



## Determinants of health-related quality of life in the postpartum period after obstetric complications<sup>☆</sup>



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### ABSTRACT

**Objective:** To determine the influence of socio-demographic, clinical parameters and obstetric complications on postpartum health-related quality of life (HRQoL).

**Study design:** We used data of three randomized controlled trials to investigate HRQoL determinants in women after an obstetric complication. The DIGITAT and HYPITAT trials compared induction of labor and expectant management in women with intra-uterine growth restriction (IUGR) and hypertensive disorders. The WOMB trial randomized anemic women after postpartum hemorrhage to red blood cell transfusion or expectant management. The HRQoL-measure Short-Form36 was completed at six weeks postpartum. Multivariable analyses were used to identify which parameters affected the Short-Form36 physical component score (PCS) and mental component score (MCS).

**Results:** HRQoL analyses included 1391 women (60%) of the 2310 trial participants. HYPITAT and DIGITAT participants had significantly lower MCS than WOMB participants. In multivariable analysis, PCS after elective and emergency cesarean section was 5–6 points lower than after vaginal delivery. Gestational hypertension, neonatal admission and delivery in an academic hospital had a small negative effect on PCS. No effect was found for randomization status, maternal age, BMI, country of birth, education, parity, induction of labor, analgesics, birth weight, perineal laceration, delivery of placenta, postpartum hemorrhage, congenital anomaly, urinary tract infection, thromboembolic event or endometritis. MCS was influenced only mildly by these parameters.

**Conclusions:** IUGR and hypertensive disorders lead to lower HRQoL scores postpartum than PPH. In a heterogeneous obstetric population, only mode of delivery by cesarean section has a profound, negative impact, on physical HRQoL (PCS). No profound impacts on MCS were detected.

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### Introduction

Health-related quality of life (HRQoL) postpartum is potentially influenced by socio-demographic parameters, clinical parameters

and obstetric complications. Socio-demographic parameters described to influence HRQoL postpartum negatively are black ethnicity [1], low education [2], low income [3] and large number of children at home [3]. A supportive social network influences postpartum HRQoL positively [1,4,5]. The influence of mode of delivery on HRQoL varies in literature though HRQoL seems either similar or compromised following cesarean section compared to vaginal delivery [3,5–8]. Common obstetric complications are intra-uterine growth restriction (IUGR), hypertensive disorders of pregnancy and postpartum hemorrhage (PPH) [9–11]. Pregnancies

<sup>☆</sup> Data of this study were collected in trials that were conducted in a total of 52 hospitals in The Netherlands.

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with these complications are at increased risk for neonatal and/or maternal morbidity and mortality [12–15]. Poor physical and mental health have been described in mothers with obstetric complications like preterm birth [16–18]. HRQoL is also compromised in women with postpartum complications like postpartum depression [5,19,20], pregnancy-related deep vein thrombosis [2] and urinary and/or fecal incontinence [21–25].

Recently, three multicenter trials were conducted that investigated maternal and/or neonatal outcomes and measured HRQoL in the postpartum period. The DIGITAT and HYPITAT trial primarily investigated the effect of induction of labor on neonatal and maternal outcome in pregnancies complicated by, respectively, IUGR and hypertensive disorders [26,27]. The WOMB trial primarily studied the effect of red blood cell transfusion (RBC) on physical fatigue in women after PPH [28]. The availability of such a large numbers of postpartum HRQoL data provided a unique opportunity to assess which parameters influence postpartum HRQoL after obstetric complications by combining data of the three trials.

We hypothesized that several socio-demographic and clinical parameters, as well as obstetric complications, affect postpartum HRQoL. Insight in these parameters will contribute to postpartum care and will provide the opportunity to develop individual strategies after obstetric complications.

## Materials and methods

We used data of three randomized controlled trials, conducted within the Dutch Obstetric Consortium: the DIGITAT, HYPITAT and WOMB trial. Details of these studies and their ethic approval have been previously published [29–31]. In the DIGITAT, HYPITAT and WOMB trial 52, 38 and 37 Dutch hospitals participated, respectively. In each trial, women who refused randomization were asked to participate as non-randomized women. Results of the trials have been described elsewhere [26–28].

The 'Disproportionate-Intrauterine-Growth-Intervention-Trial-At-Term' (DIGITAT) included women with a singleton pregnancy, a fetus in cephalic presentation, between 36 + 0 and 41 + 0 weeks gestational age, with suspected IUGR (defined as fetal abdominal circumference below the 10th percentile, estimated fetal weight below the 10th percentile and/or a decreased relative growth) [26]. Women were allocated to induction of labor or expectant management. Primary outcome was composite neonatal adverse outcome.

The 'Hypertension-and-Preeclampsia-Intervention-Trial-At-Term' (HYPITAT) included women with a singleton pregnancy, a fetus in cephalic presentation, between 36 + 0 and 41 + 0 weeks of gestation, complicated by gestational hypertension (defined as diastolic blood pressure  $\geq 95$  mmHg, measured on two occasions) or mild preeclampsia (defined as diastolic blood pressure  $\geq 90$  mmHg measured on two occasions, in combination with predefined levels of proteinuria) [27]. Again, women were allocated to induction of labor or expectant management. Primary outcome was a composite measure of maternal outcome.

The 'Well-being of Obstetric patients on Minimal Blood transfusions' (WOMB) studied women after PPH (defined as peripartum blood loss  $\geq 1000$  mL and/or decrease in Hb concentration  $\geq 1.9$  g/dL), with an Hb concentration between 4.8 and 7.9 g/dL (3.0–4.9 mmol/L) 12 to 24 h after delivery. Women were allocated to RBC transfusion or expectant management. Primary outcome was physical fatigue at day 3 postpartum, scored using the HRQoL measure multidimensional fatigue inventory.

Six hundred fifty-eight DIGITAT women (60%), 818 HYPITAT women (71%) and all WOMB women participated in the HRQoL study. Questionnaires were completed at several time points; the only common time point in the trials was six weeks postpartum.

Each trial used the ShortForm-36 version 1 (SF-36v1), a generic HRQoL measure with eight scales (physical functioning, role limitations due to physical health problems [role-physical], bodily pain, general health, vitality, social functioning, role limitations due to emotional health [role-emotional], and mental health), ranging from 0 to 100; higher scores indicate better well-being. The SF-36v1 has been validated in a random nationwide sample of the Dutch population [32]. For this study, age and gender matched reference scores were provided by this research group (unpublished data based on 367 women aged 16–40 years, Aaronson et al.). The pilot study of the WOMB trial [8] provides postpartum reference scores based on 141 women that subsequently delivered in three Dutch hospitals.

The SF-36v1 allows for computation of the summary scores physical component score (PCS) and mental component score (MCS). These are norm-based with a mean of 50 and a standard deviation of 10, based on US population reference scores [33]. No Dutch population reference scores are available for the summary scores.

## Statistical analysis

We studied the PCS and MCS at six weeks postpartum in women who suffered obstetric complications. To create a homogeneous cohort, women from the WOMB trial that delivered before 36 + 0 weeks of gestation and multiple gestations were excluded. We used multiple imputations to handle missing values of all socio-demographic and clinical parameters [34]: ten imputed data sets were created using a fully conditional specified model. Imputations were based on the relations between the covariates in the study. Data were analyzed separately in each imputed data set to obtain the effect estimates. Pooled estimates were generated from these ten imputed data sets and used to report estimates and their corresponding 95% confidence intervals.

SF-36v1 subscale scores were compared to Dutch population reference scores and to postpartum reference scores. As no Dutch population reference scores are available for the summary scores PCS and MCS, these were compared to US population references [33].

We used univariable linear regression analysis to investigate parameters that were assumed to be related to HRQoL postpartum. The following socio-demographic and clinical parameters were analyzed: randomization status, age, BMI, country of birth (Dutch vs non-Dutch), highest education, parity, hypertensive disorders, gestational age at birth, induction of labor, analgesics, mode of delivery, perineal laceration, manual placenta removal, birth weight, PPH, admission of the neonate, congenital anomaly of the neonate, urinary tract infection, thrombo-embolic event, endometritis and hospital setting. To investigate the relationship of these parameters with HRQoL, we performed multivariable linear regression analysis, including those parameters with a significant relation to primary outcome measures in the univariable analyses ( $p < 0.10$ ). Data were managed using SPSS version 20.0.

## Results

A total of 3191 women were included in the three trials. Fig. 1 shows the flowcharts of this study. A total of 2310 participated: 1399 (61%) were randomized while 911 women (39%) refused randomization but participated as non-randomized women. HRQoL data at six weeks postpartum were available in 1391 women as the response at this time point was 60% (61%, 65% and 55% in the DIGITAT, HYPITAT and WOMB trial, respectively). We will refer to responding women as responders while women with no HRQoL

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