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RESEARCH ARTICLE

Psychometric evaluation of the Assamese adaptation of the obstetrics quality of recovery score in patients undergoing caesarean delivery under neuraxial anaesthesia: a single center prospective observational study

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ABSTRACT

Background: Caesarean delivery is a surgical procedure whose recovery characteristic is unique to it. The Obstetric Quality of Recovery scoring (Obs-QoR-11) tool was developed and validated in United Kingdom for use after elective and emergency caesarean delivery. Subsequently, ObsQoR-11 has been successfully adapted in other languages. As there is no such adaptation in Assamese language, we intended to evaluate the Assamese version of ObsQoR-11 in our population. **Methodology**: After approval and permission from the institutional ethics committee, the ObsQoR-11 was translated to Assamese, according to WHO forward-backward translation methods. It was evaluated in patients whose predominant language of communication was Assamese. After pilot testing, it was tested on patients before delivery and at 24hours. To examine the test retest reliability, it was readministered to ten patients at 25h post-delivery. The ObsQoR-11 was then correlated with a numerical rating scale (NRS) of global health status to examine the convergent validity. The reliability, responsiveness, acceptability and feasibility were also tested. **Results**: The Assamese version of ObsQoR-11 correlated moderately with the global health status NRS (r=0.39; 95% confidence interval: 0.23-0.53; P<0.0001) and discriminated well between good and poor recovery (NRS score≥ 80 vs ≤ 70mm; p<0.001). The internal consistency, split half reliability and test retest reliability 0.851 (p<.001), 0.78(p<.001) and 0.839(p<.001), has a Cohen`s effect size, standardized response mean of 3.55 and 2.62 respectively and no floor or ceiling effects. All parturient completed the questionnaire [median (IQR)] time of completion of 3.6(3.5-4) minutes. **Conclusion**: The Assamese version of the ObsQoR-11 questionnaire is a promising scoring tool to evaluate quality of recovery in patient undergoing caesarean delivery.

Keywords: Caesarean section, patient-reported outcome measures, quality of recovery, obstetric anaesthesia.

Anaesthesia and surgery are one of the most invasive health care interventions. Studies on quality of recovery of anaesthesia and surgery have started to gain impetus after the publication of the landmark paper by Myles P et al [1]. In the last 20 years assessment of quality of recovery in various post-surgical patients has been studied [2, 3]. Several scales have been developed and validated to measure the quality of postoperative recovery (eg the 9-items QoR, QoR-15, ObsQoR-11 scores, or even the postoperative quality of recovery scale) [4 – 8].

Caesarean delivery (CD) is one of the most frequently performed surgical procedures all over the globe [8]. However, it should be noted that caesarean section stands apart from other non - obstetric surgeries in the sense that pregnancy is

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not a disease; rather it is a physiological change. Therefore recovery after a CD may differ from other surgeries. The obstetrics quality of recovery score (ObSQoR-11) has recently been devised and validated to evaluate recovery in the first 24hr following elective and nonelective CD [6, 8]. The questionnaire ObSQoR-11 is in English and has been validated in population from United Kingdom [6].

After thorough literature search, we found that ObsQoR-11 has not been adapted in Assamese. Assamese is the predominant language used by patients undergoing CD in our institute. Therefore, we wondered whether the adapted version of ObSQoR-11 is a validated tool to measure patient centered dimensions of functional recovery in the early post-partum after CD. We hypothesized that these adapted version is reliable, responsive, clinically acceptable and feasible scoring tool. We primarily aimed to evaluate the reliability, responsiveness, clinical acceptability and feasibility of the Assamese version of ObsQoR-11.

Methods and materials

This single center prospective observational study was conducted with prior approval from the institute ethical committee of Gauhati Medical College and Hospital, written and informed consent was obtained from the patients. The study was carried out from June 2022 to September 2022. We enrolled 120 patients who underwent caesarean section under neuraxial anaesthesia at≥ 37 weeks of gestational age. We excluded patients unable to read or understand Assamese, on analgesic or antipsychotic medication, or needed planned or unplanned admission in intensive care unit. Patients with history of substance abuse and on any opioid medication that could affect evaluation were also excluded.

The original English version of the ObsQoR-11 was translated and culturally adapted into Assamese version as per the recommendation of WHO [9]. Two independent professional translators with background in health sciences and fluent in Assamese, translated the English questionnaire according to the forward/backward translation method.

Informed consent was obtained from the women after a detailed discussion with them. Baseline demographic and clinical data (age, height, weight, body mass index, gestation, systolic and diastolic) were collected at the time of enrolment. Assamese version of ObsQoR-11 questionnaire was given to be completed by the studied women preoperatively. The Assamese version of ObsQoR-11 asked the participants to rate 11 out of the total eleven items with an 11-point numerical Likert scale (0= strongly negative; 10= strongly positive. The participants were also interviewed to obtain their general health status using a global health numerical rating scale (NRS) represented by a 100mm line marked at each end with anchors,' worst imaginable health state' to ' best imaginable health state'.

After that, participating women were shifted into the operating room and standard monitoring was started. They subsequently underwent neuraxial anaesthesia based on the preference of the consulting anaesthesiologist. Our institutional protocol suggests intrathecal access at the L3-L4 interspace with a 25- gauge whitacre needle, and deposition of 11mg 0.5% hyperbaric bupivacaine and 60 microgram of buprenorphine.

At 24hours after caesarean second, the participants were approached to complete the Assamese version of the ObsQoR-11 questionnaire. Ten randomly chosen women were asked to repeat the ObsQoR-11 questionnaire at 25 hour post operatively.

Statistical analysis: As there is no definitive method to calculate sample size for questionnaire based study, we intended to include sample size similar to those used in the index studies [6, 8]. Normal distribution of continuous variables was tested using the Shapiro-Wilk test. Normally distributed continuous variables are presented as the mean ± standard deviations (SDs) and compared using a two- sample students t-test. When the distribution was not normal, median [interquartile ranges (IQRs)] are presented and the groups were compared using a Mann-Whitney U-test between two independent groups or a Wilcoxon signed - rank test for paired data. Categorical variables are presented as numbers (percentages) and were compared between groups using the chi-square test or Fischers exact test, according to their expected counts. Correlations were measured using Spearmans correlation coefficient.

First, we evaluated the convergent, discriminate and construct validity of ObsQoR-11. To evaluate convergent validity, ObsQoR-11 scores at 24hr and 25 hr after caesarean delivery were correlated with the 100-mm NRS assessment of global health status at the same time. For discriminate validity, a comparison was made between the 24 hr ObsQoR-11 of women who had a "good" or "poor" postoperative recovery, defined by global NRS scores (≥80 vs ≤ 70 mm) $p<0.001$. For construct validity , the correlation between the ObsQoR-11 score age, weight, height, body mass index, systolic and diastolic pressure, gestational age, duration of surgery, volume of intrathecal drug, length of stay in hospital and time to complete the questionnaire.

Second, reliability was assessed by internal consistency, inter-item correlation tests, split-half reliability, and test-retest reliability. Internal consistency was measured using Cronbach`s alpha, and test – retest reliability was measured using the intraclass correlation coefficient (ICC). Floor and ceiling effects were evaluated based on whether <15% of respondents achieved either the lowest (0) or highest possible score (110).

Third, acceptability and clinical feasibility of ObsQoR-11 were evaluated using the patient recruitment rate, as determined by percentage of women who agreed to complete the scoring tool, by successful completion rate based on the recording of the number of correct ObsQoR-11 forms without missing data, and by the time required to complete the ObsQoR-11, measured and recorded by the investigators.

Results and observations

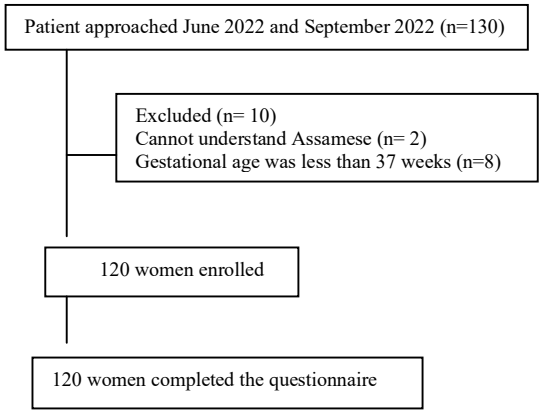

Figure 1: Patient flow diagram

We approached 130 women for possible inclusion in our study to evaluate the Assamese version of ObsQoR-11. Out of these, 2 women could not understand Assamese and 8 had a gestational age less than 37 weeks. As a result, 10 women were excluded before enrolment since they did not meet the required inclusion criteria. The patient flow diagram is given in figure 1. Demographic and clinical details of the participants are provided in table 1. The psychometric evaluation is presented below -

1. Validity-
   a. Convergent validity: We evaluated correlation of the 11 questions with postoperative global health NRS. The details are mentioned in the table below (table 2).
   b. Discriminant validity: This was evaluated with comparison of ObsQoR - 11 scores with global health NRS scores of 8 or more (defined as good recovery) versus ≤ 7 (defined as poor recovery) at 24 hr after CD. The details of comparison are presented in table 3.
   c. Construct validity: To examine construct validity, the co-relation of the scores of ObsQor - 11 with age, weight, height, BMI, systolic and diastolic blood pressure, gestational age, duration of surgery, volume of intrathecal drug, length of stay in hospital and time required to complete the questionnaire was evaluated. The details are presented in the table 4.
2. Reliability -
   Internal consistency: Cronbach's alpha was measured to evaluate internal consistency of the questionnaire. The details are mentioned in table no 5.
3. Floor and ceiling effects: None of the patients scored either 0 or 110.
4. Responsiveness:
   a. Cohen effect size: The Cohen s effect size for the ObsQor-11(Assamese) is 3.55.
   b. Standardized response mean: The standardized response mean for the ObsQor-11(Assamese) is 2.62 (Mean of change of score between preoperative and postoperative measurement 18.316667 and SD of 6.9693004)
   c. Mean ObsQoR-11 scores: Compared pre - vs 24 hr post - CD.

The mean score of preoperative and postoperative ObsQor - 11(Assamese) was 80.53 and 88.59 respectively. The two- tailed P value is less than 0.0001.

The mean of pre operative minus post operative ObsQor-11 (Assamese) equals - 8.01 with 95% confidence interval of this difference: from - 8.83 to -7.19 and standard error of difference is 0.413.

Table 1: Demographic and clinical characteristics

Parameters	Assamese (n= 120)		
	Range	Mean± SD	95% CI
Age (yrs)	20- 35	26.04± 4.13	25.3-26.78
Weight (kg)	44-73	55.89± 6.99	54.64- 57.14
Height (cm)	142-160	151.82± 4.2	151.06- 152.57
BMI	18.31- 32.02	24.23± 2.7	23.75-24.71
Systolic BP	110- 146	122.3± 10.56	120.41- 124.19
Diastolic BP	70-92	78.41± 6.42	77.26- 79.56
Gestational age (Week)	37.14- 42.86	39.08± 1.29	38.85- 39.31
Duration of surgery (Min)	30- 100	64.35± 15.74	61.53- 67.17
Volume of drug (ml)	2.2-2.5	2.4± 0.03	2.39- 2.40
Length of stay in hospital (Day)	4-11	4.99± 1.07	4.8-5.18
Time to complete the questionnaire (Min)	3-4	3.68± 0.25	3.63-3.72

Table 2: Correlation (rho) of 11 items of the ObsQor - 11 with global health NRS at 24 hours

Questions	Assamese	P-value
1. Moderate pain	0.236	0.009
2. Severe pain	-0.027	0.771
3. Nausea or vomiting	-0.027	0.771
4. Feeling dizzy	-0.157	0.086
5. Shivering		
6. Comfortable	0.407	<.001
7. Mobilize independently	0.350	<.001
8. Can hold my baby without assistance	0.344	<.001
9. Can feed/ nurse my baby without Assistance	0.278	0.002
10.Can look after my personal hygiene/toilet	0.264	0.004
11.Feel in control	0.410	<.001

Correlation of ObsQoR-11 Score with Post Op NRS

	Mean	SD	N	Pearson	P - value	Spearman	P-value
Post Op NRS	7.80	0.81	120	0.390; 95% CI (0.232-0.53)	<0.00	0.368, 95% CI (0.2-0.51)	<0.001
Post Op Score (1-11)	97.13	4.17	120				
Language = Assamese							

5. Acceptability and feasibility:
   a. Recruitment rate - A total of 120 women enrolled (recruitment rate 92.31%).
   b. Successful completion rate - All completed the Assamese version of ObsQor-11 24 hours after CS (completion rate 100%).

Table 3: Comparison of ObsQor - 11 scores with good and poor postoperative recovery.

Group	Good recovery	Poor recovery
Mean	97.99	95.58
SD	4.41	3.20
SEM	0.50	0.49
N	77	43

Table 4: Correlation of demographic and clinical parameters with ObsQor- 11

Categories		Spearman rho	Pearson r
Age (yrs)	Correl	-0.056	-0.059
	P- value	0.546	0.523
Weight (kg)	Correl	0.108	0.112
	P- value	0.239	0.223
Height (cm)	Correl	.258**	.269**
	P- value	0.004	0.003
BMI	Correl	-0.012	-0.011
	P- value	0.894	0.908
Systolic BP	Correl	-0.030	-0.048
	P- value	0.744	0.604
Diastolic BP	Correl	-0.095	-0.071
	P- value	0.301	0.443
Gestational age (Week)	Correl	0.039	0.107
	P- value	0.672	0.246
Duration of surgery (Min)	Correl	-0.143	-.186*
	P- value	0.118	0.042
Volume of drug (ml)	Correl	-0.068	-0.043
	P- value	0.461	0.640
Length of stay in hospital (Day)	Correl	-0.042	0.004
	P- value	0.645	0.965
Time to complete the questionnaire (Min)	Correl	0.058	0.094
	P- value	0.527	0.309

The two- tailed p value equals 0.0021; t= 3.1429; df= 118
Standard error of difference= 0.765

   c. Time taken to complete the questionnaire (measured and recorded by the investigator) – Assamese - median 3.6 (IQR 3.5-4 minutes).

Discussion

Our study demonstrated that reliability, clinical acceptability and feasibility of the questionnaire of the Assamese version of ObsQoR - 11 was excellent with a moderate validity and performed well with the patients who had undergone caesarean section under neuraxial anaesthesia.

The original ObsQoR-11 questionnaire has been translated in Arabic, Korean and Hindi languages and psychometric evaluation has been carried out. As the predominant language of our patient population is Assamese, we felt the need to construct and evaluate this adapted questionnaire.

The index study by Ciechanowicz S et al in elective caesarean section found a moderate correlation of ObsQoR-11 score with global NRS score of 24 hours (r=0.53,95% CI: 0.43-0.62, p<0.001)[6] and discriminated between good versus poor recovery. The study with non-elective caesarean section by Ciechanowicz S and Howle R et al demonstrated a strong correlation of ObsQoR - 11 score with NRS score at 24 hours (r=0.72, 95% CI: 0.61-0.81, p<0.0001)[8] and also discriminated well between good versus poor recovery. The study by Ryung A Kang et al also documented good discriminatory property between good and poor recovery (r=0.73, 95% CI: 0.64 - 0.81, p<0.001) [10] and so did the study done by Mukarram S et al (r=0.68,95% CI: 0.56-0.80, p<0.001) [11]. In our study, we found that questionnaire had a strong correlation and can also discriminate well between good and poor recovery.

As found in the study conducted by Ciechanowicz S et al with original version of the questionnaire, our study also couldn't find any significant correlation with respect to gestational age and so did the study by Ciechanowicz S and Howle R et al with non elective CS. However, in the study conducted by Mukarram S et al, they found a correlation with gestational age at 24 hours (r=0.22, 95% CI: 0.03 - 0.40, p=0.02)[11] duration of surgery might influence the quality of post-operative recovery, and this may be attributed to the inherent pathological variation of the disease for which the surgery was indicated. In our study, we correlated duration of surgery and couldn't find any correlation with overall post-operative recovery score. This finding may be due to the fact that, the surgeries in our study were of expected duration without any outlier and not too long to influence the outcome of our study.

In the index study by Ciechanowicz S et al, LOS and recovery score had a negative correlation at 24 hours (r= -0.39, P= 0.003) [6]. The correlation of the score to LOS at 24 hours was also weakly significant (r= -0.24, P=0.02) [8] in the study with non - elective CS study by Ciechanowicz S and Howle R et al. Similar results were observed by Mukarram S et al (r= -0.21, P=0.03) [11]. However, in our study, we found a value of r= -0.042 and P=0.645. This shows no significant correlation between the LOS and post - operative recovery score. The negative correlation of the duration of stay is an expected association. However, the LOS in our institution has been mandated to be of atleast for 3 days, according to protocol and ERAS protocol hasn't been instituted due to logistic reasons. Moreover, apart from being medically fit for discharge from institution, various logistic issues influences the LOS like availability of vehicles for transportation, availability of relatives to accompany and many such social factors.

In the study by Mukarram S et al, convergent validity at 24 hrs was strong (r= 0.68, 95% CI: 0.56 - 0.80, p< 0.001) [1]. In the original English version by Ciechanowicz S et al and English version with non - elective CS by Ciechanowicz S and Howle R et al, r - value was 0.53 and 0.72 respectively, while in the study by Ryung A Kang et al, r - value was 0.73. In our study, convergent validity was found to be 0.39 and p value = 0.001 suggesting that convergent validity was moderately valid. In the study by Mukarram S et al, discriminant validity was found to be significant. In our study, discriminant validity had a standard error of difference of 0.76 and p= 0.0021. The questions included in the study had discriminating ability to differentiate between good and poor recovery score.

Different studies have evaluated the content validity with respect to different demographic as well as clinical variables, and the associations were diverse. Content validity was significant only for height in our study. Thus, it can be observed that different variables can have association with the ObsQor - 11 questionnaire, and such associations which are reported across different studies is non- homogenous. It is easily understandable that myriads of such demographic, clinical, social and cultural factors can affect the quality of recovery. Thus, we need studies to explore various such parameters and their strength of association, if there is any. Here in, we must also understand that not all the questions can be accommodated in the questionnaire. In fact, studies document that brevity of the questionnaire is a determinant of clinical applicability.

In the original English version, internal consistency using Cronbach's Alpha was 0.85 and split half reliability was 0.76 while it was 0.75 and 0.96 in the study of non - elective CS by Ciechanowicz S and Howle R et al, which achieved the recommended values. In the study by Ryung A Kang et al, Cronbach's alpha was 0.78 and split half reliability was 0.89. Mukarram S et al in their study found the internal consistency of 0.87 at 24 hours and split half reliability at 0.75. In our study, the internal consistency was also found to be high with Cronbach's alpha being 0.849. This finding in our study is consistent with the questionnaire of all the studied language, independent of linguistic, racial and cultural barrier. This suggests that all the questions in all the studies bear relationship with each other and strive to find the same or similar inference or results.

In the original English version study by Ciechanowicz S et al, non - elective English version study by Ciechanowicz S and Howle R et al and study by Mukarram S et al, the intraclass correlation was > 0.6, while in the Korean version by Ryung A Kang et al, it was 0.4. In our study (Assamese version), interclass correlation was 0.91. This suggests that our questionnaire had strong intraclass correlation with the recovery score. All the studies had a recruitment rate of > 90% and a completion rate nearing 100%. This shows that the acceptability of the questionnaire is high among the participants.

Limitations of our study -

1. Our study was conducted in a single centre of North - eastern part of India. Assam is inhabited by people of various linguistic and ethnic communities. Our

institute being a tertiary centre caters to such a multi - cultural population. Despite such a background, Assamese is the most common language of communication.

2. Quality of recovery was followed up till 24 hours in our study. But the study by Mukarram S et al followed up for 48 hours, and didn't find any significant difference.
3. Neonatal admission in NICU or neonatal demise would inadvertently influence the quality of recovery. In our study, this fact was not taken into consideration. In fact, there can be various other factors like belief, spirituality, support system and social background that can influence the quality of recovery.

Conclusion

The Assamese version of the ObsQoR - 11 questionnaire is a promising scoring tool to evaluate quality of recovery in patient undergoing caesarean delivery.

Conflict of interest: None. **Disclaimer:** Nil.

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