrow Assessment of Nausea and Emesis (MANE) which is a 17-item scale that assesses the frequency, severity, and duration of pre- and post-chemotherapy induced nausea and vomiting (Morrow, 1992). The Brief Fatigue Inventory (BFI) is another scale that assesses the severity of fatigue among cancer patients (Mendoza et al., 1999). Unfortunately, a comprehensive, concise, and general scale that covers the most frequently reported antineoplastics' side effects among cancer patients undergoing chemotherapy in general and assesses the severity and impact of these side effects on cancer patients' lives is not yet available. Therefore, the availability of such scales in Arabic and other languages is important to address the needs of underserved patient populations and eventually improve the quality of care (Kim et al., 2012; Beisecker et al., 1997; Love et al., 1989). The objective of the present study was to develop a concise, general, and comprehensive patient-reported antineoplastics' side effects questionnaire among Arabic-speaking cancer patient population. The expectation was that an accurate evaluation of cancer patients' perceptions of antineoplastics' side effects and their impact on patient activities of daily living would improve the quality of care provided to this patient population.

2. Methods

2.1. Study design and setting

The present investigation was designed as a cross-sectional, observational, single-center study. It was conducted in the oncology clinics at a university-affiliated tertiary care hospital in Riyadh, Saudi Arabia. All enrolled patients had a confirmed diagnosis of cancer regardless of cancer type and grade, were 18 years of age or older, completed at least four weeks of chemotherapy, and were cognitively able to talk. Exclusion criteria were an age less than 18 years, length of chemotherapy shorter than 4 weeks, cognitive impairment, and inability to speak due to deafness, mutism, aphasia, or other health reasons.

2.2. Development of the antineoplastic side effects scale (ASES)

An extensive review of the relevant literature published between 1980 and 2018 was conducted to identify the most commonly reported side effects of antineoplastic drugs. (Foster et al., 2008) After a thorough review of all commonly reported antineoplastics' side effects in the literature, the authors decided to include the 40 most commonly reported side effects to be as comprehensive as possible. These include emotional and cognitive side effects (feeling nervous, feeling sad or depressed, feeling angry, higher tendency to cry, anxiety, fear, confusion, difficulty concentrating, difficulty remembering things or forgetfulness), physical side effects (pain, numbness and tingling in feet or hands, palpitation, shortness of breath, changes in how things smell or taste, painful or increased urination, dizziness, lack of energy or lethargy, disturbed sleep, problems with sexual interest or activity),

gastrointestinal side effects (dry mouth, sore mouth or throat, nausea, vomiting, diarrhea, constipation, feeling bloated, abdominal pain, increased or poor appetite, difficulty swallowing, weight loss, weight gain, excessive thirst), and cutaneous side effects (itching, hair loss, excessive hair growth, changes in skin color, skin rash, dry skin, acne, easy bruising). Also, the authors felt the need to allow patients report other side effects that are not listed in the newly developed scale should they have any. The new scale was named the Antineoplastic Side Effects Scale (ASES) and was suited for self-administration. The ASES consists of three subscales. The first subscale is descriptive and assesses the frequency of the side effects (every day, 4–6 days per week, 2–4 days per week, once a week and less than once a week). The second subscale evaluates the severity of the side effects. For each listed side effect, the patient selects a value from 0 to 10, where zero indicates that the side effect does not exist, and 10 indicates that the side effect is as bad as the patient can imagine. The lowest possible score of this subscale is 0, and the highest is 400. The third subscale assesses the extent to which the side effects – if present – interfere with the patients' daily activities. This subscale utilizes a 5-point Likert scale, with 1 indicating "not at all," 2 "a little bit," 3 "somewhat", 4 "quite a bit," and 5 "very much." The highest possible score on this subscale is 200.

The first draft of the questionnaire was reviewed by two clinical pharmacists and one oncologist and sent back to all coauthors for their evaluation and comments. After minor modifications, the draft was sent to an Arabic linguist for lingual and semantic review and comments. All remarks and comments were addressed, and the final version of ASES was approved. The face and content validity of the ASES was examined by three clinical pharmacists, an oncologist, and a psychiatrist. No outstanding issues were found.

2.3. Data collection

Patients were recruited from the oncology clinics at a university-affiliated hospital in the city of Riyadh, Saudi Arabia. An informed consent form explaining the purpose of the study and the patients' rights, including their right to withdraw from the study at any time, was presented to all participants. The study was approved by the hospital's Institutional Review Board (IRB).

The patients were interviewed by four pharmacists. The collected information included sociodemographic, and cancer type and grade characteristics which were retrieved from the patient electronic health records. Comorbidities were retrieved from the patient electronic health records and verified using the Self-Administered Comorbidity Questionnaire (SCQ) to assess the burden of illness (Sangha et al., 2003). The frequency and severity of other potential side effects that were not listed in the ASES were also assessed.

2.4. Statistical analysis

The data were analyzed using the SAS statistical software (version 9.2, SAS Institute Inc., Cary, NC, USA). Descriptive statistics were conducted using Student's *t*-test and Chi-square test, as appropriate. The reliability of the questionnaire was examined using Cronbach's alpha method (Tavakol and Dennick, 2011). The Kaiser-Meyer-Olkin test (KMO) was used to assess sampling adequacy (Kaiser, 1974). To examine the construct validity of the Antineoplastic Side Effects Scale (ASES), principal component analysis with varimax rotation was performed. Pearson's correlation coefficient was used to examine the association between the scores of the ASES subscales and the different patient medical and sociodemographic characteristics. Statistical significance was defined at $\alpha < 0.05$.

3. Results

3.1. Patients

The inclusion criteria were met by 98 patients, 78 (79.6%) of them consented to participate and were interviewed. The sociodemographic and medical characteristics of the enrolled patients are listed in Table 1. The mean age of the participants was 53.8 (12.5) years, and the majority (58.9%) were between 51 and 65 years of age. Fifty-one patients (65.3%) were female, and 66 (84.6%) were married. There were only 5 smokers, and approximately 42% of the patients were using herbal supplements.

The most frequent types of cancer were breast (30.7%) and colorectal (24.3%) cancers (Table 1). Forty-eight patients (61.5%) had poorly differentiated tumors (grade III), and 23 (29.4%) had moderately differentiated tumors (grade II). The vast majority of the patients (93.5%) underwent chemotherapy for more than 6 weeks.

Table 1
The sociodemographic and medical characteristics of the participants.

Characteristic	Frequency (%)
Age (years)	
18–25	2(2.56)
26–30	3(3.85)
31–35	3(3.85)
36–40	6(7.69)
41–45	3(3.85)
46–50	4(5.13)
51–55	19(24.32)
56–60	19(24.32)
61–65	8(10.26)
66–70	5(6.41)
71–75	2(2.56)
76–80	4(5.13)
Gender	
Male	27(34.62)
Female	51(65.38)
Marital status	
Single	8(10.26)
Married	66(84.62)
Divorced	1(1.28)
Widowed	3(3.85)
Smoking status	
Nonsmoker	73(93.59)
Smoker	5(6.41)
Use of herbal supplements	
No	45(57.69)
Yes	33(42.31)
Type of cancer	
Colorectal cancer	19(24.36)
Breast cancer	24(30.77)
Lung cancer	3(3.85)
Liver cancer	1(1.28)
Leukemia	2(2.56)
Lymphoma	5(6.41)
Uterine cancer	1(1.28)
Ovarian cancer	3(3.85)
Cervical cancer	1(1.28)
Prostate cancer	1(1.28)
Stomach cancer	1(1.28)
Pancreatic cancer	5(6.41)
Thyroid cancer	1(1.28)
Chemotherapy duration	
4–6 weeks	5(6.41)
More than 6 weeks	73(93.59)
Self-Administered Comorbidity Questionnaire (SCQ) score	
3–5	20(25.64)
6–8	37(47.44)
9–11	16(20.51)
>11	5(6.41)

Most of the patients were on antimetabolite chemotherapy (17.9%), 16.6% were treated with alkylating agent and antimetabolite agents, 11.5% were given antimicrotubular agents, and 8.9% were receiving both antimicrotubular agents and monoclonal antibodies. The self-administered comorbidity questionnaire indicated that most (74.4%) scored at least 6 points, indicating a significant burden of illness.

3.2. Development and evaluation of the antineoplastic side effects scale

The complete list of the 40 side effects included in the ASES questionnaire and their frequency in the enrolled group of patients is presented in Table 2. The most frequent side-effects, reported by 50% or more of the patients were lack of energy (lethargy) (73.08%), generalized pain (69.2%), increased or poor appetite (62.8%), disturbed sleep (58.9%), diarrhea (57.6%), hair loss (55.1%), feeling bloated (52.5%), changes in how things smell or taste (51.2%), dry mouth (51.2%), feeling nervous (50%), constipation (50%) and dry skin (50%). The ASES Cronbach's alpha value was 0.91which indicates an acceptable reliability.

When the severity subscale of the ASES was considered (Table 3), generalized pain and lack of energy appeared to be the most acutely perceived side effects, with a score of 5.3 (4.0) and 5.3 (3.7), respectively, on a scale ranging from 0 to 10. Other side effects with a high degree of severity included increased or poor

Table 2
The frequency of Antineoplastic Side Effects Scale (ASES) items.

Side effect	Frequency (%)
Feeling nervous	39(50.00)
Feeling sad or depressed	36(46.15)
Feeling angry	33(42.31)
Crying more often	18(23.08)
Anxiety	32(41.03)
Fear	18(23.08)
Confusion	16(20.51)
Difficulty concentrating	24(30.77)
Difficulty remembering things	30(38.46)
Generalized pain	54(69.23)
Numbness and tingling sensation in feet or hands	37(47.44)
Palpitation	25(32.05)
Shortness of breath	19(24.36)
Changes in how things smell or taste	40(51.28)
Painful or Increased urination	31(39.74)
Dizziness	34(43.59)
Lack of energy	57(73.08)
Disturbed sleep	46(58.97)
Problems with sexual interest or activity	13(16.67)
Dry mouth	40(51.28)
Sore mouth or throat	34(43.59)
Nausea	36(46.15)
Vomiting	25(32.05)
Diarrhea	45(57.69)
Constipation	39(50.00)
Feeling bloated	41(52.56)
Abdominal pain	29(37.18)
Increased or poor appetite	49(62.82)
Difficulty swallowing	21(26.92)
Weight loss	32(41.03)
Weight gain	25(32.05)
Excessive thirst	37(47.44)
Itching	31(39.74)
Hair loss	43(55.13)
Excessive hair growth	24(30.77)
Changes in skin color	30(38.46)
Skin rash	10(12.82)
Dry skin	39(50.00)
Acne	5(6.41)
Easily bruising	22(28.21)

Table 3
The mean scores of the Antineoplastic Side Effects Scale (ASES) severity subscale.

Side effect	Mean ± SD
Feeling nervous	3.3 ± 3.7
Feeling sad or depressed	3.2 ± 3.8
Feeling angry	2.7 ± 3.6
Crying more often	1.4 ± 3.0
Anxiety	2.3 ± 3.4
Fear	1.6 ± 3.2
Confusion	1.4 ± 3.1
Difficulty concentrating	1.6 ± 2.6
Difficulty remembering things	2.2 ± 3.1
Generalized pain	5.3 ± 4.0
Numbness and tingling sensation in feet or hands	2.8 ± 3.4
Palpitation	1.8 ± 3.0
Shortness of breath	1.5 ± 3.0
Changes in how things smell or taste	4.1 ± 4.2
Painful or Increased urination	2.5 ± 3.4
Dizziness	2.8 ± 3.7
Lack of energy	5.3 ± 3.7
Disturbed sleep	4.5 ± 4.0
Problems with sexual interest or activity	1.3 ± 3.0
Dry mouth	3.6 ± 3.9
Sore mouth or throat	3.0 ± 3.8
Nausea	3.2 ± 3.9
Vomiting	2.4 ± 3.9
Diarrhea	3.8 ± 3.9
Constipation	3.5 ± 3.8
Feeling bloated	3.5 ± 3.7
Abdominal pain	2.6 ± 3.6
Increased or poor appetite	4.8 ± 4.0
Difficulty swallowing	1.5 ± 2.7
Weight loss	2.0 ± 2.6
Weight gain	1.3 ± 2.2
Excessive thirst	3.4 ± 3.8
Itching	2.5 ± 3.5
Hair loss	4.2 ± 4.1
Excessive hair growth	1.5 ± 2.6
Changes in skin color	2.7 ± 3.7
Skin rash	0.93 ± 2.5
Dry skin	3.4 ± 3.8
Acne	0.28 ± 1.2
Easily bruising	1.7 ± 3.0
Total score	114.5 ± 64.6

appetite (4.8 [4.0]), disturbed sleep (4.5 [4.0]), hair loss (4.2 [4.1]), and changes in how things smell or taste (4.1 [4.2]). The least bothersome side effects were acne (0.2 [1.2]) and skin rash (0.9 [2.5]).

On the ASES subscale describing the impact of side effects on activities of daily living (Table 4), the highest scores (range from 0 to 5) were reported for the lack of energy (2.2 [1.7]), generalized pain (2.0 [1.8]), and disturbed sleep (1.7 [1.7]). The least consequential side effects were acne (0.1 [0.6]), skin rash (0.3 [1.1]), confusion (0.4 [1.0]), and crying more often (0.4 [1.0]).

3.3. Principal component analysis

The Kaiser-Meyer-Olkin test (KMO) indicated that the sample size was adequate to conduct this type of evaluation. From each subscale, three factors were extracted based on the ASES loadings: psycho-somatic side effects, gastro-somatic side effects, and cognitive-somatic side effects. The extracted factors alongside their items with their communality estimates that represent the proportion of each item's variance that can be explained by their assigned factors are shown in Table 5.

Finally, the Pearson's correlation coefficients that examined the relationship between the severity of side effects and patients' characteristics, and between the impact of side effects on patients' activities of daily living and their characteristics are shown in

Table 4
The mean scores of the Antineoplastic Side Effects Scale (ASES) impact on activities of daily living subscale.

Side effect	Mean ± SD
Feeling nervous	1.2 ± 1.6
Feeling sad or depressed	1.1 ± 1.6
Feeling angry	0.89 ± 1.4
Crying more often	0.47 ± 1.0
Anxiety	0.89 ± 1.5
Fear	0.56 ± 1.3
Confusion	0.42 ± 1.0
Difficulty concentrating	0.55 ± 0.99
Difficulty remembering things	0.7 ± 1.1
Generalized pain	2.0 ± 1.8
Numbness and tingling sensation in feet or hands	0.96 ± 1.4
Palpitation	0.66 ± 1.2
Shortness of breath	0.56 ± 1.2
Changes in how things smell or taste	1.2 ± 1.6
Painful or Increased urination	0.86 ± 1.3
Dizziness	0.91 ± 1.3
Lack of energy	2.2 ± 1.7
Disturbed sleep	1.7 ± 1.7
Problems with sexual interest or activity	0.65 ± 1.5
Dry mouth	1.2 ± 1.5
Sore mouth or throat	1.2 ± 1.6
Nausea	1.2 ± 1.6
Vomiting	0.93 ± 1.6
Diarrhea	1.3 ± 1.6
Constipation	1.2 ± 1.6
Feeling bloated	1.2 ± 1.5
Abdominal pain	0.91 ± 1.5
Increased or poor appetite	1.5 ± 1.6
Difficulty swallowing	0.58 ± 1.1
Weight loss	0.76 ± 1.1
Weight gain	0.66 ± 1.2
Excessive thirst	0.97 ± 1.3
Itching	0.81 ± 1.3
Hair loss	1.2 ± 1.5
Excessive hair growth	0.72 ± 1.4
Changes in skin color	0.85 ± 1.4
Skin rash	0.36 ± 1.1
Dry skin	0.93 ± 1.2
Acne	0.13 ± 0.6
Easily bruising	0.52 ± 1.0
Total score	40.3 ± 27.9

Table 5
Extracted factors from the Antineoplastic Side Effects Scale (ASES).

Severity of the side effect	Factors			Communalities (h2)
	(1)	(2)	(3)	
Fear	0.78			0.68
Anxiety	0.76			0.64
Feeling nervous	0.72			0.69
Confusion	0.70			0.64
Crying more often	0.61			0.66
Feeling sad or depressed	0.60			0.58
Feeling angry	0.56			0.50
Dry mouth	0.53			0.48
Excessive hair growth	0.40			0.21
Generalized Pain	0.36			0.32
Sore mouth or throat	0.34			0.46
Acne	0.33			0.46
Excessive thirst	0.41			0.55
Weight gain	0.08			0.31
Itching	0.26			0.63
Nausea		0.66		0.51
Lack of energy		0.62		0.63
Increased or poor appetite		0.61		0.45
Hair loss		0.60		0.42
Weight loss		0.56		0.35
Diarrhea		0.53		0.35
Vomiting		0.53		0.43
Difficulty swallowing		0.49		0.55
Abdominal pain		0.49		0.32
Constipation		0.47		0.27
Dizziness		0.46		0.25
Feeling bloated		0.29		0.24
Skin rash		0.32		0.39
Changes in skin color		0.40		0.40
Problems with sexual interest or activity		0.19		0.28
Easily bruising			0.74	0.64
Difficulty concentrating			0.59	0.47
Palpitation			0.59	0.47
Dry skin			0.50	0.47
Changes in how things smell or taste			0.49	0.33
Difficulty remembering things			0.45	0.40
Disturbed sleep			0.42	0.45
Numbness and tingling in feet or hands			0.21	0.08
Shortness of breath			0.24	0.45
Painful or Increased urination			0.26	0.55

Table 6. Among all the variables analyzed, only female gender was positively and significantly related to the severity of side effects ($P < 0.001$). Similarly, the female gender was the only variable that has shown a significant correlation with the perceived impact on activities of daily living (Table 7). In both analyses, no correlation was identified for age, marital status, smoking, use of herbal supplements, and the SCQ score.

4. Discussion

To the best of our knowledge, the new developed Antineoplastic Side Effects Scale (ASES) represents the most comprehensive tool available in the Arabic language for the evaluation of patient's perception of antineoplastics' side effects among Arabic speaking cancer patients. It is expected that the availability of an Arabic ASES will help improve the quality of care of Arabic speaking cancer patients undergoing chemotherapy. This scale had good internal consistency, with Cronbach's alpha of 0.91, significantly higher than the value of 0.7 required for validation of new instruments (Terwee et al., 2007).

It is expected that the use of ASES, which screens for 40 distinct and commonly reported side effects of chemotherapy, will result in a more comprehensive evaluation of the cancer patients' experiences with chemotherapy than the ones offered by shorter

Table 6
The correlation between Antineoplastic Side Effects Scale (ASES) severity subscale's score and participants' sociodemographic and medical characteristics.

Characteristic	Pearson correlation coefficient (r)	P-value
Age	−0.05	0.65
Female gender	0.43	<0.001[*]
Marital status	0.18	0.12
Smoking status	−0.21	0.06
Use of herbal supplements	0.02	0.88
Chemotherapy duration	−0.069	0.55
Self-Administered Comorbidity Questionnaire (SCQ) score	0.2	0.078

[*] $p < 0.05$.

questionnaires, such as the MDASI (Foster et al., 2008). Another advantage of ASES stems from the fact that the collected data can be used to prepare patients in advance for commonly reported side effects of chemotherapy and facilitate symptoms management (Greene et al., 1994). Besides the long list of commonly reported antineoplastics' side effects that ASES covers compared to the Arabic version of MDASI (Nejmi et al., 2010), it is the first antineoplastics' side effects scale that was developed and validated in Arabic by a diverse group of healthcare professionals and researchers.

Table 7
The correlation between Antineoplastic Side Effects Scale (ASES) impact on activities of daily living subscale's score and participants' sociodemographic and medical characteristics.

Characteristic	Pearson correlation coefficient (r)	P-value
Age	−0.029	0.8
Gender	0.41	<0.001[*]
Marital status	0.14	0.22
Smoking status	−0.186	0.1
Use of herbal supplements	0.01	0.92
Chemotherapy duration	−0.12	0.3
Self-Administered Comorbidity Questionnaire (SCQ) score	0.099	0.39

[*] p < 0.05.

5. Limitations of the current study

Although ASES has demonstrated good reliability, some limitations inherent in the present study have to be acknowledged. The study was restricted to a relatively small number of patients under the care of a single oncology center. Examining the validity and reliability of ASES in a larger sample of cancer patients and in different healthcare settings is essential to assess its external validity. Furthermore, the validity of the proposed scale can be further strengthened by evaluating the correlation of its scores with other commonly used antineoplastic side-effects scales such as the MDASI. Moreover, this scale is only available in Arabic since it was validated among Arabic-speaking cancer patients, which limits its usability.

6. Conclusion

The availability of a comprehensive, concise, and general scale in Arabic to explore cancer patients' self-reported antineoplastic agents' side effects and assess their impact on activities of daily living should help healthcare providers and patients alike to mitigate the negative impact of these therapeutic agents. Also, it will enable healthcare researchers in comparing and contrasting the incidence and severity of antineoplastics' side effects among Arabic speaking cancer patients and patients from other ethnicities. Future studies should examine the validity and reliability of Arabic, English, and other language versions of ASES among larger and more diverse patient populations.

Declaration of Competing Interest

The authors have declared that no competing interests exist.

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