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Original Article

Does a patient information sheet lead to better understanding of pre-eclampsia? A randomised controlled trial

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ABSTRACT

Objective: To investigate whether a structured patient information sheet would improve women's satisfaction and understanding of pre-eclampsia, its management and risks.
Study design: A randomised, controlled trial conducted in a referral centre in South Africa. Seventy-four women with early pre-eclampsia, who qualified for expectant management, were enroled. They all completed an anonymous, structured, and self-administered questionnaire before randomisation.
Cases ($n = 37$) received a patient information sheet addressing key features of pre-eclampsia; controls ($n = 37$) received a welcome note. Within 5–7 days, but still before delivery, they completed the same questionnaire again.
Main outcome measures: Primarily assessing their general understanding and knowledge of pre-eclampsia, secondarily to assess their satisfaction and the impact of the information received.
Results: The patient information sheet improved their understanding of the immediate and long-term risks ($p < 0.01$) and the chance of recurrence ($p < 0.01$). Controls had good levels of understanding and appreciation. Most women in both groups felt well informed but levels of concern remained high.
Conclusions: The structured information sheet improved patients' understanding and knowledge in a limited way but did not alleviate their anxiety. Although women appear to be generally well counselled in the study unit, measures to alleviate associated anxiety should be investigated.

Introduction

Early onset severe pre-eclampsia (EOSPE) is a frequent and dangerous complication of pregnancy that is associated with significant morbidity and mortality for both the pregnant woman and her baby [1]. While many units practice aggressive management of these cases, expectant management of stable patients with early onset, severe pre-eclampsia has been shown to be safe for the mother and beneficial for the foetus [2–6].

In general uncomplicated pregnancies are typically associated with a positive outlook and expectations, while pregnancies complicated by maternal disease and the prospect of a sub-optimal foetal outcome are extremely stressful experiences for many women [7]. The diagnosis of pre-eclampsia during pregnancy is a case in point where hospital admission, caesarean sections and separation from the partner are experienced as major stressors [8]. In addition to stressors caused by obstetrical complications, women with hypertensive disorders of pregnancy often have to deal with sudden changes such as an emergent delivery. This fear of an infant born prematurely increases the emotional burden and may even lead to acute stress disorders [9,10].

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Intriguingly stress itself can lead to hypertensive disorders of pregnancy. Cardiovascular diseases in non-pregnant patient are strongly influenced by stress [11] and share several risk factors with hypertensive diseases in pregnancy. In particular, women who experience emotional stress during pregnancy have a significantly increased risk for the development of hypertensive diseases in pregnancy [12]. To help patients cope with unexpected complications, adequate medical information needs to be relayed to the patient, as uncertainty due to insufficient information may further increase their fear. Improving patient coping mechanisms through careful disclosure of information improves their decision-making capacity [13].

Patients with pre-eclampsia need to process a significant amount of information with regards to themselves and their baby, in both the present and the future. A previous study showed that most women were not satisfied with the medical information they received when they suffered from pre-eclampsia [14]. For this reason it was decided to investigate whether a structured information sheet would assist the patient in understanding the underlying problems and risks of pre-eclampsia. The aim was also to improve patient satisfaction with the process.

Methods

This randomised control study was conducted in Tygerberg Hospital, a tertiary and secondary referral centre in the Western Cape Province of South Africa, from October 2008 to April 2010. Pre-eclampsia was defined according to the criteria of the International Society for the Study of Hypertension in Pregnancy [15]. Early onset preeclampsia was defined as onset of disease from a gestation of 20 weeks 0 day to 33 weeks 6 days.

At Tygerberg Hospital, all patients with early onset, severe pre-eclampsia are admitted, stabilised and evaluated. In cases where the mother and foetus are otherwise stable and the gestation is between 24 weeks 0 day and 33 weeks 6 days, expectant management in a dedicated high-care ward is offered [2]. Clinical care is provided by a specific (Obstetric Special Care) team. Patients are generally well counselled. On admission to the hospital the general obstetric team first counsels them and once they are referred to the Obstetric Special Care Team, they are counselled in greater detail. Therefore prior to admission to the dedicated ward, patients should have received information regarding the benefits and risks of expectant management, management itself, the expected duration of care and the impact of pre-eclampsia on future maternal and child health.

All women recruited into this study were being managed in the Obstetric Special Care Ward. Upon completion of the consent process all women were requested to complete an anonymous, structured, and self-administered questionnaire. Thereafter they were randomised using a computer-generated number sequence in a balanced block design, provided in sealed opaque envelopes, generated by the departments' statistician. The principal investigator enroled the participants and assigned the participants intervention. The participants and care providers were not blinded to the assigned interventions. Study cases received a specifically compiled, double-sided, A4 patient information sheet addressing the important issues noted above, while controls received a similar sized document welcoming them to the dedicated ward. These documents were included in the sealed randomisation envelopes. Within 5–7 days, if still before delivery, the women completed the same questionnaire again.

During preparation for the study, no appropriate evaluation instruments, specific to pre-eclampsia were found in the literature. For this reason the formulation of the questions was guided by the aims of the study, other questionnaires and expert opinion. The aim was to assess the patient's understanding of the disease and their satisfaction with the care process. The questionnaire comprised of 22 questions divided into three sections (Appendix 1). These sections were designed to evaluate their understanding, knowledge of the disease and finally their satisfaction with and the impact of the information provided. Patients completed the questionnaire by ticking appropriate boxes (yes/no/unsure or true/false/unsure) or indicating their opinions using a five point Likert scale. No open-ended questions were included.

No power calculation was performed beforehand as the impact of a patient information sheet on pre-eclamptic patients remains uncertain and this was regarded as a pilot study. Therefore the trial was ended after 25 women had completed the exit questionnaires in each arm.

Statistical analysis was carried out using Statistica 9 from Statsoft.com. Data are expressed as medians with ranges or n (%). Categorical data were analysed using the χ^2 test. Where an expected cell value was less than five the Fischer exact test was used. Continuous data were analysed with Student's T test for parametric and the Mann–Whitney-U test for nonparametric data. Statistical significance was set at a p value of <0.05. The study was performed according to the recommendation of the declaration of Helsinki and was approved by our Institution's Medical Ethics Committee (Committee for Human Research N08/02/051).

Results

All women who were approached, except for one, consented to participate in this study. The latter person also declined any further management, claiming social responsibilities as the reason. A total of 74 women were recruited for this study. The flow diagram of women who participated in this study are shown in Fig. 1.

The controls and cases showed similar baseline characteristics. The baseline demographic and clinical data of all women at entry in the study and at the time of the second questionnaire are shown in Tables 1 and 2, respectively.

On completion of the first questionnaire, answers to the individual questions from the case and control groups were similar with three exceptions. More cases than controls were satisfied with the doctors' explanation of pre-eclampsia ($p = 0.05$), more cases believed pre-eclampsia to be a common condition ($p = 0.01$) and more cases understood that pre-eclampsia is characterised by high blood pressure and proteinuria ($p = 0.04$).