Design and psychometric properties of the obstacles to postoperative pain management in dementia scale (OPPMDS): A mixed methods exploratory study

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Research article

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Abstract

Background

The severe and acute pain of surgical site after hip fracture surgery among the elderly patients with dementia can threaten the treatment consequences. Pharmacological and non-pharmacological methods are used to reduce the risk of similar problems. Nevertheless, pain management may face different obstacles due to different reasons. Identifying and clarifying the acute pain management obstacles among the elderlies with dementia by the use of instruments tailored to the cultural structure of each community can lead to providing effective interventions.

Objectives

This study aims to design and psychometrically validate the OPPMDS from the nurses' point of view.

Methods

A sequential explanatory mixed methods design was used for this study. The item-generation phase was carried out through two main methods: The inductive method (15 face-to-face and semi-structured interviews with 15 nurses) and the deductive method (literature review). Item reduction was conducted integration of qualitative, literature reviews and scale evaluation. For scale evaluation, face, content and construct validity (Exploratory Factor Analysis (EFA); N = 330) and Confirmatory Factor Analysis (CFA) ;N = 120), convergent and divergent Validity and Reliability (Internal consistency and stability) were conducted.

Results

The EFA showed that the OPPMDS has three factors elderly-related factors, healthcare providers-related factors and system-related factors, which explained 57.572% of the overall variance. The CFA results indicated that the three-factor model of OPPMDS was best fit for the data. The convergent and divergent validity results suggested that the CR and AVE values of each factor was higher than 0.7 and 0.5, respectively (AVE > CR). The internal consistency of the first factor was 0.891, of the second was 0.929 and of the third was 0.890. The cronbach's alpha coefficient of the scale was found to be 0.956. In addition, the test-retest results demonstrated high rates of agreement between the first and the second test scores ($p < 0.001$).

Conclusion

The results of this study indicate that OPPMDS can be applied as a valid and reliable scale for measuring the postoperative acute pain management among the older patients with dementia and hip fracture.

Highlights

- Dementia is one of the most frequent disorders among the old patients, which can lead to hip fractures by reducing the patient's ability to maintain his balance.
- Hip fracture is associated with acute pain and movement limitations; thus it needs interventions like surgery.
- Surgery is associated with acute pain in surgical site, which can threaten the treatment outcomes.
- One of the nurses' main tasks is to manage the postoperative acute pain, which has obstacles associated.
- Awareness of the obstacles that lie in the way of postoperative acute pain management can help the healthcare providers in planning more effective interventions.
- Accessible and dedicated instruments are needed for recognising the acute pain management obstacles among the elderly patients with dementia.
- The final version of OPPMDS has an acceptable reliability.
- OPPMDS can be used for measuring the postoperative acute pain management among the older patients with dementia and hip fracture.

Background

Dementia is the most common cognitive disorder among the elderly(1). Based on World Health Organization (WHO) (2016) reports, it is estimated that there are 47.5 million elderly suffering from dementia and the number will increase to 67.5 million by 2030. A major part of this increasing statistics is living in low- and middle-income countries(2). Results of a hospital-based study conducted in Iran indicates that 36.6% of the elderly are diagnosed with different levels of cognitive impairments(3). Dementia is not a disease but rather a syndrome that affects the cognitive function and causes disorders in memory, thinking, attention, mathematical calculation, learning abilities, language and judgment(4).

Elderly people with a diagnosis of dementia are at higher risk of falling and sustaining a hip fracture in comparison with other reasons due to difficulty in maintaining balance and gait. Griffiths et al (2012) reported that 25% of elderly with hip fracture are suffering from middle cognitive impairments(5). Hip fracture is followed by physical activity limitations among elderly individuals due to the pain they experience(6), which leads to the need of pain-relieving interventions and rapid rehabilitation. In this regard, surgery is known as a common and important treatment intervention in such a way that more than 98% of patients diagnosed with hip fracture are surgery candidates(5).

Despite the fact that although surgery yields positive results, it can still compromise the intervention outcomes by resulting in acute and severe pain in the surgical site(7). The results of Sean Morrison et al. (2003) showed that ignoring the hip fracture postoperative pain management would result in hospital consequences like longer hospitalisation time, increase of the postoperative complications, patient missing or shortening physical therapy sessions and hospital discharge outcomes like urinary tract infection, hematoma, pneumonia, surgical wound infection, gastrointestinal bleeding, tromboemboli, urinary retention and bedsore(8).

For these reasons, recognising and managing the surgical site pain in this group of patients are among the main care goals of the treatment team, and more specifically the nurses who carry the main postoperative caring tasks out. Based on International Association for the Study of Pain (IASP) terminology, pain is what the patient says it is, when the patient says they have it. This definition emphasizes the mental perception of pain and of controlling the pain and also introduces the patient as the most eligible person to express the pain(9). Understanding the patient's mental symptoms is vital, as the elderly with dementia are unable to communicate linguistically and cannot convey the pain severity and type or show the exact pain location caused by surgery and they are not able to express clearly how effective were the antinociceptive drugs in their opinion(10). This group of patients is at higher risk of inappropriate management(11).

In addition to the speech impairments preventing the elderly with dementia to express their pain, there are more obstacles to pain management such as treatment team's opinion on aging and their awareness about the subject as well as organizational obstacles like the lack of manpower and equipment which all can complicate the pain assessment and management while declining the treatment quality(11). Hence, recognising the acute pain management obstacles among the elderly with dementia by the use of a reliable and valid instrument tailored to the cultural structure of each community can clarify the current situation and lead to more effective interventions(10).

Researchers' outcome can turn to valid and reliable evidence only if assessing the variables is advanced applying the mentioned instruments(12). Meanwhile, the available instruments such as Nurses' perceived obstacles to pain assessment and management practices tool have focused mainly on the postoperative pain management among the elderly but not the structural validity and reliability(13). The unique instrument assessing the postoperative pain management in older adults with hip fracture is designed by Rantala et al (2014)(11).

Design and psychometric evaluation of Rantala's tool was not conducted using a mixed-method approach whereas aforesaid approach is the best way for designing new instruments. Combining qualitative and quantitative techniques would result in a more precise and complete image from the phenomenon under study(14). This study is aimed to design and psychometric evaluate the OPPMDS from the nurses' point of view by mentioning all the needed stages of an instrument design including item generation, validity check, pilot test, analysing the data (using factor analysis) and reliability check, which are all needed to be applied in an instrument design study(15).

Methods

Study Design

Sequential exploratory mixed methods design was employed. A mixed-method study is the one that the researchers gather, analyse and combine their data applying the qualitative and quantitative

approaches(16). This study is conducted in two stages, which include item generation and item reduction. The time period of the whole study was done from June 2019 to January 2020.

Item generation

This phase is named “question development” or “item generation”. In the inductive method, also known as “grouping” the items are generated based on qualitative outcomes from direct observations and exploratory research methods, including personal interviews and focused groups(17). Applying the qualitative research techniques before the designing a instrument would help the researcher with finding more hypotheses to test and leading him toward a more valid questionnaire(18). The deductive method, also known as “logical partitioning” (19). Both the inductive and deductive methods were applied in this study.

First Phase: Inductive Method

An explorative qualitative study aiming to explore the scale of perceived postoperative acute pain management obstacles among elderly with hip fracture. The study environment was the western regions of Mazandaran province, Iran. The researcher (first author) was working at a treatment center in this region, which eased the access to the samples and reduce the cultural differences affecting on the structure under study. Purposeful sampling was adopted to determine the 15 nurses eligible for future participation (Table 1). The inclusion criteria were willingness for participation, working in clinical practice, having at least a bachelor’s degree and having the experience of caring for an elderly with dementia after hip fracture surgery. The exclusion criteria was unwillingness for further participation.

The data was gathered using face-to-face interviews lasting 25 minutes on average and conducted in one of the nurses’ lounges after the participants’ working shifts on their will. Interviews were recorded with the consent from the participants. The following questions were addressed:

1- could you please share your experience of acute pain management among the elderly with dementia after their hip surgery with me please?

2- what is your opinion about the obstacles an older adult with dementia may face after experiencing the hip fracture surgery?

Trustworthiness of Data

The results were further checked using the four Guba and Lincoln criteria of credibility, dependability, confirmability, and verifiability(20). Completing the interviews lasted about two months and the researcher gathered the data for four months. All the transcripts, initial codes and categories were discussed and reviewed for several times by all the research team members. Member check was also carried out. The transcripts, codes and categories were reviewed by an expert outside the research team for Peer check. Maximum variability sampling was used in order to obtain as much diversity as possible in characteristics thought to be of interest for our research purposes. These included age, gender,

educational level, marital status, working experience, type of employment and experience of caring for elderly with dementia after hip fracture surgery.

Data Analysis

Graneheim and Lundman approach was used to analyse the qualitative data based on the following steps(21):

- All the interviews were transcribed word by word.
- The transcriptions were read through several times to give an overall sense of the whole material.
- Categories and subcategories were extracted using the constant comparison method.
- Codes were controlled and reviewed by the research team members.
- Similar codes were grouped together and then clustered into subcategories.
- Similar subcategories were grouped together and then clustered into categories by the use of constant comparison method. The groups were named afterwards.

Second Phase: Deductive Method

The researcher searched plenty of online citation databases and bibliographic databases, as well as print sources, to identify and retrieve the needed documents for review. Of these documents, eight relevant English-language literatures published from 2000–2017 met the study criteria (11, 22–28).

Item Reduction

Third Phase: Integration of qualitative and literature reviews phases

Qualitative stage and literature review outcomes were independently coded. Then, the extracted codes were compared, the similar ones merged and the duplicate codes were removed. Initial categories, subcategories and themes were formed independently in both cases. Categories, subcategories and the naming process was controlled for several times by the research team during a four-month period. Afterwards, an item pool, including 29 items, was formed using the data gathered from the qualitative stage (fieldwork). A sample of the item generation process is mentioned at Table. 2. The deductive phase (literature review) also generated 46 items all added to the item pool together with the items extracted from the qualitative stage. The item pool was rechecked by the research team, duplicates were removed, similars were merged and some items were adjusted. A 67-itemed instrument was developed at the end.

Scale evaluation was also conducted by measuring the face validity (qualitative and quantitative), content validity (qualitative and quantitative by measuring of the content validity ratio(CVR) and content validity index (CVI)), construct validity (EFA and CFA), convergent validity, divergent validity and the reliability. Further explanations are provided below:

Face Validity

Face validity is defined as the degree to which the items appear to measure what the instrument purports to measure. The face validity was measured considering both the qualitative and quantitative approaches.

Qualitative Face Validity

10 participating nurses were interviewed face-to-face and asked to share their opinion about the difficulty, relevancy and ambiguous levels of each item. Suggested adjustments were considered.

Quantitative Face Validity

The face validity of the scale was evaluated using the impact score method for reducing and removing the irrelevant items and determining the importance level of each one. For this purpose, a five-point likert scale (5 = it is absolutely important to 1 = it is not important at all) was used. The scale was offered to the 10 nurses, who had participated at qualitative face validity measurement section and the item impact was calculated based on the formula below:

Item Impact Score = Importance (%) × Frequency

Content Validity

The content validity was evaluated considering both the qualitative and quantitative content validity measurement approaches.

Qualitative Content Validity

10 experts, who had experience with designing instruments, qualitative studies and clinical job assignments were interviewed and asked to review the scale and share their recommendations. The main cases reviewed by the experts were the grammatical and linguistic structure, appropriate wording, correct item allocation and proper scaling (29).

Quantitative Content Validity

The CVI and the CVR were analysed to assess the content validity quantitatively:

CVR

The necessity for keeping an item from the perspective of experts is determined by CVR, firstly introduced by Lawsche (1975)(30). The same subject matter experts participating at the qualitative content analysis section were requested to determine if keeping an item along with a group of other items is essential to operate a theoretical structure. For this purpose, a 3-point likert scale (ranging from 3 = essential, 2 = useful but not essential and 1 = not essential) was used and the CVR of each item was calculated based on the formula below:

$$CVR = \left(\frac{ne - (N/2)}{N2}\right)$$

In case the total score of CVR was higher than the Lawsche table (0.62 for 10 experts in this study), the content validity of the instrument is considered to be statistically significant ($p < 0.05$) and the item is essential for it(31).

CVI

The items are checked for compatibility with the aim of study by measuring the CVI(32) based on the Waltz and Bausell method (1983)(33). The ten experts were requested to mention their comments on the four criteria of ambiguity, simplicity, clarity and specificity. They were also asked to score the relevancy of each item based on a four-point likert scale (1 = nonrelevant; 2 = needs justification; 3 = relevant but needs justification and 4 = relevant). A CVI score higher than 0.79 was supposed to be adequate(32).

Construct Validity

Construct validity is defined by the degree to which a set of items measure the theoretical construct it was designed to measure. Different methods are available for this purpose, among which the most important is factor analysis. Factor analysis is an appropriate method for exploring the internal construct of an instrument(34). In this study, the construct validity was measured using the two methods of EFA and CFA. A cross-sectional study was carried out in 2019 performing a convenience sampling to explore the construct validity of OPPMDS.

EFA

Kaiser-Meyer & Olkin sampling adequacy test (KMO) was performed to determine the fitness of Data. then, the Bartlett Test of Sphericity was applied to to ensure that the items of the instrument were sufficiently correlated. Factors with eigenvalues equal or greater than one were considered significant. Afterwards, the latent factors were extracted using the Principal Axis Factoring, Rotation Varimax and Scree Plot. Item Communalities less than 0.4 were removed. 330 samples were used for EFA analysis.

CFA

In the next phase, the extracted factors were evaluated using the confirmatory factor analysis. Several factors were assessed for determining the fitness factors of the model, including: Chi-square/degree-of-freedom ratio(χ^2/df), Parsimonious Normed Fit Index(PNFI), Comparative Fit Index(CFI), Parsimonious Comparative Fit Index(PCFI), Incremental Fit Index(IFI), Akaike Information Criterion(AFC) and Root Mean Square Error of Approximation(RMSEA). Acceptable model fit is indicated by: PNFI and PCFI (> .5), CFI and IFI (> .9), RMSEA (< 0.08) and χ^2/df.< 5 (< 3 good)(35). 120 samples were evaluated for CFA(36).

Convergent and Divergent Validity

The convergent and divergent validity of the OPPMDS were evaluated based on the Fornell and Larker (1981) approach using Average Variance Extracted (AVE), Maximum Shared Squared Variance (MSV), Average Shared Square Variance (ASV) and Composite Reliability (CR). The convergent validity is defined as the degree to which multiple items converge in measuring the concept of construct and the divergent validity is achieved when the Items of a construct are weakly correlated with the items of other constructs. The following criteria must be satisfied to ensure the establishment of convergent validity: CR > 0.7, CR > AVE, and AVE > 0.5, moreover, the MSV and ASV must be less than AVE for divergent validity(37). In this study, the construct reliability, convergent validity and divergent validity are measured based on AVE, MSV and ASV. the significance level was set to $p < 0.05$ for all the tests.

The normal distribution of data was tested handling the single- and multi-variable distribution of data and outliers data separately. The multi-variable outliers data were analysed using the Mahalanobis d-squared ($p < 0.001$) and Mardia's coefficient of multivariate kurtosis greater than 8 (38). The percentage of missing data was assessed using multiple imputation, and was then replaced with the mean response given by participants.

Reliability

The reliability of OPPMDS was evaluated using two methods of internal consistency and stability.

Internal Consistency

The internal consistency is defined as a degree of interrelatedness among the items. A common way of evaluating this method is alpha coefficient, which is known as one of the most functional techniques for this purpose and the only reliability index that needs to be conducted once and depends on samples. For keeping a question in an instrument, the alpha should be equal or greater than 0.7 while most of the researchers assume the number to be 0.8(39). In this study, the internal consistency was assessed using the cronbach’s alpha coefficient and mcdonald’s omega coefficient in a sample of 330 people. Then, the reliability of the construct was checked by the use of confirmatory factor analysis. Reliability greater than 0.7 was considered to be acceptable(38, 40).

Stability

Intraclass correlation coefficient (ICC) is a common method for assessing the reliability. This method is able to determine the stability level and measure the agreement between the test scores using the variance analysis. ICC is used as a correlation index among the repetitive measurements such as test-retest and is measured for all the subscales and the whole instrument. Based on Walz et al (2010) recommendation, a two week interval between the tests is generally accepted (12). The value of ICC ranges between zero to one and an instrument with a stability coefficient of 0.8 is supposed to be a greatly stable one(40). This value was estimated using the two-way mixed effects method with a confidence interval of 95% in our study. Subsequently, the construct reliability was measured by measuring the ratio of variance of CFA observable to latent variables (Multiple correlation squared)(41). Construct reliability of 0.7 is considered as acceptable.

The scale was given to 30 nurses within a two-weeks interval. The researcher reviewed the responses looking for missed items and asked the participants in case he found any. The stability of the situation during the test-retest interval was also controlled in a manner that the participants were questioned if they have experienced changes like severe stress, diagnosing new diseases and facing severe emotional or mental damages, which could possibly affect their responses. a participant was withdrawn in case they had an unstable situation during the time interval.

Standard Error of Measurement (SEM)

The value of SEM for all the subscales and the whole scale was measured and the Minimal detectable Change (MDC) and the Minimal Important Change (MIC) were compared for determining the final agreement.

Scoring

After determining the weight of each item, the standard 0–100 scoring scale was used. The Linear transformation formula was applied for converting the scores to a 0-100 scale(42):

$$ransformed\ score = \frac{actual\ raw\ score - \ lowest\ possible\ raw\ score}{possible\ raw\ score\ range} \times 100$$

Statistical Analysis

The EFA and statistical tests were conducted in SPSS software v. 26.0, CFA in AMOS v. 24.0 and McDonald’s omega coefficient in JASP.

Results

The results show that most of the participants were female (87 / 9%). The mean age of the samples was 36.42 ± 7.76 years. Most of the samples were married (74.2%) and had a bachelor's degree (89.4%). The highest work experience was 5–10 (26.1%) and worked in the surgery department (34.5%). the most of samples had no history of acute pain (87%) and no history of surgery (66.4%).

Face and Content Validity

10 and 3 items were removed due to having a factor loading of 1.5 or less considering the qualitative and quantitative face validity approaches respectively. Therefore, 63 items were reduced to 50 for the instrument. 3 items were reviewed after qualitative content validity evaluation and all the items were adjusted based on the experts’ recommended changes. The quantitative content validity was evaluated using the CVR and CVI techniques. 9 items were removed for having a CVR score of < 0.62 and 4 for having a CVI score of < 0.79. Afterall, a 41-itemed instrument was removed for construct validity evaluation (Table. 3).

Construct Validity

The results have shown that the sampling adequacy index was 0.879 and Bartlett's test results were significant (df = 741; x^2=9148.396; p = < 0.001). The latent factors of the test were extracted using the Principal Axis Factoring and varimax rotation method. Three factors of “elderly-related factors”, “healthcare providers-related factors” and “system-related factors” were extracted considering the eigenvalues over one and scree plot (Fig. 1).

Based on the results of Table 4, the three extracted factors cover 57.572% of the overall variance of pain management obstacles among the elderly with dementia after hip fracture surgery. After varimax rotation, the items of “nurses’ unwillingness for providing the prescribed painkillers to the older patients, especially the ones with dementia or delirium due to fear from medicinal overdose” and “having the elderly is going to die anyway- attitude” were removed since having a factor load less than 0.4. The first factor (elderly-related factors) has ten items, among which the one with the greatest factor loading was “Mood changes like depression or anxiety” and the one with the least was “not reporting the pain to nurses”.

The second factor (healthcare providers-related factors) has 25 items as the most factor loading was for the item “ignoring the assessment of physical factors affecting the pain (e.g. full bladder, urinary tract infection or constipation)” and the least was for the item “contrast between the knowledge of nurses about providing pro re nata (PRN) medicines”.

The third factor (system-related factors) includes 4 items, among which the greatest loading factor was for the item “Lack of valid instruments for assessing pain among the older patients with dementia after a hip fracture surgery” and the least was for “Lack of organised caring system for searching through main painkillers and providing the medicines”.

The initial model showed no fitness before the adjustments considering the CFA approach. The chi-square goodness-of-fit was after model justification and achieved by drawing the correlation between the measured errors. Afterwards, other indexes were applied, which all approved the fitness of the final model (PCFI = 0.836; PNFI = 0.78; CMIN/DF = 1.959; RMSEA = 0.064; IFI = 0.923; CFI = 0.901). The correlation between the measurement errors of e4/e6, e14/e16, e19/e25, and e33/e35 were discovered considering the final model of factor structure of OPPMDS construct (Table 5 and Fig. 2).

Convergent and Divergent Validity

The AVE of all the factors was greater than 0.5 (0.51–0.70) and the AVE of each factor was greater than the ASV (0.41–0.48) and MSV (0.4–0.51) of that factor based on Table. 5. Our results have approved that the OPPMDS construct has acceptable convergent and divergent validity (Table 6).

Reliability

The internal consistency of OPPMDS construct was measured using cronbach’s alpha and McDonald’s omega coefficients. The results have indicated that the measured coefficient value of all the items was greater than 0.7, besides the overall cronbach’s alpha coefficient was calculated to be 0.656. The

achieved scores of each testing stage were compared using ICC and results showed a significant relationship ($p < 0.001$). The overall ICC index of the whole instrument was 0.923 (Table 7).

Standard Error of Measurement (SEM)

Results have shown that the value of MDC was more than MIC (Table 8).

Scoring

The final edition of OPPMDS includes 39 items categorised into 3 factors of elderly-related items (10 questions), healthcare providers-related factors (25 questions) and system-related factors (4 questions). a five-point likert scale (5 = highly agree; 4 = agree; 3 = no comments; 2 = disagree; 1 = highly disagree) was used to quantify the items. The minimum score of the scale is 39 and the maximum is 195. Reverse scoring was not required for the items.

Discussion

Inductive and deductive methods were employed for item generation in this study. The combination of these methods is introduced as the most appropriate technique for this purpose by Boateng et al 2018 (43).

Face-, content- and construct-validity and reliability were assessed for this instrument. Qualitative and quantitative approaches can be used for face validity assessment(44), and we applied both of them. Nurses (the targeting group) were interviewed assessing the qualitative face validity approach, which could guarantee the suitability and completeness of the content of the instrument as well as easing the comprehension of items and completion of instrument.

The impact score method was used to assess the quantitative face validity approach. The minimum acceptable item's impact score was assumed 1.5 considering a 5-point likert scale with an average of 3.0 and an abundance of 50%.

Two approaches of qualitative and quantitative methodologies were used for assessing the content validity in this study. Expert's panel was asked to review the grammar, wording, item allocation and scaling of the instrument. Exploring the content of instruments by experts is known as one of the most suitable forms of evidence gathering in support of credibility. In this study, CVI and CVR were measured for assessing the quantitative content validity. Tuyntha et al (2004) believed that two points need to be mentioned for exploring the content validity: one is making sure of the selection of the most important and appropriate content, and the other is designing the items in the most suitable form for content validity assessment. The first is earned by CVR and the second by CVI(45).

The construct validity was tested by factor analysis, which is known as a precious tool for categorising the items into factors (subscales). Each factor represents a unique feature and guides the researcher through grouping and interpretation of items. Factor analysis is done using the two methods of EFA and CFA(46).

The KMO index and Bartlett's test were conducted before the exploratory factor analysis for controlling the sample adequacy. Results have indicated the value of KMO to be 0.879 and the significance of Bartlett's test (x^2=9148.396; P < 0.01). KMO values of 0.7–0.8 are considered adequate and 0.8–0.9 as highly adequate(47).

Principal Axis Factoring method, Varimax rotation and scree plot were used to determine the aspects of OPPMDS. This analysis was performed to 330 samples considering the eigenvalue > 1 and factor loading > 0.4. Scree plot is a visual aid to determine the appropriate and effective number of extractable factors(48). Three factors of "elderly related-factors (10 questions)", "healthcare providers-related factors (25 questions)" and "system-related factors (4 questions)" having an eigenvalue and factor loading greater than one were extracted by varimax rotation. Based on the Three indicator rule, there should be at least three observable items for each latent item(46). In this study, each factor was named considering the common variables of that factor having a meaningful factor loading.

Confirmatory Factor Analysis was employed to examine the fit of OOPMDS. Results have shown that all the CFA indexes, RMSEAR, CFI, NFI and Chi-squared values confirm the fit of the model, considering the fact that they all need to be assessed for such a confirmation(46, 49).

The correlation between the measurement errors of e4/e6, e14/e16, e19/e25 and e33/e35 were discovered considering the final model of factor structure of OPPMDS construct. Munro (2005) stated that the correlation between the measurement errors happens when a variable of a model is not directly assessed, unclear or affects the item responses(46). Correlated errors might be the side effects of working procedures (e.g. self-report method assessment procedure) or appeared due to vocabulary meaning similarities in each item(50).

The reliability of OPPMDS was evaluated using two methods of internal consistency and stability. Results have indicated a value of 0.956 for the cronbach's alpha coefficient of the whole instrument, which shows a good internal consistency or reliability. Conventionally, This coefficient needs to be greater than 0. 7(51).

The stability of the scale is measured using test-retest and ICC methods. Terwee et al (2007) introduced repeatability, which includes agreement and interclass coefficient, as a needed index for measuring the reliability of a scale(52).

Results have shown that the value of MDC was more than MIC, that indicates the positive agreement.

Conclusion

OPPMDS is a valid and reliable 39-itemed instrument, which includes three aspects of "elderly-related factors", "healthcare providers-related factors" and "system-related factors", and can be used for measuring the acute pain management obstacles among the elderly (over 60 years) with dementia after hip fracture.

Limitations

- OPPMDS is a self-report and includes all the limitations of a self-report instrument.
- Geographically-limited sampling is a limitation itself, as social, cultural and regional factors can affect the participants' experiences, and therefore, influence over the formation of scale's items. Hence, further studies on this instrument in different cultural contexts are needed.

Clinical Implication

- Fairly large sampling size, the method of sampling from different hospitals of different cities and the application of sequential exploratory mixed-method design are among the strength points of this study.
- Inductive and deductive methods were applied for item extraction.
- The scale evaluation is performed using face validity (with both qualitative and quantitative approaches), qualitative and quantitative content validity (CVR and CVI), construct validity (EFA and CFA) convergent and divergent validity and reliability measurement methods.
- SEM measurement and scale scoring by the use of standard 0–100 scoring scale is among the strength points of this study.

Abbreviations

OPPMDS
Obstacles to Postoperative Pain Management in Dementia Scale
EFA
Exploratory Factor Analysis
CFA
Confirmatory Factor Analysis
WHO
World Health Organization
IASP
International Association for the Study of Pain
CVR
Content Validity Ratio
CVI
Content Validity Index
KMO
Kaiser-Meyer & Olkin
χ^2/df
Chi-square/degree-of-Freedom Ratio
PNFI

Parsimonious Normed Fit Index

CFI

Comparative Fit Index

PCFI

Parsimonious Comparative Fit Index

IFI

Incremental Fit Index

AFC

Akaike Information Criterion

RMSEA

Root Mean Square Error of Approximation

AVE

Average Variance Extracted

MSV

Maximum Shared Squared Variance

ASV

Average Shared Square Variance

CR

Composite Reliability

ICC

Intraclass correlation coefficient

MDC

Minimal detectable Change

MIC

Minimal Important Change

PRN

pro re nata

Declarations

Ethics approval and consent to participate

This study received approval from the ethics committee of Babol University of Medical Sciences (R.MUBABOL.HRI.REC.1398.097). Participants were explained regarding the Study protocols and aims and their consent was obtained. They were assured about the confidentiality of their information.

Consent for publication

None declared.

Availability of data and materials

Data generated or analysed during this study are included in this published article and are available from the corresponding author on reasonable request.

Competing interests

The authors declare no conflict of interest.

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Author Contributions

F.D. researched data. A.SH. wrote the manuscript and researched data. F.GH. reviewed/edited the manuscript. All authors contributed to discussion and reviewed/edited the manuscript. A.SH. and F.D. researched data and contributed to discussion.

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Tables

Table. 1 Personal Information of the Participants of the Qualitative Stage

No	Age (years)	Educational Level	Job Title	Type of Employment	Work experience (years)	Marital status	Working ward
1	25	bachelor's	Nurse	Apprentice	3	married	Surgery
2	45	bachelor's	Nurse	Permanent	16	married	Surgery
3	33	bachelor's	Nurse	Permanent	8	married	Surgery
4	42	bachelor's	Nurse	Contractual	17	married	Surgery
5	40	bachelor's	Nurse	Contractual	15	married	Surgery
6	38	bachelor's	Nurse	Permanent	15	married	Surgery
7	50	bachelor's	Nurse	Contractual	18	married	oncology
8	40	master's	Clinical Supervisor	Permanent	16	married	Nursing Office
9	48	master's	Clinical Supervisor	Permanent	22	single	Nursing Office
10	52	bachelor's	Nurse	Permanent	27	married	ICU
11	32	bachelor's	Nurse	Contractual	8	married	ICU
12	48	bachelor's	Nurse	Permanent	23	single	Post CCU
13	33	bachelor's	Nurse	Third Party Employee	8	married	Emergency
14	25	bachelor's	Nurse	Apprentice	3	single	ICU
15	35	bachelor's	Nurse	Permanent	13	married	Surgery

Table 2. A sample of item generation

Items generated from participants' responses	items
- I don't have enough time to provide comprehensive care (like non-pharmacological interventions) for an older adult with dementia after a hip fracture surgery. The ward is so crowded that I have even no time caring for the younger patients let alone a dying older one with dementia. Caring for such patients needs mood and patience. They have a lot of caring needs. They cannot even express their pain and fill the pain assessment instruments out.	- Lack of time for applying non-pharmacological pain revealing treatments (e.g. cold compress or patient repositioning by the nurse). - "He's old and he's going to die anyway"- attitude among the ward's staff. - adversities in pain assessment and instrument application due to cognitive disorders. - Ignoring the usage of pain assessment common questions for older patients (e.g. asking do you feel comfortable/uncomfortable instead of have you pain?).
- I usually don't prescribe PRN painkiller with other medicines, as these patients are already taking a lot of pills and tablets due to their age and other diseases. I am afraid injecting them narcotics because they have brain-related problems which might end in an overdose, coma or consciousness decrease.	- Ignoring the physicians' orders of providing PRN painkillers for older patients. - Nurses' fear from painkillers' side effects.
- giving painkillers to an elderly, especially an elderly with dementia, is hard. They resist. They hardly accept taking the pill.	- Resisting against taking oral medicines.
- sometimes we face a shortage of warm or cold compress; so we must give painkillers to the patients instead. We need to compensate for our supply shortage by asking the other wards or calling the supervisor. There is no time for such actions when the ward is crowded.	- Shortage of comforting equipments (e.g. warm/cold packs, mattresses and chairs as the alternatives or complementaries to pain killing medicines).
- we don't have a precise and exclusive instrument for assessing the pain of these elderly. I explain visual instruments to them but it takes time and they forget the whole process.	- Lack of valid instruments for assessing pain among the older patients with dementia after a hip fracture surgery.

Table 3. Summary of face and content validity results of OPPMDS

Removed Item	
1. Older patients' unwillingness for taking painkillers due to fear of getting addicted. 2. Hardly believing the patient's pain reports due to his unstable mood and difference between his verbal and non-verbal behavior. 3. "He's old and he's going to die anyway"- attitude among the ward's staff. 4. Ignoring the use of prescribed painkillers like PRN. 5. Lack of access to the results of elderly's pain assessments done by other healthcare providers. 6. Ignoring the changes of mental condition during the pain assessment (like start or increase of confusion, testiness, aggression or depression). 7. Ignoring the use of common and elderly-specialised pain phrases. 8. Ignoring the pain assessment with symptoms like whining, sighing, crying or shouting. 9. Lack of instructions, guides or policies which help me increase my knowledge about acceptable elderly's pain management and assessment. 10. Lack of a documented pain assessment approach for each older patient.	Qualitative Face validity
1. Lack of time for educating the elderly about subjects like PRNs, alternative medicines, addiction etc. 2. Lack of chance for a direct discussion with palliative care team members on pain management of an older patient. 3. Lack of trust in nurses' pain assessment among the physicians.	Quantitative Face Validity
1. Elderlys' willingness for enduring the chronic pain. 2. Pain denial for denying the disease process among the elderly. 3. Difficulty of contacting the physicians about the older patients' pain assessment results. 4. Lack of chance for consulting clinical pharmacists about relieving the elderly's pain. 5. Concentrating on previously prescribed medicines routinely and not recommending the painkillers like PRN, unless the patient asks himself. 6. Documenting only if the pain relief was unsuccessful or the patient ignores receiving his medicines. 7. Difficulty of contacting the physicians when the prescribed dose of painkiller needs to be reviewed. 8. Ignoring the consultation with other coworkers. 9. Ignoring the use of narcotics for decreasing the pain severity	CVR score of <0.62
1. Ignoring the existence of pain by the elderly with dementia. 2. Unwillingness for taking painkillers among the older patients due to fear from side effects like constipation, the feeling that medicine shares etc. 3. Not reconsidering the routine in special conditions like when the prescribed painkiller dose is not effective any more. 4. Not probing the pain's side effects every 2 hours during the first 24 hours after surgery.	CVI score of <0.79

Table 4. Factor loading of OPPMDS items calculated by varimax rotation method.

Factors	Items	Factor Loading	h2	Eigenvalue	% of Variance
Elderly-related factors	1. Cognitive problems (e.g. delirium, restlessness and judgement disorders).	0.637	0.341	28.753	11.978
	2. Not reporting the pain to nurses.	0.543	0.264		
	3. Verbal and contacting disorders (e.g. wording or pronouncing problems).	0.813	0.638		
	4. Physical problems (e.g. hearing and vision problems).	0.809	0.655		
	5. Unwillingness for taking painkillers due to fear from side effects like drug-dependency or constipation.	0.655	0.437		
	6. Unwillingness for expressing the pain, so that the nurse doesn't get distracted.	0.667	0.386		
	7. Mood changes like depression or anxiety.	0.779	0.612		
	8. Cultural differences like dialect, beliefs and religious beliefs.	0.759	0.515		
	9. Contrast between the pain severity report of elderly and his family members.	0.741	0.536		
	10. Resisting against taking oral medicines.	0.750	0.565		
Healthcare providers-related factors	11. Lack of time for applying non-pharmacological pain revealing treatments (e.g. cold compress or patient repositioning by the nurse).	0.490	0.340	44.993	6.988
	12. contrast between the knowledge of nurses about providing PRN medicines.	0.454	0.336		
	13. Unawareness about the real pain severity due to lack of time for using pain assessment instruments.	0.482	0.382		
	14. Lack of access to physicians for reporting pain assessment and treatment results.	0.646	0.406		
	15. Ignoring the physicians' orders of providing PRN painkillers for older patients.	0.793	0.680		
	16. Improper interaction between the nurse and patient.	0.790	0.627		
	17. Nurses' distrust of the effectiveness of prescribed painkillers.	0.784	0.626		
	18. Nurses' unawareness of elderly's pain tolerance threshold.	0.451	0.354		
	19. Nurses' fear from painkillers' side effects.	0.801	0.622		
	20. Physicians disregard for nursing staff reports and recommendations about the pain severity or the effect of prescribed painkillers.	0.715	0.476		

	21. Unawareness about painkillers' instructions and needed consumption cautions.	0.638	0.395		
	22. Ignoring the documentation of pharmacological and non-pharmacological intervals in a written format accessible for other nurses or caregivers.	0.647	0.482		
	23. Ignoring the elderly's pain assessment in special conditions (e.g. sudden movements of patient repositioning during night or physiotherapy sessions).	0.870	0.750		
	24. Ignoring the pain continuity symptoms (e.g. blood pressure increase, surgery site bleeding, increase of heart rate, arrhythmia or blood glucose increase).	0.874	0.758		
	25. Not following the outcomes of pharmacological interventions.	0.796	0.634		
	26. ignoring the assessment of physical factors affecting the pain (e.g. full bladder, urinary tract infection or constipation)	0.878	0.769		
	27. Nurses disregard for patient's requests for painkillers.	0.872	0.755		
	28. Ignoring the application of dose-equivalent table (e.g. for converting mEq to mL or estimating the new consumption doses in case new narcotics are prescribed).	0.592	0.460		
	29. Physicians' unwillingness for prescribing new painkillers.	0.801	0.711		
	30. Not using several pain management solutions (e.g. educating the patient/family members or using pharmacological/non-pharmacological interventions).	0.814	0.643		
	31. Not asking the family caregivers about the behavioral changes resulted by elderly's pain (e.g. ignoring requests, turmoil or facial expressions change).	0.814	0.641		
	32. Ignoring the behavioral changes resulted by pain relief (e.g. anger, ignoring the treatment team's requests or movement disorders).	0.856	0.723		
	33. Delayed pain examination.	0.563	0.473		
	34. Ignoring the usage of pain assessment common questions for older patients (e.g. asking do you feel comfortable/uncomfortable instead of have you pain?).	0.860	0.737		
	35. Unclear physicians' instructions for the consumption of requested painkillers.	0.695	0.536		
System-related factors	36. lack of organised caring system for searching through main painkillers and providing the medicines.	0.501	0.392	57.572	3.478
	37. Shortage of comforting equipments (e.g. warm/cold packs, mattresses and chairs as the alternatives or complementaries to pain killing medicines).	0.569	0.389		
	38. Lack of certain instructions for the use of most appropriate pain management techniques.	0.720	0.566		

	39. Lack of valid instruments for assessing pain among the older patients with dementia after a hip fracture surgery.	0.724	0.538		

.h2: communalities

Table 5 Fit indices of the confirmatory factor analysis of the OPPMDS

CFA Index	X^2	DF	$P-VALUE$	$CMIN/DF$	$RMSEA$	$PNFI$	CFI	$PCFI$	IFI	
Primary model	1965.397	699	0.001	*2.812*	0.09	0.68	0.751	0.672	00.791	1241.34
secondary model	1360.083	694	0.001	1.959	0.064	0.78	0.901	0.836	0.923	954.26

Abbreviations; OPPMDS: obstacles to postoperative pain management in dementia scale; CMIN/DF: Chi-square/degree-of-freedom ratio; RMSEA: Root Mean Square Error of Approximation; PCFI: Parsimonious Comparative Fit Index; AIC: Akaike Information Criterion; PNFI: Parsimonious Normed Fit Index; IFI: Incremental Fit Index; CFI: Comparative Fit Index.

Table 6. Convergent and Divergent Validity of OPPMDS Constructure.

Factor	ASV	MSV	AVE
Elderly-related factors	0.416	0.448	0.510
Healthcare providers-related factors	0.483	0.518	0.523
System-related factors	0.451	0.518	0.701

Table 7. Reliability of OPPMDS (ICC and Stability)

Factor	Number of the Items	ICC	CI 95%	P value	CR	α	Ω
Elderly-related factors	10 (Q1-Q10)	0.705	0.655-0.750	P<0.001	0.906	0.891	0.878
Healthcare providers-related factors	25 (Q11-Q35)	0.924	0.911-0.935	P<0.001	0.963	0.929	0.934
System-related factors	4 (Q36-Q39)	0.860	0.834-0.883	P<0.001	0.902	0.890	0.901
total	39 (Q1-Q39)	0.923	0.908-0.936	P<0.001		0.956	

Table 8. Comparing SEM, MDC and MIC values for OPPMDS.

Factor	Range of scores	SEM	MDC	MIC	agreement
Elderly-related factors	27-50	2.49	6.92	1.03	positive
Healthcare providers-related factors	39-130	4.64	12.88	3.86	positive
System-related factors	5-20	1.42	3.96	0.625	positive
total	82-199	5.84	16.19	4.20	positive

Figures

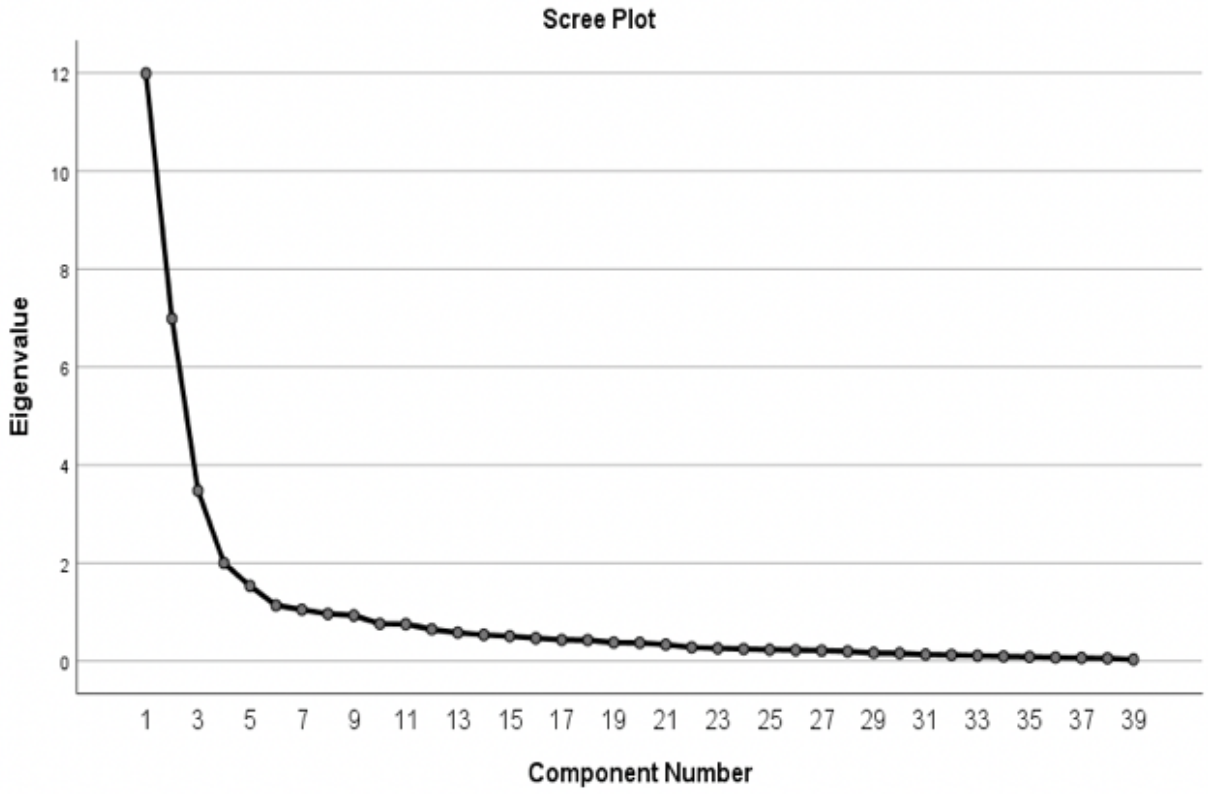

Figure 1

Scree plot indicating the number of appropriate extractable factors.

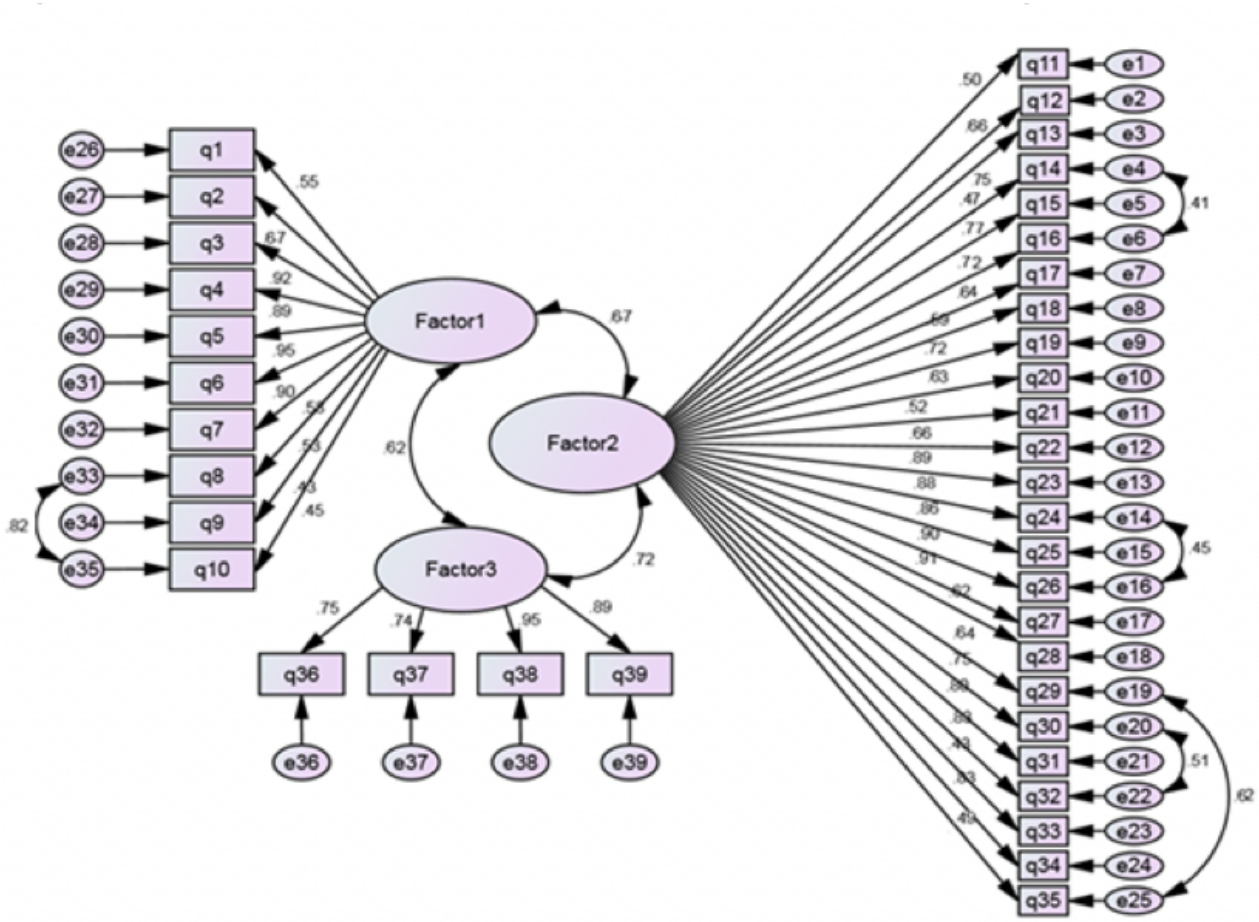

Figure 2

OPPMDS construct: modified model of confirmation factor analysis