Development and validation of the specific instrument for assistance complexity of puerperal and newborns: Fantinelli Scale

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Abstract

Objectives: to develop and validate a care complexity assessment system adapted for mothers and newborns, based on two pre-existing scales.

Methods: this is a cross-sectional study of psychometric validation of instruments, applied in a roomming-in, in 2016. The instrument has 13 indicators, submitted to the evaluation of a panel of judges for validation. For the psychometric analysis of the instrument, five criteria were adopted: a) internal consistency through Cronbach's alpha (αC); (b) intraclass correlation coefficient (ICC); c) correlation between categorical items, mediating Kendall correlation; d) ceiling and floor effect; e) Kaiser-Meyer-Olkin test.

Results: after evaluating the judges on the categories, the agreement was satisfactory, being equal to or greater than 80%. The mean total score of the 13 items was 22.5 ± 4.2, with an intermediate level score of 52.9%. For psychometric validation purposes, the instrument presented αC scores of 0.73 points, between minimum items of 0.70 and maximum of 0.74 points. In the correlation of αC by items and the total score, the instrument showed high relationships (r2: 0.84). In the ICC assessment of 0.73 points (CI95%= 0.71-0.75; p<0.001).

Conclusion: the questionnaire presented psychometric indicators of acceptable content validity, with statistical evidence of reliability, obtained by satisfactory inter-rateragreement.

Key words *Validation, Neonatal nursing, Rooming-in care*

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Introduction

The increasing complexity in care production processes and changes in the demand for patient care in hospital area have required restructuring in health organizations and management models.[1,2] This context has become a challenge for the management of health institutions in Brazil, as effective and efficient assistance needs to be met with adequate management of human resources.[3] In this sense, it is considered important to discuss issues related to the degree of dependence of patients, with regard to nursing assistance, as well as about its impact on the workload of the nursing team.[3]

The concept of patient classification system (PCS), in health practice, contributes to the improvement of models used to determine the workload of the nursing team, valuing the average work time dedicated to patients classified in different categories of care. This enables the adequacy of methods used until then to determine costs of the assistance provided.[4] For this reason, the system has been considered an essential instrument of administrative practice, providing information for the decision-making process regarding thecosts of nursing care, organization of services and planning of nursing care.[4]

The PCS is a process in which one seeks to categorize patients according to the amount of nursing care required, that is, based on the complexity of the care provided.[5] This classification process, according to Perroca,[6] produces a data source that can be used for the qualitative and quantitative planning of human resources, as well as the material resources necessary to ensure safe nursing care. In addition, using a patient classification system allows to know the profile of users and to plan care in a more individualized way, focused on the needs of patients and the nursing team.[6]

Fugulin *et al*.[4] classify patients according to the degree of dependence on nursing, being extremely useful for the improvement of official parameters related to the theme of dimensioning nursing staff in hospital institutions.[6] Thus, the central point of the study was to develop and validate a scale that contemplates the evaluation of the puerperal woman in its entirety, focusing on the mother-baby binomial (Fantinelli Scale). An evaluation system of care complexity was developed for the puerperal woman, using the evaluation criteria of the Fugulin Method[7] and UNICEF[7] precepts based on breastfeeding as a reference. In this sense, this study intends to readapt the evaluation criteria more broadly, contemplating significant aspects for the integral and holistic evaluation of the puerperal woman and the newborn. The adapted scale, which received the name of Fantinelli Scale, presents criteria that will contribute to the planning of the dimensioning of personnel, as well as to the readjustment of the nursing team regarding workload and time to dismiss the patients. Thus, the aim of this study is to develop and validate a care complexity assessment system adapted for puerperal women and newborns cared for in the rooming-in.

Methods

This is a cross-sectional, descriptive and analytical study, for the purpose of developing and validating a specific instrument to assess the care indicator in health service, both for identification and for controlling the degree of complexity of care required by the puerperal women and newborns.

The study was developed from July 2016 to November 2016. The survey was performed on the puerperal women and their newborns, hospitalized in the rooming-in, in a private hospital located in the South Zone of the city of Porto Alegre / RS. As exclusion criteria, we considered hospitalized mothers who were unable to participate in the study due to medical reasons.

After reviewing the literature and identifying the basic needs of the puerperium, 13 assessment indicators were created, such as: mental status, therapeutics, feeding, elimination, vital signs, wander, body care, skin integrity, mother's general observations, baby position, latch-on and suction. Each indicator item has a gradation of increasing intensity of care complexity, so that the first item corresponds to the lowest level of care complexity and the last to the maximum level of complexity. Each of these indicators is subdivided into 4 items, on a *Likert* scale, graded from one to four, which sum can vary from 13 to 52 points.

In order to homogenize its application, different values were assigned to each level of dependence in relation to the care provided and the time available to the patient. The sum of values obtained in each area and the definition of each care category determines the care complexity to be provided to the patient. Minimal care was considered between 13 and 19 points; intermediate care, from 20 to 26 points; semi-intensive care, from 27 to 33 points; intensive care, above 34 points. The adapted scale follows the same definitions as the care categories of the Fugulin scale.[6]

For content validation purposes, the instrument was sent to a nursing group (judges), consisting of

seven members, with extensive professional experience, guaranteeing the participation of specialists in the maternal and child issue (with a postgraduate degree in pediatric nursing or in obstetrics or in maternal and child nursing). These participants had a minimum professional experience of five years in the practice or teaching of maternal and child nursing, since knowledge of the subject was an essential condition for this work.

To analyze the consistency of content and related references, a form was structured with three adjustment options: a) item according to the theme, with no need for adjustment or exclusion; b) item according to the theme, with adjustment needs and c) item without agreement with the theme, requiring exclusion or replacement. Among the 13 items explored, none received attribution (c), only concepts (a/b) were considered. Thus, the concept assignments (b) received adjustments regarding the researchers' suggestions.[8]

Data were organized in a table in the Microsoft Access database (Microsoft Corporation, Redmond, Washington, United States of America), version 2013 and exported to SPSS statistical software (Statistical Package for the Social Sciences, New York, United States of America) version 20 for Windows. The following tests were carried out: Kaiser-Meyer-Olkin criterion (KMO), for analysis of the inverse correlation matrix; Bartlett´s sphericity test, to test correlated hypotheses, and the Varimaxrotation test, in order to analyze the factor loads of each domain; Cronback's α coefficient (αC), intraclass correlation coefficient (ICC) and Kendall's correlation for the purpose of validating the internal consistency of the instrument. Data were expressed by absolute and relative frequencies for categorical variables and standard deviation for continuous variables.

In the statistical analysis, Cronbach's alpha (αC) was used,[9] which assesses whether an instrument is able to always measure what it is intended to measure in the same way, performing an average correlation between questions and answers. Acceptable values were used for scores α-C >0.70 and <0.95. In the correlation between categorical items, Kendall's correlation was used, whose acceptable values are r≥0.3 [10] and the intraclass correlation coefficient (ICC),[10] in order to measure the homogeneity of measurements. This is useful for interpreting the proportion of total variability attributed to the measured object, adopting a cut-off point ≥ 0.70 for classification of the total score (excellent). For ceiling and floor effects, which evaluate the substantial values of answers, provided that they exceed 20%, criteria 1 (Agree/Floor) and 5 (Disagree/Ceiling) were used. In the factorial validity of the domains, three tests were applied: the Kaiser-Meyer-Olkin (KMO) test, with acceptable levels >0.6, the Bartlett´s sphericity test, with acceptable levels of X^2 for $p<0.001$ and the Varimaxfactorial rotation test, with acceptable levels >0.6.[11]

The study was approved by the Research Ethics Committee (REC) of the proposing institution, under the consolidated opinion nº 2.612.347/2018. All participants signed a Free and Informed Consent Form (FICF).

Results

To validate the questionnaire, the study was carried out from July to November 2016, and 1,396 puerperal women were evaluated, with mean age of 31.1 ± 5.7 years and gestational age of 37.9 ± 2.3 weeks, predominantly Caucasian (869; 62.2%) and predominantly in the first pregnancy (708; 50.7%), through hospitalizations by health insurance (1,207; 86.5%). Regarding the application of the questionnaire, the average of the total score of 13 items was 22.5 ± 4.2, with a classification in the intermediate level in 739 (52.9%), as shown in Table 1.

In the factorial assessment of the items by domain, the questionnaire presented values within the acceptable ones for the three tests applied. Thus presented: Kaiser-Meyer-Olk in criterion (KMO=0.735), Bartlett´s sphericity test, showing values of $X^2=p<0.001$ and *Varimax* rotation test, presenting five factors, with a minimum load of 0.527 and a maximum of 0.765, as shown in Table 2.

The αC was applied for the punctuation of the total score of the 13 items, with scores of 0.73 points and between minimum items of 0.70 and maximum of 0.74 points. In addition, in the αC correlation by items and the total score, the instrument showed high relations ($r^2= 0.84$), with minimum relations of $r^2=0.11$ and maximum of $r^2= 0.57$, all with significance values <0.05. In the evaluation of ICC, the value presented for the total score was considered acceptable, with an ICC of 0.73 (CI95%= 0.71-0.75; $p<0.001$), as shown in Table 3.

In the evaluation of the ceiling and floor effects, ten (76.9%) of the items presented values above 20% for floor effect (I agree) and only two (15.4%) for ceiling effect (I disagree), as shown in Table 3.

When assessing the correlation between items and through the score of the mean total punctuation (Table 4) only two items of the questionnaire did not show correlations with the total scores of the questionnaire (items 1 and 2).

Table 1

Overall classification of the 1,396 puerperal women evaluated from July 2016 to November 2016 in Porto Alegre / RS.

	$\bar{X}$ ± SD	N	%
Age of puerperal women (years)	31.1 ± 5.7		
Ethnicity/Race			
White		869	62.2
Black		326	23.4
Brown		201	14.4
Gestational age (months)	37.9 ± 2.3		
Number of pregnancies	1.7 ± 1.0		
First pregnancy		708	50.7
From 2 to 3 pregnancies		647	46.3
From 4 to 5 pregnancies		37	2.7
More than 5 pregnancies		4	0.3
Newborn (Neonatal)		229	16.4
Type of hospitalization/pregnancy			
Private		105	7.5
Health insurance		1,207	86.5
Others		84	6.0
Month of hospitalization/pregnancy			
July		288	20.6
August		304	21.8
September		279	20.0
October		294	21.1
November		231	16.5
Care complexity questionnaire			
Punctuation of total score	22.5 ± 4.2		
Classification of total score			
Minimal care		406	29.1
Intermediate care		739	52.9
Semi-intensive care		245	17.6
Intensive care		6	0.4

Table 2

Factorial test through Kaiser-Meyer-Olkintest, Bartlett´sphericity test and *Varimax* rotation test criteria (n=1,396).

	Question	Factor 1	Factor 2	Factor 3
Motility, mobility, activity and wander	Q3	0.765		
Eliminations	Q8	0.730		
Overall observation of mothers and breasts	Q10	0.628		
Baby position	Q11	0.716		
Latch-on	Q12	0.619		
Suction	Q13	0.646		
Feeding	Q4		0.565	
Skin integrity	Q6		0.524	
Behavior, feelings and thoughts	Q7		0.566	
Therapeutics	Q9		0.567	
Mental state and sensory perception	Q1			0.527
Vital signs	Q2			0.756
Body care, friction and shearing	Q5			0.669

Table 3

Evaluation, punctuation and classification of the psychometric analysis, using αC and ceiling and floor effects of the 13 items of the questionnaire (n = 1,396).

Frequency of answers per item		I agree		I partially agree		I partially disagree		Disagree		$\overline{X}$ ± SD	r^2	αC
		n	%	n	%	n	%	n	%			
Q1	Mental state and sensory perception	1379	98.8†	17	1.2	0	-	0	-	1.0±0.1	0.30*	0.74
Q2	Vital signs	625	44.8†	768	55.0	2	0.1	1	0.1	1.6±0.5	0.29*	0.76
Q3	Motility, mobility, activity and wander	756	54.2†	182	13.0	173	12.4	285	20.4†	2.0±1.2	0.61*	0.70
Q4	Feeding	1,015	72.7†	360	25.8	19	1.4	2	0.1	1.3±0.5	0.28*	0.72
Q5	Body care, friction and shearing	49	3.5	278	19.9	1,021	73.1	48	3.4	2.8±0.6	0.29*	0.72
Q6	Skin integrity	57	4.1	104	7.4	1,216	87.1	19	1.4	2.9±0.5	0.11*	0.74
Q7	Behavior, feelings and thoughts	1,172	84.0†	178	12.8	17	1.2	29	2.1	1.2±0.6	0.23*	0.73
Q8	Eliminations	781	55.9†	201	14.4	34	2.4	380	27.2†	2.0±1.3	0.57*	0.70
Q9	Therapeutics	254	18.2	1,048	75.1	89	6.4	5	0.4	1.9±0.5	0.29*	0.72
Q10	Overall observation of mother and breasts	1,117	80.0†	216	15.5	53	3.8	10	0.7	1.3±0.6	0.27*	0.72
Q11	Baby position	870	62.3†	290	20.8	217	15.5	19	1.4	1.6±0.8	0.52*	0.70
Q12	Latch-on	750	53.7†	278	19.9	342	24.5	26	1.9	1.7±0.9	0.48*	0.71
Q13	Suction	988	70.8†	283	20.3	101	7.2	24	1.7	1.4±0.7	0.41*	0.71

Frequency of answers per care		Minimum		Intermediate		Semi-intensive		Intensive				
TS	Total Score	406	29.1	739	52.9	245	17.6	6	0.4	22.6±4.2	0.83*	0.73

αC= Cronbach's alpha coefficient; r^2 = correlation of αC; * *p*-value of $r^2<0.05$.
† ceiling/floor effect for items with a prevalence above 20% of answers.

Table 4

Correlation test between items and total score (n=1,396).

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	TS
Q1	1.00	0.05	-0.06*	0.00	0.04	-0.01	-0.03	-0.06*	-0.03	-0.01	-0.03	-0.04	-0.03	0.00
Q2		1.00	-0.29**	-0.14**	0.17**	0.03	0.00	-0.18**	-0.01	-0.03	-0.10**	0.10**	-0.10**	-0.01
Q3			1.00	0.38**	0.32**	0.07**	0.03	0.58**	0.24**	0.06*	0.16**	0.11**	0.13**	0.54**
Q4				1.00	0.15**	-0.02	0.17**	0.36**	0.02	0.16**	0.05*	0.03	0.09**	0.36**
Q5					1.00	0.06*	0.05	0.32**	0.24**	0.06*	0.10**	0.16**	0.06*	0.43**
Q6						1.00	-0.04	0.06*	0.24**	0.03	0.06*	0.09**	0.04	0.18**
Q7							1.00	0.04	-0.12**	0.40**	0.27**	0.17**	0.26**	0.25**
Q8								1.00	0.29**	.064*	0.10**	0.13**	0.09**	0.55**
Q9									1.00	0.00	0.17**	0.23**	0.13**	0.39**
Q10										1.00	0.33**	0.17**	0.27**	0.32**
Q11											1.00	0.49**	0.56**	0.50**
Q12												1.00	0.44**	0.52**
Q13													1.00	0.43**
TS														1.00

Q= Question corresponding to the questionnaire number; TS= Total score of the questionnaire; ** *p* of r<0.01; * *p* from r<0.05 to 0.01; Kendall's correlation test.

Discussion

It is extremely important, in the current context, to develop a specific instrument to assess the specific degree of assistance complexity in the care of puerperal women and their newborns, in order to determine, monitor and evaluate the individualized care needs for each binomial. The use of appropriate tools for this type of patient will be of great help in the management of the nursing service, in the sense of verifying the workload of your team, using resources that allow you to better reevaluate the attention and planning, as well as the distribution in control of the professional staff. Thus, the present study had as its primary objective the development and validation of a specific instrument in order to assess the care complexity for puerperal women and their babies cared for in the rooming-in, based on the form of observation and assessment of breastfeeding recommended in the guidelines of the World Health Organization (WHO), in the United Nations Children's Fund (UNICEF) and the Fugulin Scale.

Among the recommended breastfeeding promotion actions, there is the observation of mother and newborn during breastfeeding. To guide this practice, a breastfeeding observation protocol was developed by UNICEF, in which it is possible to evaluate the desirable behaviors of mothers and babies and other indications of problems perceived by the nurse.[12]

The process of validating an instrument is arduous and long, but it is essential that instruments have reliability and validity to minimize the possibility of subjective judgments.[13] Validation processes that include careful and systematic steps can guarantee the quality of the results.[14]

The construction and validation of instruments that measure the quantity and content of information are essential in an attempt to improve the knowledge of puerperal patients. The clarity index generated by professionals and patients determined that the proposed instrument is easy to understand for the population to be evaluated.[10,15,16]

In assessing clarity, the instrument met the minimum prerequisites for structuring, relevance, credibility and balance, through intelligible, consistent items and expressions befitting the attribute, expressing a single idea to the proposed instrument.[10,17,18]

This can be stated, since only 3 of the 13 questions answered by the nurses had doubts and did not obtain 100% positive answers, which is equivalent to 80%. Where a high abstention rate was obtained, however, these values were already expected, given that the levels of abstention reported in the literature are 30 to 50% in the first round and 20 to 30% in the subsequent ones.[19]

The participation of specialist nurses who have extensive professional experience in the areas of care, teaching and research, was essential for the improvement and validation of the instrument. Their expertise contributed to the construction of knowledge, enhancing these dimensions, given the importance of the theme under study.

The experts pointed out activities that were clearly and objectively described and all considered that they were relevant and represented the practice of puerperal nursing care.They also made suggestions related to the following aspects: title of the instrument, standardization of writing style and inclusion of assistance with the binomial mother and baby in the neonatal intensive care unit.

Regarding the validity of the questionnaire content, through factorial analysis of the items by domain, the results showed values within acceptable patterns for the 1,396 tests applied, demonstrating a good factorial correlation between the 13 items and the 4 domains proposed, such as: (KMO=0.735, Bartlett´s=p<0.001 and minimum *Varimax* rotation of -0.527 and maximum of 0.765).

The validity of the internal consistency through the Chronbach alpha demonstrates that the application of such a coefficient allows us to evaluate the consistency between items, as well as their responses, providing an estimate of the true viability of an instrument for proper measurements, in which values below 0.70 are considered weak and above 0.95 are redundant. Thus, the values attributed to the αC coefficient in this study demonstrate that there is good reliability between questions (items) and their answers in the *likert* scale format (αC = 0.73). When applying the αC (r^2) correlation, we found all values above the expected ≥0.3, reinforcing that there is a positive association between items and categories.

The content validation of the instrument for the Assessment of the Degree of Dependence of the puerperal woman and the newborn proved to be relevant, clear and objective, enabling its application in a reliable way, thus being able to contribute as a parameter for the nursing dimensioning.[20]

Regarding the nurses who helped validate the content, an excellent degree of agreement was obtained between them, with a minimum value of 0.72 being found in the guidelines for applying the instrument. Thus, it is considered that the scale proposals considered the needs in relation to what was intended to be questioned, according to the nurses.

The data regarding internal consistency and reliability determined the questionnaire's homogeneity and stability, demonstrating that multiple applications can generate similar and accurate results.[21-23] Regarding the sample size, a number of 238 patients hospitalized in rooming-in were used, according to a 95% confidence level and a sampling error of 5% per item, proposed in processes of instrument construction and validation.[10,24]

The FUGULIN instrument is the validated instrument closest to the proposed context, as it is evaluating, mainly, the hospitalized patient in an inpatient unit. However, the aspects addressed are different from those proposed by the present study under validation.

In addition, in this study, complementary assessments were applied to those analyzed by the two instruments (Fugulin + Observation and Breastfeeding Assessment Form), as in the case of the ceiling and floor effect, being considered an important assessment in the validation process of instruments that use responses in likert format, verifying how much the minimum or maximum alternatives influence the answers of the evaluated person. The values found with the application of the ceiling/floor effects show that 10 items (76.9%) obtained prevalence of the minimum answer option (never), which ended up influencing the average of the total questionnaire 22.6 ± 4.2.

There is a gap in the literature about other researches, national and international, developed with this type of patients, making it impossible to compare the results obtained. This reality represents limitations for the discussion of this research. The fact that it was also carried out in a single place, that is, only one maternity hospital, can be a methodological limitation.

The future performance of these tests will make it possible to verify their applicability in care and management practice, as well as to correlate each of these activities with the time spent to perform them, in order to constitute an instrument that determines the workload of the nursing team in these units.[22]

Thus, it is suggested to expand the focus on the factors that influence planning and management, considering all the complexity inherent to health services and the dimensioning of personnel as indicators for quality of care and the occurrence of adverse events.

The study made it possible to draw a profile of the unit and hospitalized puerperal women, as well as identifying the days of greatest nursing care demand. Therefore, the identification of the profile of this study unit allows the provision of services in assistance with more quality and with the necessary number of collaborators.

The categorization of nursing care is one of the necessary and important parameters in the management of a health service, since it demonstrates the degree of complexity of the care required by the patient, in addition to guiding a possible need for restructuring the management models in rooming-in. Therefore, access to a specific care category in the rooming-in, for the mother-baby binomial, will bring benefits to the organization in care line.

Analyzing the degree of need for patient care,it was possible to observe a greater concentration in semi-intensive care, followed by minimal, intermediate and intensive care. It is believed that this research has brought contributions to overcome the difficulties related to the proposal of parameters for dimensioning nursing staff in the rooming-in, in view of the excellence of care and safety of patients assisted in this area.[22]

Finally, the values obtained in the present study showed that the Fantinelli Scale is a valid instrument for a specific patient classification system for postpartum care, suggesting that the scale can be used in the management of a health service for the classification of these patients hospitalized in the rooming-in. Given the good prevalence and, if properly used, it can become a valuable tool for health care indicators in the identification and control of the degree of complexity of care required by the patient, in addition to guiding a possible need for restructuring management models in the rooming-in.

Authors' contribution

Fantinelli AA contributed to the elaboration of the project, data collection and writing of the manuscript. Borges RF participated in the elaboration of the project and review of the manuscript. Stein RT and Dal Molin RS wrote and revised the manuscript. Roncada C carried out project guidance, statistics, writing and revision of the manuscript. All authors approved the final version of the article.

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