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ORIGINAL RESEARCH

Development of the Readiness for Hospital Discharge Scale for Patients with Bile Duct Carcinoma Catheterized After Percutaneous Transhepatic Cholangial Drainage: A Validity and Reliability Study

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Objective: We develop the Readiness for Hospital Discharge Scale (RHDS) for patients with bile duct carcinoma catheterized after percutaneous transhepatic cholangial drainage (PTCD) and test the reliability and validity of the scale, so as to provide a quantitative tool for evaluating the discharge readiness of patients catheterized after PTCD.

Methods: The initial scale was developed following literature review, qualitative interviews, expert consultation, and other methods based on Meleis' Theory of Transition. We selected a total of 286 patients with bile duct carcinoma catheterized after PTCD from four tertiary A-grade hospitals in Nantong City. We conducted a cross-sectional survey using the initial scale to test the validity and reliability of the scale.

Results: RHDS for patients catheterized post-PTCD consisted of five dimensions, with a cumulative variance contribution rate of 74.6%. The Cronbach's α coefficient of the scale was 0.856, and that of each dimension was between 0.740 and 0.891; the scale-content validity index (S-CVI) was 0.875.

Conclusion: RHDS for patients with bile duct carcinoma catheterized after PTCD developed in this study, has good reliability and validity, and can be a useful tool for evaluating the discharge readiness of patients with bile duct carcinoma catheterized after PTCD.

Keywords: bile duct carcinoma, discharge readiness, percutaneous transhepatic cholangial drainage, scale

Background

Although immune checkpoint inhibitors (ICIs) have revolutionized the treatment landscape of bile duct carcinoma,[1–4] percutaneous transhepatic cholangial drainage (PTCD), which causes relatively minor trauma and can rapidly relieve patients' jaundice symptoms while ameliorating liver function, has become the best treatment for malignant obstructive jaundice caused by bile duct carcinoma.[5–7]

For patients with advanced cholangiocarcinoma who have lost the opportunity for radical surgery, PTCD drainage tube plays an important role in relieving biliary obstruction, and it is also a "life pipeline", so it is particularly important to teach patients how to maintain the pipeline and always keep the pipeline in place and unobstructed before discharge. At present, commonly, patients are discharged from hospital and live with a catheter after PTCD, but there still exist problems such as long survival time with catheter and high complications in catheter nursing after the patient is discharged with a catheter.[8] In the current clinical practice, most studies involving patients' discharge readiness adopt universal scale and some assessment tools for discharge readiness of special groups involve parturients, surgical patients, schizophrenia patients, and so on. Obviously, it lacks tools to evaluate whether patients with a catheter after PTCD are discharged with the required knowledge of the disease,

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whether they have the ability to maintain catheters, their psychological status, whether they are well-prepared for discharge, and other aspects remain a challenge, which affects the quality of managing hospital treatment and post-discharge nursing. Thus, it is important to effectively explore tools for evaluation of discharge readiness in patients post-PTCD. In this study, we aimed to develop a Readiness for Hospital Discharge Scale (RHDS) suitable for patients with bile duct carcinoma catheterized after PTCD and to test the validity and reliability of the scale, so as to provide a quantitative tool for evaluating the discharge readiness of patients catheterized post-PTCD.

Study Design

Theoretical Framework and Operational Definition

In this study, we adopted the following operational definition of the discharge readiness of patients with bile duct carcinoma catheterized after PTCD based on Meleis' Theory of Transition:[9] Discharge readiness of patients with bile duct carcinoma catheterized after PTCD refers to the catheterized patients' ability to adapt to the transition from hospital to home after PTCD for bile duct carcinoma. Based on literature review, analysis of existing RHDS,[10–16] experiences of catheterized patients with bile duct carcinoma after PTCD, domestic medical and cultural background, and other aspects, we finalized the dimensions of this scale to include physiological status, psychological status, role adaptation, social support, and self-efficacy.

Development of the Initial Scale

We generated the item pool mainly through literature analysis, qualitative interviews, expert consultation, and other methods, which are detailed below:

1. Literature analysis: According to the definition of "discharge readiness of patients with bile duct carcinoma catheterized after PTCD" and the definition and description of RHDS dimensions, we systematically searched Chinese and English databases using keywords such as "PTCD", "percutaneous transhepatic cholangial drainage", "discharge readiness", "psychological status", and "self-efficacy", and collected literature on the nursing and discharge readiness of patients catheterized post-PTCD as sources for item generation for RHDS for patients catheterized post-PTCD.[12]
2. Qualitative study: In view of the diversity in gender, age, economic level, education, and other characteristics, for this study, we selected patients catheterized post-PTCD from a tertiary A-grade hospital in Nantong City from August to September 2021 using maximum difference purposive sampling for in-depth semi-structured interviews. Interviewees were asked to share their experience, including their actual experiences (needs), and we adopted methods such as phenomenology[17] to explore the deep knowledge and insight of the lived experience that the participants shared in the interviews.

Additionally, in order to ensure the accuracy and preciseness of the study, the research team held repeated discussions based on Meleis' Theory of Transition and the definition of discharge readiness, and after a thorough literature analysis, identified the domains before drafting the preliminary interview guide. Data were processed and analyzed using Colaizzi's descriptive phenomenological method, which consists of a seven-step analysis.[18] We identified the corresponding thematic concepts from the interview data transcripts. Finally, we extracted five themes on the condition based on the experience and feeling (needs) of patients catheterized post-PTCD collected in these semi-structured interviews, which provided the reference for exploring the dimensions of the scale and constructing the item pool.

1. Referring to existing RHDSs: The item pool of the scale was established by referring to the relevant aspects in questionnaires or scales such as the "Readiness for Hospital Discharge scale, RHDS",[13] "Readiness for Hospital Discharge Scale – New Mother Form (RHDS-NMF)",[14] "Readiness for Hospital Discharge Scale for Enterostomy",[14] and "Readiness for Hospital Discharge Scale for Stroke Patients".[16]
2. Evaluation by experts: The items to be validated were screened and supplemented by expert judges. Seventeen medical experts from the intervention department or hepatological surgery department were invited to participate

in the Delphi expert consultation. They were asked to score the importance of the items in the scale by email. The total points were averaged, ensuring that the mean point was at least 4.0 and the variable coefficient was at least 0.25. The items were screened based on this; the consultation was completed after experts reached a consensus. At the same time, the response rate of questionnaires in two rounds of expert consultation was counted, based on which the expert consultation was achieved.[19] The positivity was measured; the expert positivity coefficient was calculated, and the result was the proportion of valid questionnaires in the total; a number of more than 70% indicated that experts were highly positive.[20] Formal questionnaire is shown in Supplementary Material 1.

The results showed that the positivity coefficients in two rounds of expert consultation were 100%, the overall expert authority coefficient was 0.892, and the coordination coefficients were 0.179 and 0.095 (Supplementary Material 2). The items of the scale were screened and modified using expert consultation. The initial scale of discharge readiness of patients after PTCD of bile duct carcinoma consisting of 32 items across 5 dimensions was developed and pre-tested.

Testing of Validity and Reliability of the Scale

Patients

We used convenience sampling to identify patients with bile duct carcinoma catheterized after PTCD. They were selected from four tertiary A-grade hospitals in Nantong City from August 2021 to August 2022. Inclusion criteria were as follows: (1) Patients with bile duct carcinoma catheterized after PTCD, diagnosis confirmed by pathology findings; (2) Age ≥ 18 years; (3) Patients with no psychiatric disorder and with normal comprehension, listening, and speaking capabilities; (4) Patients who gave their signed informed consent. Exclusion criteria were as follows: (1) Patients with congenital biliary tract disease; (2) Patients in severe condition or with unstable vital signs.

According to factor analysis, the ratio of scale items to sample size was required to be 1:5–10,[21] and including invalid questionnaires, the sample size was determined to be 200. We, however, distributed a total of 300 questionnaires, and effectively recovered 286, with a response rate of 95.3%.

Tools

The questionnaire consisted of two parts: (1) General data: consisting of gender, age, education, catheterization duration, jaundice grade, and so on; (2) The self-developed initial "RHDS for Patients with Bile Duct Carcinoma Catheterized after PTCD" consisting of 32 items across five dimensions.

Methods

Survey Implementation and Quality Control

The researcher and trained nursing staff from four hospitals conducted a one-on-one survey with patients catheterized post-PTCD. The questionnaires were collected back immediately after patients completed them and were checked carefully to ensure no items were omitted or missed. Specifically, 1) Before the commencement of the questionnaire survey, the nurses who were involved were given full information about the survey and trained on how to guide participants to complete the questionnaires; 2) The questionnaires were collected back immediately after patients completed them and were checked for integrity of responses; 3) The questionnaires were double-checked throughout, from editing to data collection, to ensure accuracy; 4) After the questionnaires were collected, those where the respondents took too long a time (≥20 min) or too short a time (≤2 min) for filling it up were eliminated. (The study was approved by the ethics committee of the hospital before implementation)

Statistical Analysis

Item Analysis

We analyzed the heterogeneity and homogeneity of scale items as follows: 1) Critical ratio method: Scores of the scale were calculated, and the first 27% samples were selected as the high-score group and the last 27% samples as the low-score group according to the order of the scores. We used the independent sample *t*-test to determine their corresponding critical ratios, with the critical ratio < 3.0 as the deletion criteria; 2) Correlation coefficient method: We analyzed the correlation between the item and the scale score, with the correlation coefficient < 0.4 as the deletion criteria;[22] 3)

Cronbach's α coefficient method: If the total score had a relatively higher Cronbach's α coefficient after an item was deleted, this suggested that the attribute of the item to be measured in the scale was different from that of other items, and was deleted;[23] 4) Factor analysis: This involved two indicators, namely "communality" and "factor load based on which we analyzed the relationship between the item and the scale; when the factor load value was <0.4 or common load occurred, the item was deleted.[24]

Validity Evaluation

1) Content validity: 10 medical experts from the intervention department or hepatological surgery department were invited to evaluate the content validity. We ensured balance in age, work experience, designation, education level, and other aspects when selecting them. The experts were asked to rate the importance of items using a 5-point rating scale, wherein 5 indicated "Very important" and 1 indicated "Very unimportant and we then calculated the content validity index (CVI) of the scale.[25] 2) Construct validity: We evaluated the construct validity of the scale using exploratory factor analysis.[26,27] It included three aspects: a. The factor loading value of the item under the relevant dimension was >0.40; b. The loading value of the item under other dimensions was smaller, with a difference value > 0.25; c. Dimensions' variance contribution rate > 50%.

Reliability Evaluation

The reliability of the scale was evaluated by calculating the Cronbach's α coefficient and split-half reliability coefficient. The Cronbach's α coefficient of the scale was >0.7, suggesting that the scale had good reliability.

Results

General Data

In this study, we distributed a total of 300 paper questionnaires, of which we recovered 287, including 286 valid questionnaires, with a valid response rate of 95.33%. In this survey, there were 161 patients over 61 years, accounting for 56.3% of the total sample. There were 155 patients with catheterization duration of 1–9 months, accounting for 54.2% of the total sample. General data of the respondents are shown in Table 1.

Item Analysis

Results of the study showed that there were significant differences in the critical ratios of items between the high-score group and low-score group ($P < 0.05$), except for item 13 and item 22. The critical ratios were between 4.24 and 13.57, suggesting that these items had a high degree of differentiation. No relevant items were deleted in the correlation analysis method, Cronbach's α coefficient method and factor analysis method. Based on the above item analyses, we deleted two items.

Exploratory Factor Analysis

Results of the exploratory factor analysis on the RHDS for patients catheterized after PTCD (initial version) were that the Kaiser–Meyer–Olkin (KMO) value = 0.839, the Bartlett's test of sphericity test chi-square value was 8619.492, and $P < 0.001$, suggesting that the data were suitable for factor analysis.[28,29] Subsequently, we used principal component analysis (PCA) and varimax orthogonal rotation, combined with characteristic root, scree plot, and communality, and we obtained five dimensions with the characteristic root greater than 1 as the dimensions of the scale, with 30 items, with the cumulative variance contribution rate of 74.586%. Results are shown in Tables 2, 3, and Figure 1.

Reliability Analysis

The Cronbach's α coefficient of the scale was 0.820; Cronbach's α coefficients of dimensions are physiological status was 0.958, psychological status was 0.777, role adaptation was 0.896, social support was 0.948, and self-efficacy was 0.960.

Validity Analysis

Validity is a criterion for judging the accuracy and effectiveness of a scale, which mainly consisted of content validity and construct validity.

Table 1 General Data of Patients

Characteristics	Group	Number of Cases	Percentage (%)
Sex	Male	194	67.8
	Female	92	32.2
Age (year)	18–45	20	7.0
	46–60	105	36.7
	≥61	161	56.3
Marriage	Unmarried	4	1.4
	Married	274	95.8
	Divorced or widowed	8	2.8
Education	Primary school or below	46	16.1
	Junior high school	154	53.8
	Senior high school	65	22.7
	Junior college or above	21	7.3
Occupation	Worker	10	3.5
	Farmer	197	68.9
	Individual occupation	28	9.8
	Retired	51	17.8
Living pattern	Alone	35	12.2
	With family	251	87.8
Catheterization duration	1–9 months	155	54.2
	9–18 months	94	32.9
	> 18 months	37	12.9
Payment of medical expenses	Self-funded	10	3.5
	State expense	5	1.7
	Medical insurance	264	92.3
	Cooperative medical care	7	2.4

Table 2 Explanatory Variance of Five Domains in Factor Analysis

Item/factor	Initial Eigenvalue			Sum of Squares of Rotated Load		
	Total	Variance Percentage	Cumulative %	Total	Variance Percentage	Cumulative %
1	7.486	24.953	24.953	7.297	24.322	24.322
2	5.831	19.438	44.391	5.668	18.894	43.216
3	4.214	14.047	58.438	4.166	13.885	57.102
4	3.441	11.471	69.909	2.719	9.064	66.165
5	1.403	4.677	74.586	2.526	8.42	74.586

Content Validity

The item-content validity indexes (I-CVI) were between 0.75 and 1.00, all of which were greater than 0.700; the scale-content validity index (S-CVI) was 0.875.

Construct Validity

RHDS for patients catheterized post-PTCD included five dimensions, with a cumulative variance contribution rate of 74.586%. We analyzed the relationship between the total score of the scale and the point of each dimension, and the correlation coefficient was between 0.404 and 0.597, suggesting that the scale had good construct validity. Details are shown in Table 4.

Table 3 Rotated Component Matrix in Factor Analysis

Items	Component				
	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5
Increase 1	0.912				
Increase 2	0.858				
T1	0.8				
T2	0.855				
T3	0.831				
T7	0.78				
T8	0.809				
T10	0.819				
T11	0.882				
T26	0.949				
T9				0.687	
T12				0.792	
T14				0.684	
T17				0.66	
T18				0.713	
Increase 3					0.836
T19					0.851
T20					0.915
T15			0.833		
T22			0.91		
T23			0.937		
T25			0.922		
T27		0.924			
T28		0.909			
T29		0.905			
T30		0.879			
T31		0.914			
T32		0.846			
T33		0.896			
T34		0.925			

Discussion

Reliability of the Scale

Reliability indicates the accuracy of the scale and its stability. In general, when the Cronbach's α coefficient is greater than 0.8, the scale has good internal consistency.[28,29] In this study, we tested the reliability of internal consistency to determine the reliability of the scale. The results showed that the Cronbach's α coefficient of the RHDS for patients catheterized post-PTCD was 0.820, and that for each dimension was in the range of 0.777–0.960, both of which were above the standard reliability value of 0.70, suggesting that the scale had good consistency and reliability. This also suggested that researchers avoided relevant influencing factors, and having been trained, they had mastered the skills and precautions to be taken during observation and conducting qualitative interviews.

Validity of the Scale

The validity of the scale refers to the correctness of scale measurement, and the higher the validity, the higher is the accuracy of scale measurement. In this study, we evaluated the construct validity of the scale using exploratory factor analysis. As one of the common methods for evaluating construct validity, exploratory factor analysis requires that the load of each item on its factor should be greater than 0.4 and that the cumulative variance contribution rate of the extracted common factor should be greater than 50%. Validity is the degree to which the scale can correctly measure the

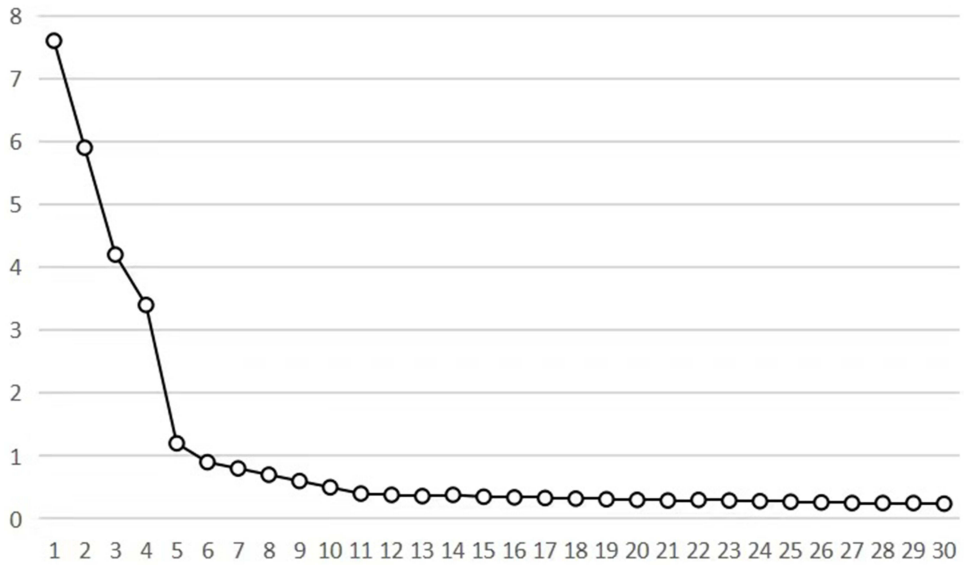

Figure 1 Exploratory factor scree plot.

characteristics to be measured.[25] Validity is target-oriented, and each scale has its own special purpose and function. A scale with high validity is applicable to its special group and has its special purpose. Validity is the most important consideration in measurement evaluation.

Content validity refers to the applicability and representation between the scale content and items, namely, whether the content of the scale can reflect the parameters to be measured among patients discharged with catheters after PTCD of bile duct carcinoma. We mainly generated the items of RHDS for patients with bile duct carcinoma catheterized after PTCD from qualitative interviews, which were used to explore the aspects that affected the discharge readiness of patients. Pre-testing proved that items were able to accurately reflect the psychological change and condition-related experiences of patients with bile duct carcinoma catheterized after PTCD. The Delphi expert consultation ensured that the scale items complied with the objective of the study.

In clinical verification, the I-CVI of the scale items was between 0.75 and 1.00 (which was higher than 0.700); the S-CVI was 0.875 (which was higher than 0.800). This suggested that the scale had good content validity. The results of factor analysis indicated that RHDS for patients catheterized post-PTCD included five dimensions (physiological status, psychological status, role adaptation, social support, and self-efficacy), with a cumulative variance contribution rate of 74.586%. We analyzed the relationship between the total scale score and the point of each dimension, and the correlation coefficient was between 0.404 and 0.597, suggesting that the scale had good construct validity, and the different dimensions were independent and also correlated.

Table 4 Correlation Coefficient Between the Total Score of the Scale and the Score of Each Dimension

Items	Physiological Status	Self-Efficacy	Social Support	Psychological Status	Role Adaptation	Total Score
Physiological status	1.000					
Self-efficacy	0.083	1.000				
Social support	0.058	0.464	1.000			
Psychological status	−0.115	0.049	0.117	1.000		
Role adaptation	−0.045	−0.029	−0.018	−0.102	1.000	
Total score	0.597	0.445	0.431	0.431	0.404	1.000

Scientific and Practical Significance of Scale Development

In this study, the initial item pool was generated using methods such as qualitative interviews, relevant literature analysis, and by referring to existing RHDSs based on Meleis' Theory of Transition. Items were screened using two rounds of Delphi expert consultation and pre-tested, thus forming the initial scale for the discharge readiness of patients with bile duct carcinoma catheterized after PTCD.

After item analysis and exploratory factor analysis, we developed the RHDS consisting of 30 items in 5 dimensions for patients with bile duct carcinoma catheterized after PTCD. This included dimensions such as physiological status, psychological status, role adaptation, social support, and self-efficacy involving the four factors of Meleis' Theory, namely, the nature of transition, conditions of transition, response mode, and nursing therapeutics. All dimensions in the scale had been included in the theoretical dimension that was originally conceived. This indicates that the theoretical model of the initial scale is reasonable.

We consider possible catheter blockage, catheter falling off, catheter displacement, and catheter infection in patients with bile duct carcinoma catheterized after PTCD after discharge, as well as the main risk links in continuing nursing such as the self-monitoring of aggravation of the disease and the improvement of self-efficacy. Accordingly, we included these relevant aspects, which were reflected in items 21 and 28–34. These items were clear, relevant, and easy to understand and observe, and were helpful in identifying these risks in patients being prepared for discharge. All these suggested that the scale was developed scientifically and was specific in its clinical evaluation.

The significance of this study is that the developed scale can be used as an assessment tool to understand the readiness of patients for discharge and return home and find out the inadequacy of patients' discharge readiness. Therefore, suggestions for improvement could be put forward to continuously improve the quality of discharge service. Thus, the occurrence of unplanned readmissions and complications caused by improper self-care could be reduced. At the same time, the scale could be used to identify factors affecting the discharge readiness of patients wearing catheters, which provided guidance for the formulation of personalized extended care plan and the improvement of clinical nursing quality. The generalizability of the developed scale to an international audience may warrant further research in the corresponding population.

Conclusion

In this study, the scale items were screened strictly and had good validity and reliability, thus providing a quantitative evaluation tool for clinical nursing staff to assess the discharge readiness of patients catheterized post-PTCD. Yet, the study had certain limitations, and further verification of the scale needs to be done in multi-center studies.

Data Sharing Statement

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethics Approval and Consent to Participate

This study was conducted with approval from the Ethics Committee of Nantong First People's Hospital (No: 2020YKS048). This study was conducted in accordance with the declaration of Helsinki. Written informed consent was obtained from all participants.

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Disclosure

The authors declare that they have no competing interests.

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