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Construct and criterion validity of the Comfort Assessment Breast Cancer Instrument☆

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Abstract
Objective: To examine the validity of the Comfort Assessment Breast Cancer Instrument (CABCI) and compare the results of CABCI with that of salivary cortisol examination.
Method: For assessing construct validity, second-order confirmatory factor analysis (CFA) was performed with M-Plus, and for assessing criterion validity, salivary cortisol examination was performed.
Results: The results of CFA indicated that the model was a good fit ($X^2 = 283.654$, $df = 10$, $p = 0.000$, RMSEA = 0.000, p RMSEA $\leq 0.05 = 0.797$, CFI = 1.000), and the 33 items of CABCI were found to be statistically significant ($t > 1.96$; $p < .05$). A significant correlation was found between patient discomfort and salivary cortisol level ($r = 0.416$; $p = .016$).
Conclusion: The study proves the construct and criterion validity of CABCI, and therefore indicates its validity for predicting discomfort in breast cancer patients.

Introduction

Feelings of discomfort are common among breast cancer patients and their families, and comfort is a pivotal component in the treatment of breast cancer patients. It is difficult for nurses to assess patients' troubles, and to accordingly meet their needs in terms of comfort.[1] Various studies have developed instruments to estimate patient discomfort, in both western and Asian countries.[2–7] However, very few have taken into account cultural values and differences.[8]

An ideal tool is one that is sensitive to patients' cultural and religious values, as cultural and spiritual factors may significantly influence a patient's health. In particular, a patient's cultural values can affect their response to illness

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and treatment. Further, religion and belief play an essential role in the formation of patient behaviors toward health. As a country with remarkable religious and cultural diversity, it is central for nurses in Indonesia to assess the cultural and spiritual needs of their patients. However, there are currently no standardized instruments that are accepted and used to assess comfort, particularly in the Indonesian context. Therefore, it is necessary to re-examine and improve the already known assessment tools for measuring patient comfort.

Assessment of comfort is essential for Indonesian nurses with regard to providing good nursing care. Indonesian nurses currently cannot assess patient discomfort satisfactorily because there is no proper assessment instrument. Appropriate assessment is required to take appropriate action in terms of ensuring patient comfort. To better assess patient comfort by taking into account their cultural and spiritual needs, in the present study, we evaluated the Comfort Assessment Breast Cancer Instrument (CABCI), in the context of Indonesia. This instrument has not been validated in other countries and populations. The results of previous studies on 55 patients showed that CABCI had good validity and reliability for assessing comfort among breast cancer patients in Indonesia army hospital.[9] Here, we have examined the construct and criterion validity of the instrument using the MPlus software. Second-order confirmatory factor analysis (CFA) was used for the assessment of construct validity, and the CABCI findings were compared with salivary cortisol levels to determine the criterion validity. Salivary cortisol examination was used because the cortisol hormone is considered to be a crucial indicator of stress and may, therefore, be an effective indicator of patient discomfort. Moreover, the measurement of salivary cortisol is simple and non-invasive. However, saliva collection in cancer patients may be quite challenging since most cancer patients have mouth sores and dry mouth.

A survey conducted at Dharmais Cancer Hospital, which is one of the participating hospitals in this study, revealed that 60% of the total patients were in the advanced stage of cancer.[10] In this advanced stage, extreme discomfort is common, but it is challenging to measure patient comfort on account of its subjective nature. Therefore, nurses cannot solely rely on the results of patient observation, but they require a valid tool to measure patient comfort.

Measurement instruments are essential in research on human subjects. These instruments are assessed according to their validity, which is defined as the magnitude to which a test generates information that is beneficial for a particular purpose.[11] Validity is classified into face validity, content validity, predictive and concurrent validity (criterion validity), and construct validity.[12] In this study, we did construct and criterion validity.

Method

The present study was conducted with a purposive sample of breast cancer patients from both the inpatient and outpatient units of three referral hospitals in Jakarta, Indonesia. Based on the inclusion criteria, the study population included adult females who were conscious with stable vital signs; diagnosed with stage IIb, III, and IV breast cancer; and willing to participate in the study. The exclusion criterion was the presence of cognitive impairments due to metastasis of breast cancer to the central nervous system. A total of 308 patients were included for the evaluation of the validity of CABCI, and 33 of them were included in examining the criterion validity with the cortisol saliva test. We chose 33 of these patients because those who were willing to take salivary to study cortisol hormone levels. Other patients find it difficult to remove saliva because of the dry mouth as therapy effect.

Before data collection, we received the approval of the Ethics Committee of the Faculty of Nursing Universitas Indonesia and the Ethics Committee of the three participating hospitals. The study, including the protocols and procedures, was reviewed and approved by the ethics committee of the research hospital. There were three steps in the data collection process: (1) The interviewer requested respondents to fill out their demographic information. (2) The respondents' comfort was evaluated using CABCI. (3) Saliva samples were collected for cortisol measurement.

Saliva samples were collected using Salimetrics® Kit 1606547 (Salimetrics®, Philadelphia), which is an expanded range high-sensitivity salivary cortisol enzyme immunoassay kit,[13] and the manufacturer's information was followed for cortisol measurement. Further, the respondents were requested to gargle and wait for at least 30 min after rinsing to avoid sample dilution. They were asked to drool saliva into a funnel until a sufficient amount of sample was collected. Re-collection was conducted if the samples were contaminated with blood. The time and date of sample collected were recorded, and the tubes were labeled with a barcode and kept in $-20\,^{\circ}C$ temperature to prevent bacterial growth. The samples were sent in insulated transport containers to the PT Prodia Widya Husada Laboratory in Jakarta for cortisol examination.

Results

Construct validity

We examined the construct validity of CABCI by using second-order CFA to validate the hypothetical constructs loaded into select underlying subconstructs. In the first-order analysis, 37 items that measured five dimensions of comfort were analyzed: physical comfort (11 items), psychospiritual comfort (13 items), sociocultural comfort (5 items), financial comfort (4 items) and environmental comfort (4 items). We excluded two items each from the physical and psychosocial dimensions due to their low factor loadings. This left us with 33 items for the second-order analysis.

For the second-order analysis, we used the unidimensionality technique to unify all five dimensions into a single comfort dimension. The results of the second-order CFA revealed that the model fit the data ($X^2 = 283.654$, $df = 10$, $p = 0.000$, RMSEA = 0.000, p RMSEA $\leq 0.05 = 0.797$, CFI = 1.000); further, the 33 items of CABCI were found to be statistically significant ($t > 1.96$, $p < .05$). Furthermore, the unidimensional model was found to be representative of all five sub-dimensions (Table 1).

Table 1 Construct validity by confirmatory factor analysis.

	X^2	*df*	*p* (from X^2)	RMSEA	Prob. RMSEA ≤0.05*	CFI**	Deleted items
Comfort	283	10	.000	.000	.797	1.000	
Physical	2215	36	.000	.065	.072	.980	2 & 9
Psycho-spiritual	2331	66	.000	.063	.060	.967	6 & 7
Socio-cultural	417	10	.000	.098	.050	.971	
Financial	2304	6	.000	.000	.667	1.000	
Environmental	777	6	.000	.096	.106	.993	

* Root Mean Square Error of Approximation (RMSEA). RMSEA is a measure that attempts to improve the tendency of chi square statistics to reject models with large sample sizes. The probability value of RMSEA must be more than 0.05.
** CFI must be more than 0.9 for the fit model.

Table 2 Factor loadings for comfort items.

Dimension	Item	*Est.*	*S.E.*	*t*	*p*
Physical comfort	1. Powerlessness	.868	.021	40.989	.00
	2. Weaknesses	.814	.028	28.860	.00
	3. Suffering	.653	.041	15.833	.00
	4. Sickness	.722	.035	20.344	.00
	5. Lack of appetite	.675	.040	16.864	.00
	6. Swelling and numbness	.324	.056	5.801	.00
	7. Dizziness	.471	.052	9.127	.00
	8. Dry mouth & skin	.690	.041	16.727	.00
	9. Fatigue	.730	.034	21.414	.00
Psycho-spiritual comfort	10. Sadness	.754	.030	25.308	.00
	11. Hopelessness	.758	.037	20.596	.00
	12. Worship	.819	.027	30.000	.00
	13. Survive	.780	.032	24.167	.00
	14. Anxiety	.670	.038	17.833	.00
	15. Anger	.649	.044	14.881	.00
	16. Lonely	.637	.042	15.106	.00
	17. Physical changes	.580	.041	14.132	.00
	18. Fears	.652	.042	15.622	.00
	19. Bored	.512	.051	10.066	.00
	20. Offended	.502	.048	10.372	.00
Socio-cultural comfort	21. Dependent	.592	.048	12.416	.00
	22. Disturbing others	.944	.049	19.316	.00
	23. Talk about disease	.676	.047	14.242	.00
	24. Worry about family	.219	.063	3.451	.00
	25. Communication with healthcare team	.266	.066	4.044	.00
Financial comfort	26. Cost of treatment	.781	.031	25.288	.00
	27. Transport fee	.921	.015	61.377	.00
	28. Cost of living	.943	.013	69.994	.00
	29. Lost revenue	.490	.056	8.754	.00
Environmental comfort	30. Disturbed	.678	.041	16.386	.00
	31. Feel at home	.908	.039	23.016	.00
	32. Smell	.798	.035	23.027	.00
	33. Comfort	.262	.077	3.402	.00

The results demonstrated that all factor loadings had a *t* value greater than 1.96. The results also showed that the *p*-value for all the items was less than .05. Thus, the findings indicated that all 33 items were statistically significant and that the model was a good fit. The instrument was, therefore, proven to be valid for the measurement of the constructs (Table 2).

Criterion validity

According to the findings, the mean score for patient discomfort was 68.27 (*SD* = 13.83), which means that the patients had a moderate level of discomfort. Furthermore, the mean salivary cortisol concentration was 3.00 μg/L (*SD* = 2.00), which indicates that the cortisol level was relatively high

Table 3 Distribution of patient discomfort and salivary cortisol levels.

Variable	Mean	SD	Median	Min–max	95% CI
Discomfort (score: 33–132)	68.27	13.83	69.00	44–100	63.37–73.18
Salivary cortisol (μg/L)	3.00	2.00	2.30	.89–8.92	2.29–3.70

Table 4 Spearman's Correlation analysis of discomfort (with CABCI) and salivary cortisol levels.

Parameter	r	R^2	p
Discomfort with CABCI and salivary cortisol level	.416	17.3%	.016

(Table 3). We analyzed the correlation between discomfort according to CABCI and salivary cortisol levels with the Spearman test. Our analysis showed a moderate and linear association between patient discomfort and salivary cortisol level ($r = 0.416$). Salivary cortisol level, nevertheless, could only explain 17.3% of the variation in patient discomfort, even though the relationship was significant ($r^2 = 17.3\%$, $p = .016$). The analysis indicated that CABCI is a valid instrument for predicting discomfort in breast cancer patients (Table 4).

Discussion

Construct validity

We carried out the construct validity with the CFA test to prove the validity of the CABCI instrument using a large sample of 308 breast cancer patients. The result of construct validity, we omitted four items from the second-order CFA. The results revealed that all 33 items were statistically significant, the model was a good fit, and the unidimensional model represented all five sub-dimensions. Our study furthermore analyzed factor loadings for each item. The results indicated that the instrument was valid for the measurement of the comfort constructs. Chi-Square values are less sensitive for large sample sizes. To overcome this, we must use other values, namely Root Mean Square Error of Approximation (RMSEA), the probability of RMSEA, and Comparative Fit Index (CFI) to prove this instrument model is fit. The models have a satisfactory to good fit when: CFI > 0.90 and p RMSEA > 0.05.[12,14]

Criterion validity

Previous studies support the results of our study. Some of the previous studies showed that there was a significant correlation between the increase in cortisol and an increase in pain or physical discomforts[15] and stress or emotional discomfort.[16,17] Moreover, the criterion validity study of the functional instrumentality scale component of Short-Form Health Survey (SF36) (version 1) that compared self-reported functional health status with cortisol measurement also confirmed the relationship between functional state and cortisol levels ($r = -0.31$, $p < 0.01$).[18] The SF36 instrument was also used to determine the relation between the quality of life and comfort levels of breast cancer patients.[19]

Patient discomfort can be assessed using other objective measures, such as electroencephalography.[20] The result of this previous study suggests that different objective examinations be used to measure the validity of patient discomfort instruments. The CABCI instrument has been tested for validity with another more objective measuring, namely salivary cortisol hormone levels. The last stage was the assessment of the criterion validity. The Spearman correlation test demonstrated significant relationships between patient discomfort according to CABCI and salivary cortisol level. This indicates the ability of CABCI to predict discomfort in breast cancer patients. Therefore, this tool could help nurses understand patient needs in terms of comfort, which is important for the provision of nursing care.

In the present study, CABCI has been proven as a valid tool through several validation stages. Therefore, it can be used to assess comfort in patients with breast cancer. Nurses should perform an accurate and holistic assessment of comfort to determine the most suitable nursing care strategy for patients. Holistic comfort assessment encompasses the physical, psychosocial, environment, sociocultural, and financial aspects of comfort. Currently, most nurses focus only on the physical aspect of comfort, but it is important that they focus on the other aspects as well. This tool will be useful to nurses for performing appropriate comfort assessment prior to administering nursing interventions in order to help patients and their families to feel comfortable with their situation.

Conflict of interests

The authors declare no conflict of interest.

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