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Hyperemesis in Pregnancy Study: a pilot randomised controlled trial of midwife-led outpatient care

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ABSTRACT

Objective: To assess the feasibility of implementing a complex intervention involving rapid intravenous rehydration and ongoing midwifery support as compared to routine in-patient care for women suffering from severe nausea and vomiting in pregnancy, (NVP)/hyperemesis gravidarum (HG).

Study design: 53 pregnant women attending the Maternity Assessment Unit (MAU), Newcastle upon Tyne NHS Foundation Trust, Newcastle, UK with moderate-severe NVP, (as determined by a Pregnancy Unique Quantification of Emesis and Vomiting [PUQE] score ≥nine), consented to participate in this pilot randomised controlled trial (RCT). Subsequently 27 were randomised to the intervention group, 26 to the control group.

Women in the intervention group received rapid rehydration (three litres Hartman's solution over 6 h) and symptom relief on the MAU followed by ongoing midwifery telephone support. The control group were admitted to the antenatal ward for routine in-patient care.

Quality of life (QoL) determined by SF36.V2 score and PUQE score were measured 7 days following randomisation. Completion rates, readmission rate, length of hospital stay and pregnancy outcomes data were collected.

Results: Groups were comparable at baseline. Questionnaire two return rate was disappointing, only 18 women in the control group (69%) and 13 women in the intervention groups (44%). Nonetheless there were no differences between groups on Day 7 in terms of QoL, mean PUQE score, satisfaction with care, obstetric and neonatal outcomes or readmission rates. However, total combined admission time was higher in the control group (94 h versus 27 h, $p = 0.001$).

Conclusions: This study suggests that day-case management plus ongoing midwifery support may be an effective alternative for treating women with severe NVP/HG. A larger trial is needed to determine if this intervention affects women's QoL.

Introduction

Nausea and vomiting in pregnancy, (NVP), is a frequently occurring but often debilitating condition, which affects 50–85% of pregnant women [1]. In most cases symptoms are mild to moderate and self-limiting. However 0.3–1% of pregnancies are affected by hyperemesis gravidarum, (HG), defined as severe intractable vomiting, ketosis, fluid and electrolyte disturbances, nutritional deficiencies and weight loss (usually more than 5% of the pre-pregnancy weight) [1]. There is no clearly defined point at which NVP becomes HG and women are usually categorised according to the severity of their symptoms.

Severe NVP/HG has implications for the health and wellbeing of the mother and baby. A recent systematic review reported that women with HG were more likely to deliver preterm and to have a baby that was small-for-gestational age, although the associations are inconsistent, however there was no evidence of an association with congenital anomalies or perinatal death [2,3].

Severe NVP also causes emotional and psychological distress and can have a profound effect on women's quality of life (QoL)

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[4,5]. Recent observational studies have reported higher incidences of depression, anxiety and stress in women diagnosed with HG which can last throughout pregnancy and into the post-natal period [6,7]. As a result women with HG make greater use of health care resources; HG accounts for 30% of admissions before 20 weeks gestation [8].

Management of NVP/HG tends to focus on the alleviation of symptoms and prevention of serious morbidity. Historically women have been admitted to hospital for intravenous (IV) fluid therapy and antiemetics while less time is spent dealing with their psychological, social and emotional needs or providing information and guidance about the condition. The result is that women can feel unsupported, dissatisfied with care and experience negative interpersonal interactions with health care providers [9].

The aim of this pilot randomised trial was, therefore, to investigate the feasibility of a midwifery led out-patient intervention, consisting of rapid intravenous hydration and ongoing support versus standard in-patient management. Secondary outcomes included differences in QoL, satisfaction with care, readmission rate and pregnancy outcomes.

Methods

All pregnant women less than 20 weeks gestation attending the Maternity Assessment Unit, (MAU), at Newcastle upon Tyne Hospitals NHS Foundation Trust for the first time with moderate-severe NVP, over a twenty month period commencing in January 2004, were considered for inclusion in the study. A formal sample size calculation was not performed as this was a pilot feasibility study and recruitment continued for as long as was practicable and funds were available.

To assess the severity of their symptoms, women were asked to complete a 'Pregnancy Unique Quantification of Emesis and Vomiting Score' (PUQE score) [10–12]. The scale quantifies the amount of nausea, vomiting and retching over the preceding 12 h, each on a scale of one to five (i.e. maximum score 15). Women scoring nine or higher, (the mid-range point for the moderate category), were deemed suitable for inclusion in the study.

Women were excluded if they had an underlying medical condition such as type 1 diabetes mellitus, renal or cardiac disease, were aged less than 16 years, required an interpreter or were planning to have a termination of pregnancy. Ethical approval was granted by the Newcastle and North Tyneside Local Research Ethics Committee (reference number: 2003/207, approval date 25th February 2004).

After gaining written informed consent women were randomly allocated to receive either standard care (control group) or midwifery-led management on the MAU, (intervention group), using a web based system. The computer generated sequence was produced by a statistician independent of the study team using a fixed block size of six and 1:1 allocation.

Women allocated to the intervention group remained on the MAU. After routine clinical observations (temperature, pulse, blood pressure, weight and urinalysis) an intravenous (IV) cannula was sited and bloods taken for urea and electrolytes, liver function and full blood count. Cyclizine, 50 mg IV, was given followed by three litres of compound sodium lactate, (Hartman's), solution over six hours; the first litre over one hour, the second over two hours and the third over three hours. Women were then given 50 mg of oral thiamine and discharged home with a prescription for oral cyclizine, 50 mg to be taken three times daily for seven days. They were advised to see their General Practitioner (GP) if they needed additional antiemetics. Arrangements were made for the study research midwife to contact all women by telephone on day three and day seven after randomisation to offer ongoing support, reassurance, advice, identify any problems and encourage compliance with anti-emetics following a standard proforma.

Women allocated to the control group were admitted to the antenatal ward, an IV cannula sited and bloods taken. Intravenous cyclizine was given (50 mg IV), IV fluids, (one litre of Hartman's solution eight hourly until rehydrated), and a daily dose of oral thiamine (50 mg). Temperature, pulse, blood pressure, urinalysis, fluid balance and frequency of vomiting were recorded daily. Oral fluids were gradually introduced, followed by a bland light diet. Women were discharged home when they were tolerating diet with a prescription for oral cyclizine (as in the intervention group). All participants were given an information sheet about NVP which included simple self-help measures and advice that could be followed at home.

Immediately after randomisation women completed Questionnaire One, which consisted of basic demographic questions, the SF-36v.2, [www.sf36.org, [13]], (a quality of life scale which looks at eight dimensions of physical, emotional and mental wellbeing). Women were then given Questionnaire Two which asked them to complete a PUQE score at the same time every day for the following six days, a further SF-36v.2 score seven days after randomisation together with a short satisfaction survey [14]. Participants were reminded to complete this questionnaire when they received their follow up telephone calls, (intervention group), or whilst they were inpatients (control group). A freepost envelope was provided to facilitate return of this questionnaire.

Women re-attending the MAU because of persistent or increasing NVP within seven days of randomisation were offered a second cycle of the treatment to which they had been allocated. If women re-attended a second time within seven days of randomisation they were admitted and received standard care on the antenatal ward.

Data analysis

Analysis was by intention-to-treat using SPSS for Windows (Statistical Package for Social Sciences Version 21). Serial PUQE scores were analysed by calculating the area under the curve to generate a single summary statistic for each participant [15]; groups were then compared using an independent sample *t*-test, cross tabulations and chi-squared analysis were used to detect differences between groups. Analysis of co-variance was used to detect differences between the SF36 mean summary scores and the PUQE scores on days one and seven. Customised growth centile charts were used to calculate birth centiles [16]. Small for gestational age (SGA) was defined as a birthweight less than the 10th centile for gestational age, maternal parity and sex.

Results

A total of 184 women presented at the MAU during the 20-month recruitment period, 126 of which were eligible to participate. Of these 50 women were not approached by the clinical staff, (either because the women presented at hospital overnight or the MAU was exceptionally busy), 23 declined participation and 53 were randomised. A Consort diagram is presented in Fig. 1.

The baseline characteristics of the women in the trial are shown in Table 1. There were no differences between the groups in any of the variables, serum urea and electrolyte concentrations were within normal ranges for all women. Of the 27 women randomised to the intervention, 20 (74%) received the first telephone call on day three and 16 (59%) received the second call on day seven; 14 (52%) received both telephone calls, with each call lasting between 2 and 10 min.