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ORIGINAL ARTICLE

Good reliability and validity for a new utility instrument measuring the birth experience, the Labor and Delivery Index

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Abstract

Objectives: To validate the Labor and Delivery Index (LADY-X), a new delivery-specific utility measure.

Study Design and Setting: In a test-retest design, women were surveyed online, 6 to 8 weeks postpartum and again 1 to 2 weeks later. For reliability testing, we assessed the standard error of measurement (S.E.M.) and the intraclass correlation coefficient (ICC). For construct validity, we tested hypotheses on the association with comparison instruments (Mackey Childbirth Satisfaction Rating Scale and Wijma Delivery Experience Questionnaire), both on domain and total score levels. We assessed known-group differences using eight obstetrical indicators: method and place of birth, induction, transfer, control over pain medication, complications concerning mother and child, and experienced control.

Results: The questionnaire was completed by 308 women, 257 (83%) completed the retest. The distribution of LADY-X scores was skewed. The reliability was good, as the ICC exceeded 0.80 and the S.E.M. was 0.76. Requirements for good construct validity were fulfilled: all hypotheses for convergent and divergent validity were confirmed, and six of eight hypotheses for known-group differences were confirmed as all differences were statistically significant (*P*-values: <0.001-0.023), but for two tests, difference scores did not exceed the S.E.M.

Conclusion: The LADY-X demonstrates good reliability and construct validity. Despite its skewed distribution, the LADY-X can discriminate between groups. With the preference weights available, the LADY-X might fulfill the need for a utility measure for cost-effectiveness studies for perinatal care interventions. © 2015 Elsevier Inc. All rights reserved.

Keywords: Patient-reported outcome measure (PROM); Labor experiences; Obstetrics; Utility measure; Measurement properties; Questionnaire

1. Introduction

Economic evaluations are used to inform decision making in health care, for example, allocation of scarce resources. The preferred outcome measure in these evaluations is the quality adjusted life year (QALY). QALYs summarize the impact of a

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treatment on patients' length of life and quality of life [1]. The Q, or quality-adjustment factor, is assessed by utility measures such as the EuroQol-5 dimension (EQ-5D) and Short form-6 dimension (SF-6D) [2,3]. In contrast to multidimensional sum score measures, for example, measuring quality of life, utility measures make use of so-called preference-weighted classification systems. For each outcome, or health state, the system integrates the scores on different dimensions of quality of life into one composite score, a utility for that state, ranging from 0 to 1, generally defined as death and perfect health, respectively. Utility values for the health states of the classification system (also called the tariff) are calculated based on preferences assessed in a sample of the general public or of the relevant patient group [1].

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Ethical approval: The Medical Ethics Committee of the Leiden University Medical Center gave approval for this study.

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What is new?

Key findings

• The Labor and Delivery Index (LADY-X) demonstrates good reliability and construct validity.

What this adds to what was known?

- Until now, no birth-specific utility measure reflecting the course of labor and birth yet existed.
- Based on the good measurement properties and because of the availability of preference weights for this new instrument, derived in a discrete choice experiment performed previously, the LADY-X might fulfill the need for a utility measure for (cost-)effectiveness studies of perinatal care interventions.

What is the implication and what should change now?

• From now on, this birth-specific utility measure can be used in cost-effectiveness studies for perinatal care interventions.

Although regarded as the ideal outcome for economic evaluations [4], for the evaluation of some types of health care interventions, QALYs as measured by a generic quality of life measure are less suitable, for example, in situations where the health effects under investigation are only apparent during a short period of time or where generic classification systems lack sensitivity to measure effects in specific disease contexts [1]. Both situations occur for most perinatal care interventions. Because of the relatively short duration of labor, differences between interventions affecting only the course of labor and birth and not the health of the child will not be reflected in QALY estimates. Furthermore, the items of generic classification systems are considered too crude to capture the aspects of health that could be affected in the perinatal phase [5]. Because of the unsuitability of generic classification systems, costeffectiveness studies in perinatal research often present several birth-specific outcomes or domains, with possibly contradicting results, and often not reflecting what is important for women [6,7]. Examples of outcomes used are pain [8,9], labor duration [10,11], or anxiety [12,13]. A birthspecific utility measure reflecting the course of labor and birth would be more informative, as Petrou and Henderson [5] pled for in 2003.

To fulfill this need, we have developed a new birthspecific utility questionnaire, called the Labor and Delivery Index (LADY-X). In a mixed-method study, the view of women who recently gave birth and the view of professionals in the field of obstetrics were investigated and led to the selection of a set of seven birth-specific domains to include in this new measure [14]. Based on the seven selected domains, we formulated items and response categories that construct the LADY-X. Subsequently, in a discrete choice experiment, preference weights were estimated for each birth situation as classified by the LADY-X, to calculate the LADY-X utility score [14].

The aim of the present study was to evaluate the measurement properties of this questionnaire. For this aim, we assessed the test—retest reliability and the construct validity including convergent and divergent validity as well as known-group measures.

2. Methods

2.1. Design

This study had a within-subjects design with two measurement points. Measurement point one (T1) was 6 to 8 weeks postpartum; therefore, data from less than 39 days or more than 59 days postpartum were excluded from the analyses. T1 data were used for the hypothesis testing concerning the convergent validity and known-group differences. T2 was 7 to 14 days after T1; data more than 14 days after T1 were excluded from the analyses. T1 and T2 data combined were used for the reliability analyses. The Medical Ethics Committee of the Leiden University Medical Center gave approval for this study.

2.2. Sampling and questionnaire administration

To be included in the study, women had to be at least 18 years old, have given birth between June and October 2013, and be conversant in Dutch. We held no restriction on any obstetric characteristic. Fourteen midwifery practices and one academic medical center recruited women during pregnancy or during the postpartum period. Additionally, we recruited women through advertisements in regional newspapers and by calls on the intranet and the official Web site of a Dutch academic medical center and its Twitter and Facebook accounts. We administered the three online questionnaires during July 2013 and February 2014. Unique links to the online questionnaires were e-mailed to the respondents 5.5-6.5 weeks postpartum for T1 and 7-10 days later for T2. Two reminders were sent for each measurement point. An informed consent statement was included in the questionnaire, confirming to be sufficiently informed and taking part in the study voluntarily was a prerequisite to continue with the questionnaire.

2.3. Measurement instruments

2.3.1. The Labor and Delivery Index

2.3.1.1. Development and pilot testing of the LADY-X. A process of domain identification and selection preceded this

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