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Research Article

Development and validation of a questionnaire to measure post-intensive care syndrome

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ABSTRACT

Objective: This study aimed to develop a Post-Intensive Care Syndrome Questionnaire (PICSQ) and assess the psychometric properties of PICSQ in intensive care unit survivors.
Methods: PICSQ items were generated through relevant literature reviews, qualitative interviews among survivors, and multiple rounds of content validity evaluations by experts. Data were collected from 536 survivors at seven health care facilities in three cities of Korea from June to August 2018. The validity and reliability of PICSQ were assessed using exploratory factor analysis, confirmatory factor analysis, internal consistency and correlation coefficients.
Results: The final PICSQ consisted of 18 items. Through exploratory factor analysis, three factors (mental, cognitive and physical) were derived. The reliability of PICSQ was represented by a Cronbach's α of 0.93, while the internal consistency of each factor was good (Cronbach's $\alpha = 0.84$ to 0.90). The model fit of PICSQ was satisfactory and confirmatory factor analysis demonstrated good convergent and discriminant validity of the questionnaire.
Conclusion: Because PICSQ is valid and reliable, it is recommended for use in clinical practice and research to assess post-intensive care syndrome in intensive care survivors.

Implications for clinical practice

The Post-Intensive Care Syndrome Questionnaire:
- Reliable and valid tool to measure post-intensive care syndrome in intensive care unit survivors.
- Multidimensional tool that integrates the mental, cognitive and physical areas of post intensive care syndrome.
- Self-report tool, can be easily and conveniently administered to intensive care unit survivors.
- Can be used to assess the need for and effectiveness of nursing interventions for survivors.
- Can be used in studies to improve the quality of life and survival of survivors.

Introduction

With the survival rate in intensive care units (ICUs) as high as 80–90% (Hill et al., 2016), there has been an increased interest in survivors' long-term outcomes. ICU survivors may experience a variety of health problems besides the existing illnesses after ICU discharge and more than two-thirds of these survivors find it difficult to live independently without the help of others (Desai et al., 2011). These problems not only negatively affect the survivors' quality of life but also lower the survival rate after ICU discharge. About one-third of ICU survivors die within a year and their mortality rate is five times higher than that of the general population (Park et al., 2018; Wright et al., 2003). In 2010, the Society of Critical Care Medicine (SCCM) named this collection of mental, cognitive and physical problems in ICU survivors "post-intensive care syndrome" (PICS). PICS can either develop or worsen after ICU

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treatment and can last for months to years after discharge (Needham et al., 2012).

The operational definition and assessment criteria of PICS remain unclear; however, PICS has been measured using tools from other fields. In systematic reviews of PICS (Jensen et al., 2015; Parry et al., 2015), the necessity of developing a unique tool to measure PICS was highlighted because the tools used in the individual studies were too diverse and complex. Turnbull et al. (2016) reported that 250 different tools were used in a review of 425 studies on the outcomes of ICU survivors. Diverse tools make it difficult to compare the results of assessments and integrate the evidence that may interfere with the clinical application of the results.

To measure PICS, mental, cognitive and physical dimensions that involve complex and interrelated problems need to be considered (Parker et al., 2013). To date, most studies have involved the assessment of and intervention in specific areas of PICS only, including early exercises for improving physical function (Schweickert et al., 2009) or an ICU diary for preventing mental health problems (Jensen et al., 2015). However, these approaches can mask problems in other areas experienced by survivors. The complex problems experienced by ICU survivors and the multiple interventions required for their rehabilitation necessitate the development of a multi-dimensional tool for measuring all three areas of PICS.

Moreover, existing tools do not completely reflect the characteristics of survivors. The six-minute walk test and the 'Timed Up and Go' test, commonly used to measure physical problems of PICS (Kang et al., 2018), are not suitable for frail survivors. The Hospital Anxiety and Depression Scale (Turnbull et al., 2016), widely used for measuring mental health, does not reflect the characteristics of PICS such as re-experiencing ICU events and memory distortion (Kang and Jeong, 2018). Furthermore, because existing tools were not developed based on the experiences of ICU survivors, problems with internal validity may exist.

Finally, we need a tool that can be applied easily for the continuous assessment of PICS and interventions for PICS (Myers et al., 2016). Previous studies reporting PICS (Kim and Kang, 2016; Jensen et al., 2015) have used three or more different tools. Some tools require specific equipment, assessor training, or space (Hermans et al., 2014; Nasreddine et al., 2005); however, these requirements can interfere with the clinical application of the tools. To assess and manage PICS more effectively, it is necessary to develop a self-reported type of measurement tool that does not require specific equipment or assessor training.

This study aimed to develop a PICS Questionnaire (PICSQ) based on a conceptual framework that reflected the experiences of ICU survivors and evaluate its validity and reliability.

Methods

Design

This methodological study developed and evaluated the psychometric properties of PICSQ.

Phase 1: Development of the questionnaire

Conceptual framework and item generation. Through a review of the literature, we found that ICU survivors experience mental health problems such as fear, anxiety, depression and post-traumatic stress disorder (PTSD) (Choi et al., 2016; Huang et al., 2016); cognitive problems, such as decreased memory, concentration, executive function and delayed psychomotor activities (Hopkins and Jackson, 2009; Jackson et al., 2014); and physical problems, such as motor weakness and various symptom experiences (Desai et al., 2011; Hermans et al., 2014; Griffiths et al., 2006).

Subsequently, we conducted one-to-one interviews with 15 survivors aged 20–82 years. The qualitative analysis of the interviews revealed three themes: mental deterioration, cognitive problems and physical weakness. We could also collect vivid details of PICS. For example, survivors repeatedly recalled bad memories about the ICU and sometimes had nightmares. Some survivors experienced memory breakdowns and physical weakness, including worsening of handwriting. The results of the qualitative interviews were published elsewhere (Kang and Jeong, 2018).

The conceptual framework of the current study, based on the aforementioned literature review and qualitative interviews, was similar to the SCCM model of PICS. The definition of PICS included multidimensional problems that were newly developed or exacerbated due to ICU treatment, consisting of cognitive, mental, and physical areas. Among the three areas of PICS, the mental area included anxiety, depression, and PTSD. The cognitive area included memory impairment, concentration problems, executive function problems and visuospatial perception abnormality. The physical area included functional decrease, daily activity limitation and symptom experience.

We generated 62 items based on the conceptual framework. The type of measurement was structured as a Likert scale to measure the degree of PICS experience. Considering that the respondents were ICU survivors, we chose a four-point scale. Although the sensitivity of a four-point scale is lower than that of a five-point scale, the reliability of the response can be improved by lowering the fatigue of the respondent through a four-point scale.

Content validity testing. Ten experts in the field of critical care medicine, rehabilitation, nursing, and scale development evaluated the 62 individual items to determine how well they reflected the attributes of PICS using a four-point scale. After three rounds, 31 items with a content validity index of 80% or more were selected (Lynn, 1986). One Korean linguist reviewed the readability of the items. Through these processes, a preliminary questionnaire of 31 items consisting of 11 mental, 11 cognitive and nine physical areas was composed.

Phase 2: Evaluation of the psychometric properties

Sample and procedure. We conducted surveys at seven health care facilities in Korea from June to August 2018. Participants were 1) admitted to ICU for 48 hours or more, 2) discharged for four weeks to one year, 3) over 18 years old and 4) able to communicate. When exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) were performed, the use of different samples was recommended (Tay and Jebb, 2017). To perform two factor analyses with 31 items, 496 subjects were required when the number of appropriate samples was eight times the number of items (Tinsley and Tinsley, 1987). A total of 550 questionnaires were distributed considering a 10% dropout rate. Of these, 538 were returned and 536 were used for the final analysis except for two questionnaires with no answered items.

Data analysis. The collected data were analyzed using SPSS/WIN 24.0 and AMOS/WIN 24.0 (IBM Inc., Armonk, NY). Participants' characteristics were analysed using descriptive statistics, analysis of variance (ANOVA), chi-square tests, and t-tests.

For item analysis, the means, kurtoses, item-item correlations (IIC), and item-total correlations were calculated. EFA and CFA were conducted to verify construct validity. Keizer-Meyer-Olkin (KMO) measure of sampling adequacy and Bartlett's sphere test were conducted to check whether the data were suitable for EFA. Factors in the EFA were extracted using principal components analysis and the Promax kappa 4 of the oblique rotation.

To assess criterion validity, correlations between PICSQ and the Japan frailty scale (JFS) and 36-Item Short Form Health Survey ques-

tionnaire (SF-36) were analysed. Frailty is a multi-dimensional concept involving physical, mental, cognitive, and social problems, similar to those of PICS. It has been reported that the frailty of an ICU survivor is related to PICS (Marra et al., 2018). JFS, also known as the Kihon Checklist, was developed by the Ministry of Health, Labour and Welfare of Japan, and the validity and reliability of the Korean version have been reported (Lee et al., 2011). In the previous study by Lee et al. (2011), the reliability was represented by Cronbach's $\alpha = 0.80$; in the current study, it was 0.90.

Analysis of the correlation between PICSQ and SF-36 assumed that PICS negatively affects the quality of life of ICU survivors (Needham et al., 2012). The quality of life was measured using SF-36 version 2 that was developed and validated by Ware and Sherbourne (1992) and consists of a mental component summary (MCS) and a physical component summary (PCS). The reliability of SF-36 in the current study was represented by Cronbach's $\alpha = 0.95$ for PCS and Cronbach's $\alpha = 0.93$ for MCS.

To evaluate the reliability of PICSQ, the Cronbach's α of internal consistency was obtained, and test-retest was performed. Retesting was conducted seven days after the initial test with 50 participants who agreed to the second survey in advance.

Ethical considerations

This study was approved by the Institutional Review Board (IRB) of Dong-A University (#2-1040709-AB-N-01-201802-HR-001-04). Informed consent was obtained from participants

Results

Participants' characteristics

A total of 536 ICU survivors participated in the study. Their mean age was 57.0 ± 14.5 years, and 56.2% were male. Using the SPSS program, 268 of the participants were randomly assigned to EFA and the remaining 268 were assigned to CFA. There was no significant difference between the two groups (Table 1).

Validity and reliability estimates

Item analysis

The questionnaire items were analysed to remove the items that lowered discrimination and reliability. First, item 30, of which the mean score was extreme and the kurtosis exceeded −1, was deleted. Items 3, 6, 15, and 18 were also deleted because the IICs were over 0.80. The IICs of item 28, "*I get tired easily*," and item 29, "*I have no energy*," were also over 0.80. However, we did not remove these two items because both content validity indices were 1.0 and were common problems experienced by ICU survivors.

Construct validity

EFA was performed on 26 items, excluding the five deleted items, from the item analysis. The KMO value was 0.94, and the result of Bartlett's test was $\chi^2 = 5765.60$ ($p < .001$); therefore, the sample was suitable for conducting EFA (Hair et al., 2018). The

Table 1
Characteristics of the Participants (N = 536).

Characteristics	Categories	Total n (%)	EFA group n = 268	CFA group n = 268	t or χ^2 (p)
			n(%)/M ± SD		
Gender	Male	351(65.2)	174(64.9)	177(66.0)	0.07(0.785)
	Female	185(34.8)	94(35.1)	91(34.0)	
Age (yrs)	<40	66(12.3)	35(13.1)	31(11.6)	0.48(0.787)
	40–59	219(40.9)	111(41.4)	108(40.3)	
	≥60	251(46.8)	122(45.5)	129(48.1)	
Fulltime caregiver	Yes	467(87.1)	230(85.8)	237(88.4)	0.82(0.367)
	No	69(12.9)	38(14.2)	31(11.6)	
Job prior to admission	Yes	327(61.0)	169(63.1)	158(59.0)	0.95(0.330)
	No	209(39.0)	99(36.9)	110(41.0)	
Current job	Yes	123(22.9)	61(22.8)	62(23.1)	0.01(0.918)
	No	413(77.1)	207(77.2)	206(76.9)	
Diagnosis	Cerebrovascular	242(45.1)	118(44.0)	124(46.3)	9.35(0.155)
	Spinal injury	50(9.3)	23(8.6)	27(10.1)	
	Liver, Gastrointestinal	38(7.1)	16(6.0)	22(8.2)	
	Cancer	62(11.6)	33(12.3)	29(10.8)	
	Cardio, pulmonary	82(15.3)	46(17.2)	36(13.4)	
	Renal	33(6.2)	22(8.2)	11(4.1)	
	Musculoskeletal	29(5.4)	10(3.7)	19(7.1)	
Surgery	Yes	348(64.9)	172(64.2)	176(65.7)	0.13(0.717)
	No	188(35.1)	96(35.8)	92(34.3)	
Types of ICU	Medical	129(24.1)	70(26.1)	59(22.0)	2.52(0.641)
	Surgical	214(39.9)	99(36.9)	115(42.9)	
	Neurological	160(29.9)	81(30.2)	79(29.5)	
	Cardiac	25(4.7)	14(5.2)	11(4.1)	
	Mixed	8(1.5)	4(1.5)	4(1.5)	
ICU admission route	Emergency room	369(68.8)	189(70.5)	180(67.2)	0.71(0.401)
	Others	167(31.2)	79(29.5)	88(32.8)	
Cardiopulmonary resuscitation	Yes	22(4.1)	8(3.0)	14(5.2)	1.83(0.400)
	No	430(80.2)	219(81.7)	211(78.7)	
	Unknown	84(15.7)	41(15.3)	43(16.0)	
Ventilator treatment	Yes	140(26.1)	64(23.9)	76(28.4)	1.70(0.428)
	No	316(59.0)	165(61.6)	151(56.3)	
	Unknown	80(14.9)	39(14.6)	41(15.3)	
ICU admission days		11.10 ± 10.34	10.66 ± 9.40	11.55 ± 11.20	−1.00(0.318)
Months after discharge		6.87 ± 3.85	6.60 ± 3.75	7.14 ± 3.93	−1.63(3103)
Readmission	Yes	186(34.7)	92(34.3)	94(35.1)	0.00(1.00)
	No	350(65.3)	176(65.7)	174(64.9)	

EFA = exploratory factor analysis; CFA = confirmatory factor analysis, M = mean; SD = standard deviation; ICU = intensive care unit.

Table 2
Factor loadings from exploratory factor analysis.

Items	Factor			Communality
	1	2	3	
14. It's hard to memorise numbers.	0.966	−0.029	−0.065	0.827
16. People around me say that I repeat what I said before.	0.802	−0.273	0.161	0.604
17. I cannot concentrate on reading.	0.758	0.025	0.050	0.650
20. Money management is difficult.	0.745	0.168	−0.074	0.645
21. It is hard for me to find the way.	0.614	0.302	−0.072	0.601
22. I am confused with date or time.	0.613	−0.002	0.168	0.534
1. I have nightmares.	0.103	0.814	−0.075	0.687
2. I am easily startled	0.041	0.780	−0.048	0.598
7. I have no hope.	−0.052	0.763	−0.030	0.514
8. I am annoyed or angry.	−0.142	0.660	0.143	0.465
10. I am worried.	−0.036	0.512	0.165	0.369
11. My heart is stuffy	0.078	0.474	0.206	0.461
23. My hand grip is weak.	0.005	−0.008	0.793	0.626
24. My sexual performance has changed.	0.136	−0.054	0.715	0.599
25. My joints are stiff.	−0.071	0.127	0.678	0.519
26. I can hardly climb the stairs.	−0.040	0.207	0.657	0.608
28. I get tired easily.	0.067	−0.061	0.629	0.404
31. I feel sick everywhere in my body.	0.120	0.081	0.624	0.582
Eigen value	8.38	1.80	1.35	
Explained variance (%)	46.55	10.00	7.49	
Total explained variance (%)	46.55	56.55	64.04	

number of factors was determined to be three, taking into account the scree plot and cumulative explained variance. The criteria for factor extraction were set to 0.30 for communality and 0.40 for factor loading. In addition, we removed items with a cross load of 0.30 or greater and a difference of less than 0.20. The EFA procedure was repeated five times, and eight items were deleted. As a result, 18 items consisting of three factors were selected, which accounted for 64.0% of the total variance (Table 2). Each factor was named to reflect the conceptual framework of PICS: cognitive, mental and physical areas.

CFA was conducted to examine the dimensionality of PICSQ derived from the EFA. First, the fitness of the model was analysed to meet the minimum standards of goodness of fit: $\chi^2 = 406.569$ ($p < .001$), degree of freedom (df) = 132, standard χ^2 (chi-square mean/df [CMIN/df]) = 3.08; root mean square residual (RMR) = 0.05; standardized root mean square residual (SRMR) = 0.06; root mean square error of approximation (RMSEA) = 0.09; Tucker Lewis index (TLI) = 0.90; and comparative fit index (CFI) = 0.90 (Table 3).

Next, the standardized factor loading (λ) was calculated to test the convergent validity. The λ value of all the items was above the reference value of 0.50 (Fig. 1). As a result of the analysis of discriminant validity, the criterion that the value of "$r \pm 2 \times$ standard deviation" between factors should not include 1 (Woo, 2012) was met.

For criterion validity, the correlation between PICSQ and JFS was r=0.73 ($p < .001$). The correlation between PICSQ and SF-36 was r = -0.38 ($p < .001$) for PCS and r = -0.51 ($p < .001$) for MCS.

Reliability

Regarding the internal consistency of each factor, Cronbach's α was 0.87 for the mental area, 0.90 for the cognitive area, and 0.84 for the physical area. The overall internal consistency of PICSQ was represented by Cronbach's α = 0.93. In the test-retest analysis, the correlations for each factor between the first and second measures were r = 0.82 to 0.88 ($p < .001$), and the correlation between the two total scores was r = 0.90 ($p < .001$).

Final questionnaire

The final PICSQ included three factors: mental, cognitive, and physical areas. The total number of items was 18, with six items for each factor. The time required for an ICU survivor to respond to PICSQ was less than 5 min. The responses to each item are either 0 (Never), 1 (Sometimes), 2 (Most often), or 3 (Always). The total PICSQ score can be between 0 and 54, and the mean can be between 0 and 3 (Table 4). The PICSQ score of the 426 participants in the current study was 23.82 ± 10.55, and the mean score was 1.32 ± 0.59. The mean score for each PICSQ area was 1.30 ± 0.67 for the mental area, 1.22 ± 0.71 for the cognitive area and 1.46 ± 0.66 for the physical area.

Discussion

The dimensions of the final PICSQ were constructed similar to the initial conceptual framework set up for the tool development. The first factor, the mental area, consisted of six items reflecting PTSD, depression, and anxiety. These are common mental problems experienced by ICU survivors. More than two-thirds of ICU survivors experience one or more episodes of PTSD, depression, or anxiety, with 36% of survivors having all three problems simultaneously (Huang et al., 2016). Previous studies reported that PICS did not cover all areas of mental health or used multiple measurement tools to assess mental health (Huang et al., 2016; Kim and

Table 3
The fitness indices of the model.

	χ^2	df	Standardized χ^2 (CMIN/DF)	RMR	SRMR	RMSEA (90% CI)	TLI	CFI
Criteria	>0.05		≤3.0	≥0.05	≥0.05	≤1	≥0.90	≥0.90
Model	406.57 (<0.001)	132	3.08	0.05	0.06	0.09 (0.08–0.10)	0.90	0.90

Note. df = Degree of Freedom; CMIN/DF = Chi-square Mean/Degree of Freedom, RMR = Root Mean Square Residual; SRMR = Standardized Root Mean Square Residual; RMSEA = Root Mean Square Error of Approximation; TLI = Tucker Lewis Index; CFI = Comparative Fit Index.

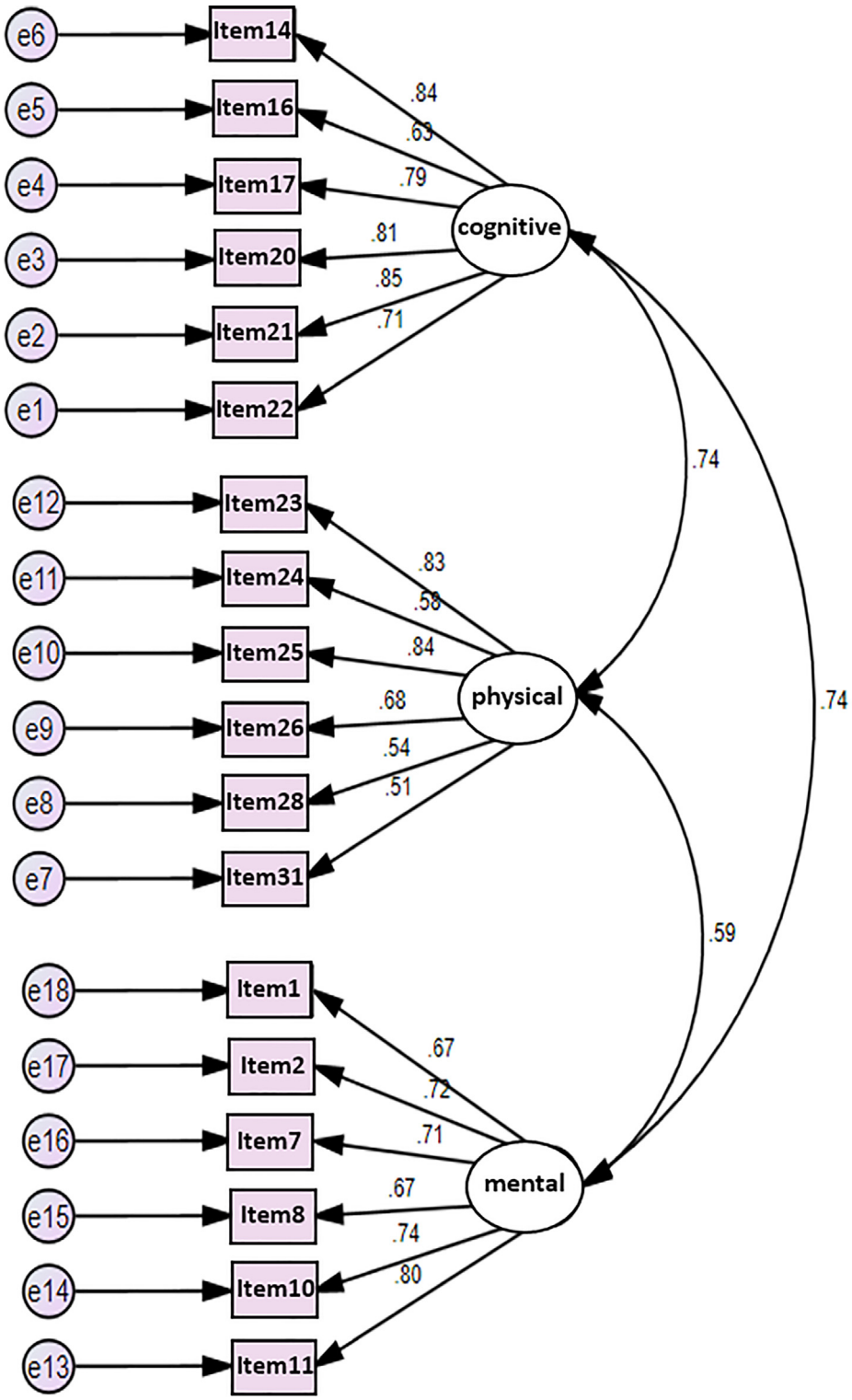

Fig. 1. The standardized estimates of confirmatory factor analysis model.

Kang, 2016; Marra et al., 2018). Unlike those, PICSQ is a relatively simple questionnaire, and it provides a comprehensive assessment of mental health problems.

The second factor, the cognitive area, consisted of six items reflecting memory disturbance, executive dysfunction, and visuospatial perception abnormality. Tools such as the Montreal Cognitive Assessment (Nasreddine et al., 2005) and the Repeatable Battery for the Assessment of Neuropsychological Status (Randolph et al., 1998) that are frequently used to measure cognitive function require assessor training and also have limitations regarding time, space, and cost. Since PICSQ was developed in a self-report format, it is expected to be more convenient in clinical practice. In the course of developing the PICSQ items, we attempted to describe the cognitive problems that are often experienced by survivors in their own language. For example, the item "People around me say that I repeat what I said before" was

Table 4
Final version of the post intensive care syndrome questionnaire.

Items	Never	Sometimes	Most often	Always
1. It's hard to memorise numbers.	0	1	2	3
2. People around me say that I repeat what I said before.	0	1	2	3
3. It is hard for me to find the way.	0	1	2	3
4. I cannot concentrate on reading	0	1	2	3
5. Money management is difficult.	0	1	2	3
6. I am confused with date or time.	0	1	2	3
7. My joints are stiff.	0	1	2	3
8. My hand grip is weak.	0	1	2	3
9. I can hardly climb the stairs.	0	1	2	3
10. My sexual performance has deteriorated.	0	1	2	3
11. I get tired easily.	0	1	2	3
12. I feel sick everywhere in my body.	0	1	2	3
13. My heart is stuffy.	0	1	2	3
14. I have nightmares.	0	1	2	3
15. I am worried.	0	1	2	3
16. I am annoyed or angry.	0	1	2	3
17. I am easily startled	0	1	2	3
18. I have no hope.	0	1	2	3

developed to reflect the actual statements of the survivors. These items are expected to increase the sensitivity of PICSQ as a measurement tool.

The physical area consisted of six items reflecting decreased physical function, limitation of daily activities, and symptom experience. Among these, "*I get tired easily*" and "*My hand grip is weak*" reflect the fatigue and weakness experienced by survivors. Over 90% of ICU survivors experience more than one symptom, and the most common symptoms are fatigue and weakness (Choi et al., 2014). Many survivors experience fatigue associated with ICU-acquired weakness that affects their daily activities (Desai et al., 2011). Thus, it is necessary to develop interventions that can improve these problems.

PICSQ is consistent with the criteria that the number of preliminary items should be three to four times the final items (DeVellis, 2016) and that four to six items are required to measure one factor (Ji and Kim, 2015). The variance of the PICSQ items selected through EFA was 64.0%, which satisfies the criterion of 60% (Ji and Kim, 2015). The Cronbach's α of PICSQ was good, and the correlation between test-retest scores was high. In other words, PICSQ is a reliable instrument with internal consistency and repeatability. We also estimated the criterion validity of PICSQ by verifying the correlation with JFS and SF-36. The high correlation with JFS and SF-36 reflects the criterion validity of PICSQ.

Strengths and Limitations

The current study is significant in that it has developed a reliable and valid self-report tool to measure PICS. It is expected that PICSQ will be used for future studies on the long-term outcomes of ICU survivors and the development and assessment of related nursing interventions. However, there are some limitations to this study. First, the study subjects were conveniently selected from three cities in Korea. Therefore, care should be taken to generalise the findings to other ICU survivors, and further research that expands the samples and settings are required. Second, in the current study, surveys were conducted among survivors who expressed their willingness to participate. Therefore, it is possible that the degree of PICS was underestimated by the fact that survivors with severe disabilities that could have affected communication were excluded. Third, we cannot be certain of the causal relationship between PICS and quality of life because we conducted a cross-sectional survey. Prospective studies are needed to more accurately estimate the predictive validity of PICSQ.

Conclusion

We developed a questionnaire to measure PICS experienced by ICU survivors and assessed its psychometric properties. A preliminary tool was developed through a literature review, qualitative interviews, and expert content validity analyses, followed by a survey of 536 ICU survivors and factor analyses to complete the final PICSQ with three factors and 18 items. The internal consistency and test-retest reliability of PICSQ were satisfactory. Construct validity, convergent validity, and discriminant validity, which were estimated through CFA, met the criteria. In addition, the criterion validity based on the correlation with other validated tools was also appropriate. Because PICSQ is a valid and reliable tool, it is recommended that this tool be used in clinical practice and in relevant research to assess PICS in ICU survivors. We also propose a tool standardization study to analyses the norm score for survivors with different characteristics by applying PICSQ to a larger sample.

Role of the funding source

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This funding source had no role in the study design, analysis, data interpretation, or decision to submit for publication

Authors' contributions

All authors contributed to the study conception and design. Y. J. J. was responsible for data collection, and Y. J. J. and J. K. analysed the data. Y. J. J. drafted the manuscript, and all authors carried out critical revisions of the paper.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.iccn.2019.102756.

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