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OBSTETRICS & GYNECOLOGY | RESEARCH ARTICLE

Post-traumatic stress disorder in women and their partners, following severe post-partum hemorrhage: A study protocol for a prospective cohort study

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Abstract: *Background:* Post-traumatic stress disorder is a Trauma- and Stressor-Related Disorder resulting from exposure to an event that is considered as traumatic. It is recognized in relation to traumatic childbirth that both patient, partner and health-care provider can develop a post-traumatic stress disorder. The most important risk factors in women are depression during the pregnancy, fear of childbirth, severe pre-eclampsia, preterm premature rupture of membranes, and severe neonatal complications. The prevalence rate in women in Western countries is estimated between 1 and 3%. The prevalence in partners witnessing childbirth is unknown. Post-traumatic stress disorder in relation to severe post-partum haemorrhage, in either women or partners, has not been extensively researched yet. *Methods/design:* This is a prospective cohort study in a hospital setting, with the objective to evaluate whether women and their partners have a higher risk to develop a post-traumatic stress disorder or symptoms, following a severe post-partum hemorrhage of 2.0 l or more, compared to a control group. The primary outcome variable is diagnosis of post-traumatic stress disorder. Secondary outcome variables are post-traumatic symptoms according to the post-traumatic stress disorder criteria, psychiatric comorbidities and seeking psychological help. A total of at least 130 women and 130 partners, must be included according to power calculations. Patients, partners and

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PUBLIC INTEREST STATEMENT

Post-traumatic stress disorder is a Trauma- and Stressor-Related Disorder resulting from exposure to an event that is considered as traumatic. It is recognized in relation to traumatic childbirth that both patient, partner and health-care provider can develop a post-traumatic stress disorder. The most important risk factors in women are depression during the pregnancy, fear of childbirth, severe pre-eclampsia, preterm premature rupture of membranes, and severe neonatal complications. The prevalence rate in women in Western countries is estimated between 1 and 3%. The prevalence in partners witnessing childbirth is unknown. Post-traumatic stress disorder in relation to severe post-partum haemorrhage, in either women or partners, has not been extensively researched yet.

controls are selected in eight hospitals through complication registers. They are asked to complete a digital questionnaire four to six weeks after delivery, to screen for a post-traumatic stress disorder or symptoms. Participants with scores above cut off values are asked to participate in a telephone interview. For secondary outcomes, risk factors will be evaluated by multivariable analysis. *Discussion:* This study is designed to give insight into the frequency of post-traumatic stress disorder and post-traumatic stress symptoms following a severe post-partum hemorrhage, both in patients and their partners. We strive to minimize the non-response bias, a common problem in this type of research, through early and active participant recruitment. *Trial registration:* NL50273.100.14.

Subjects: Post-traumatic Stress Disorder in Adults; Trauma and Dissociation; Obstetrics; Anxiety & Mood Disorders

Keywords: PTSD; PPH; DSM-5; hemorrhages; post-partum; traumatic birth; stress; psychotrauma; partner

1. Introduction

1.1. Post-traumatic stress disorder

Post-traumatic stress disorder (PTSD) is a Trauma- and Stressor-Related Disorder resulting from exposure to an event that is considered as traumatic. PTSD symptoms are intrusion, avoidance, negative cognitions and mood, and hyperarousal, as described by the Diagnostic and Statistical Manual of Mental Disorders - 5 (DSM-5) (Phillips et al., 2013). It was first described and is best known in relation to war traumas, but is also recognized in relation to any potential traumatic event. For example, it was shown that a near death experience during cardiac arrest can lead to PTSD (Wilder Schaaf et al., 2013). Also, the type of exposure to the event may differ: both victims as well as spectators can develop PTSD. The life time prevalence of PTSD in the Netherlands is 7.4% (de Vries & Olff, 2009).

Without treatment, PTSD often does not spontaneously regress and can be a disabling disorder that may exist for years. Treatment usually starts with managing psychiatric comorbidities that may stand in way of treatment, such as substance abuse, severe depression and suicidality (National Institute for Health & Care Excellence, 2005; van Balkom, et al., 2013). As treatment of PTSD after childbirth, cognitive behavioral psychotherapy specified on traumatic childbirth and eye movement desensitization and reprocessing therapy have shown to be effective (Poel, Swinkels, & de Vries, 2009; Stramrood et al., 2012).

1.2. PTSD in women after traumatic childbirth

PTSD was first recognized in relation to traumatic childbirth in 1990, and the awareness has slowly increased since then. Previous studies have shown a PTSD incidence in women as a result of traumatic childbirth between 0 and 5.9% worldwide, and between 1 and 3% in Western countries (Grekin & O'Hara, 2014; Olde, van der Hart, Kleber, & van Son, 2006; Polachek, Harari, Baum, & Strous, 2012). A large study in the Netherlands showed a 1.2% incidence rate, which is around 2,000 women each year (Stramrood et al., 2011).

There are multiple risk factors that may play a role in developing PTSD after childbirth. We generally divide risk factors in three categories: patient characteristics, obstetrics and childbirth situation. Patient characteristics describe personality traits and mental health throughout the pregnancy and childbirth. The most important risk factors in this group are a history of PTSD or depression, a depression during pregnancy and severe fear of childbirth (Ford & Ayers, 2011; Grekin & O'Hara, 2014; Söderquist, Wijma, Thorbert, & Wijma, 2009; Söderquist, Wijma, & Wijma, 2006; Stramrood, Paarlberg, et al., 2011). Obstetric risk factors include obstetric complications, such as severe pain during the

delivery, pre-eclampsia (PE), preterm premature rupture of membranes (PPROM), an emergency birth intervention and neonatal complications (Ayers, Jessop, Pike, Parfitt, & Ford, 2014; Engelhard et al., 2002; Grekin & O'Hara, 2014; Hoedjes et al., 2011; Soderquist, Wijma, & Wijma, 2002; Stramrood, Paarlberg, et al., 2011, Stramrood, Wessel, et al., 2011). Childbirth situation includes the variables of the situation in which childbirth has taken place and the way the patient has experienced this. A lack of social support, either by family or health care providers, an experience of powerlessness or loneliness during the delivery, and peritraumatic dissociation increase the risk to develop PTSD (Ayers et al., 2014; Ford & Ayers, 2011; Grekin & O'Hara, 2014; Harris & Ayers, 2012; Olde et al., 2005).

1.3. PTSD in men after traumatic childbirth

As described earlier, witnesses of traumatic birth, such as partners and health care providers, also have a risk of developing PTSD and depression (Stramrood et al., 2013). Traumatic birth may not only have major consequences for the patient, but also for their partners. Several studies have been done to explore obstetrical and patient characteristic risk factors in partners. Although there is a lack of good qualitative and quantitative studies, the prevalence of PTSD is estimated between 0 and 5% six weeks post-partum (Bradley & Slade, 2010). One Dutch study showed that symptoms of depression and PTSD during the pregnancy experienced by the woman, give a higher risk of the partner developing PTSD and depression after birth complications, such as pre-eclampsia or PPRM (Bradley & Slade, 2010). However, the prevalence, risk factors and treatment for PTSD and post-traumatic stress (PTS) symptoms in partners needs further investigation. Our clinical experience is that partners often experience uncertainty and powerlessness when confronted with a life-threatening situation of the patient or their newborn child.

1.4. Post-partum hemorrhages and PTSD

1.4.1. Mild and severe post-partum hemorrhage

The most common causes for a post-partum hemorrhage (PPH) are uterine atony, retained placenta, vaginal and cervical tears, placenta praevia and coagulation deficits (Mousa & Alfirevic, 2003; Smit, Chan, Middeldorp, & van Roosmalen, 2014). Usually, hemorrhages until 1 l are well tolerated in healthy patients. A mild PPH is defined in the Netherlands as blood loss of 1 l or more, within 24 h after vaginal birth or a caesarean delivery. Internationally other definitions are used, for example a blood loss of 0.5 l or more according to the World Health Organization (World Health Organization, 2012), or a 10% hemoglobin concentration decline (Combs, Murphy, & Laros, 1991). The signs and symptoms as a result of a mild PPH are palpitations, lightheadedness, tachycardia, confusion, sweating and weakness (Bonnar, 2000; Hofmeyr & Mohlala, 2001).

The definition of a severe PPH is usually blood loss of 2.0 l or more, but also differs internationally. For example, it is sometimes defined as a hemorrhage that resulted in a blood transfusion of 4 packed cells or more, or resulted in an embolization or hysterectomy. The incidence of severe PPHs in America between 1998 and 2008 was 3.0 per 1,000 deliveries (Kramer et al., 2013) and 4.5 per 1,000 deliveries in the Netherlands between 2004 and 2006 (Zwart et al., 2008). Severe PPH can result in extremely low blood pressure, lethargy, dyspnea, anuria, and eventually collapse and death (Bonnar, 2000; Hofmeyr & Mohlala, 2001).

1.4.2. Traumatic post-partum hemorrhage

Severe hemorrhages are often accompanied by physical symptoms (Bonnar, 2000), and therefore more likely to be perceived as traumatic. Patients often experience severe PPH as a near-death experience, describing it as if they were slowly bleeding to death. One Dutch study explored PPHs, among other potential risk factors, and their relation to PTSD. It was not found to be a risk factor for PTSD. This study however, also included mild hemorrhages, as they used patients with PPHs of 1 l or more (Stramrood, Paarlberg, et al., 2011). Another recent study from England also explored PTSD after PPH of 1.5 l or more, and found a significant increase of post-traumatic stress symptoms (Furuta, Sandall, Cooper, & Bick, 2014). There is no research on PTSD in partners that have witnessed PPH, so numbers remain unknown.

1.4.3. *Post-traumatic stress after post-partum hemorrhage*

In most studies, only DSM criteria for PTSD are used as end points. However, there is a group of patients that suffers from clinically relevant post-traumatic stress (PTS) symptoms that do not meet the criteria for PTSD. There is some evidence that the prevalence of significant symptoms of intrusion, avoidance and hyperarousal is high, between 9.4 and 28.9% of the women suffers from at least one of the symptoms. Risk factors for developing PTS-symptoms are similar to those of developing PTSD (Hoedjes et al., 2011; Polachek et al., 2012).

2. Methods and design

2.1. Aims

A prospective evaluation in a hospital setting on the frequency of PTSD and PTS symptoms following a severe PPH of 2.0 l or more, compared to deliveries without a PPH, both in patients as well as in their partners. We hypothesize that women with a severe hemorrhage post-partum, and partners who have witnessed post-partum hemorrhage, have a higher risk of developing PTSD and PTS-symptoms as compared to controls. This study will provide insight in risk factors of traumatic childbirth, and may ultimately lead to improved screening for PTSD after childbirth.

2.2. Design

2.2.1. *Selection and inclusion*

This study is a prospective cohort study. Patients and controls are selected from the complication and birth registers in ten hospitals by designated investigators from each hospital. Before patients and controls leave the hospital, they are personally approached by the doctors on the ward. The patient and her partner receive a short information card, an information letter and they are asked to fill out an informed consent. They will be informed they will be invited for participation four to six weeks after birth. The address, phone number and native language of the women are available in the hospital registers. If they are English speaking patients, they will receive the letter and consent in English. A separate question is added in the consent for women that do not want to participate, asking for permission to use their medical details, so we can include their partner.

2.2.2. *Digital questionnaire*

Between 4 and 6 weeks post-partum, patient, partner and controls are asked through e-mail to complete a digital questionnaire. This time frame has been chosen because PTSD can only be diagnosed when the complaints exist for more than four weeks after a traumatic event. A first (1 week) and second (2 weeks) reminder will be sent to non-responders. The questionnaire we will use is the PTSD Checklist for the DSM-5 (PCL-5) with several added questions about co-morbidities such as use of alcohol, drugs and medication. This questionnaire will be available in Dutch and English. Completing it will take around 10–15 min.

2.2.3. *Telephone interview*

Based on the score of the digital questionnaire, patients are selected for a telephone interview. The cut-off value will be a total score of ≥ 11 in combination with a severity score of ≥ 3 . This chosen cut-off is lower than the official score for PTSD to prevent we will miss participants with posttraumatic stress symptoms. In this interview we will use the Clinician Administered PTSD Scale for the DSM-5 (CAPS-5), which will be available in Dutch and English. All interviewers are trained to perform the CAPS-5. The interview will take around 20–90 min, depending on the amount of complaints the participant has. In addition, the personal details and the ability to understand the questions are confirmed. The CAPS-5 is the gold standard for the diagnosis of PTSD, and the DSM-5 version is currently being validated in English and Dutch. During the CAPS-5 interview, we ask patients to describe the traumatic event, but we also ask about other traumatic events in the participants' history or an earlier diagnosis of PTSD. If this is the case, we will ask the participant to focus on the traumatic event during the delivery. We will continue the interview when patients were diagnosed with PTSD before, but they will be excluded from the study, since it is very hard to differentiate if the complaints are

caused by the first traumatic event or by the second. It is practically not feasible to submit all patients and controls to a telephone interview, due to time limitations. Also, it is found unnecessary to do an interview when patients score below the cut off values of the PCL-5.

2.2.4. Risk factors

The medical details of the participants such as amount of blood loss, medical interventions, medical history etc. will be registered in a case report form (CRF) for every patient, partner and control. These factors will be searched for in their medical records and are obtained via the questionnaire and interview. As for the partners, limited information will be available, since they are usually not registered patients in the hospital. Therefore questions about their medical history and use of medication are added in the questionnaire.

2.3. Patient population

2.3.1. Patient groups

We will have two groups of patients; a patient group and a partner group. In the patient group we will include patients with a PPH of 2.0 l or more. In the partner group we will include the partners of these patients. This study will be performed in eight hospitals in the Amsterdam region. All PPHs will be registered as a complication in the hospital registers. Patients are thereby selected via these register databases. The aim is to select a minimum of 260 patients and 260 partners, based on the response rate and sample size calculation. With a response rate based on earlier research of approximately 50% (Furuta et al., 2014; Stramrood, Paarlberg, et al., 2011), we aim to have response of at least 130 patients and 130 partners.

2.3.2. Control groups

We will have two control groups; a patient-control group and a partner-control group. Control group patients are selected by selecting the following and preceding birth after a PPH, from the birth register. This is a common method for control group selection in this type of research. The partner-control consists of partners of women in the patient-control group. We expect a lower response rate compared to the patient groups and aim to select at least 260 couples.

2.3.3. In-/exclusion criteria

All participants are assessed for eligibility based on the inclusion and exclusion criteria. All patients must be 18 years of age or older. A medical history of PTSD and the inability to understand Dutch or English are used as exclusion criteria for all participants. We also accept proficient English speaking patients, because of the high number of international patients in Amsterdam. For the control group, a PPH of 0.5 l or more according to the definition of the WHO, is also used as an exclusion criterion. All other obstetric complications are accepted in all groups, because we expect the same complications in each group. A partner or partner control can only be included in our research when the patient is also participating or when the patient is not participating, but has explicitly given permission to use her medical history of the pregnancy and delivery in the informed consent. This permission is needed, because otherwise we are not allowed to use the information of the pregnancy and delivery.

2.4. Materials

The measuring instruments are the PCL-5 and CAPS-5. The PCL-5 is an internationally used screening tool for PTSD, which focuses on a specific traumatic event. The questionnaire has undergone preliminary validation for the DSM-5 in English, and is currently being validated in Dutch. Cut off values will be used according to these validation studies. The questionnaire is a 20 item self-report tool to monitor symptom changes during and after treatment, to screen individuals for PTSD and diagnose a provisional PTSD. The rating scale of each item is from 0 to 4, described in the same order as “Not at all,” “A little bit,” “Moderately,” “Quite a bit,” and “Extremely.” A score between 0 and 80 can be obtained (Weathers, Litz, et al., 2013). When a participant scores 11 or higher in total and at least three or higher on any of the symptoms, they are contacted for a CAPS-5 interview.

The CAPS-5 is a 30-item questionnaire, corresponding to the DSM-5 diagnosis for PTSD. CAPS-5 symptom cluster severity scores are calculated by summing the individual item severity scores for symptoms corresponding to a given DSM-5 cluster: Criterion B (items 1–5); Criterion C (items 6–7); Criterion D (items 8–14); and, Criterion E (items 15–20). A symptom cluster score may also be calculated for dissociation by summing items 29 and 30. The rating scale of each item is from 0 to 4, described in the same order as “Absent”, “Mild/subthreshold”, “Moderate/threshold”, “Severe/markedly elevated” and “Extreme/incapacitating”. A symptom is considered present only if the corresponding item severity score is rated 2 or higher. The DSM-5 PTSD diagnostic rule requires at least 1 criterion B item, 1 criterion C item, 2 criterion D items and 2 criterion E items, and has to meet criterion F (question 22) and G (questions 23 to 25). Patients can also be diagnosed with the dissociative subtype (questions 29 and 30) (Weathers, Blake, et al., 2013).

Extra questions (see Addendum 1) are added to the questionnaire (and explored during telephone interview) about duration of symptoms, functional significance, co-morbidities and search for treatment. Furthermore, questions are added to explore a medical history of PTSD, depression and use of antidepressant medication during pregnancy and complaints from hypotensive shock as a result of the PPH.

2.5. Outcomes

2.5.1. Primary outcome

The primary outcome variable is the diagnosis of PTSD based on the DSM-5 criteria.

2.5.2. Secondary outcome

The secondary outcome variables are post-traumatic stress symptoms B to E based on the DSM-5 criteria. We will also evaluate co-morbidities, such as alcohol, drug and medication abuse, and whether a participant has already searched for psychological treatment. The latter will be asked for in the questionnaire. For the secondary outcome, cut off values are used as for the primary outcome, but are graded per criterion. Patients must score two or higher on at least one B item for the outcome “intrusion”. They must score two or higher on at least one C item for the outcome “avoidance”. They must score two or higher on at least two D items for the outcome “negative cognitions and mood”. And they must score two or higher on two E items, to suffer from “hyperarousal”. They can score above the cut-off value for multiple symptoms. They can only score positive on symptoms when duration of the symptoms is four weeks or longer, and have a functional significance due to subjective distress, impairment in social functioning or impairment in occupational functioning. Data of women and partner not coupled at first, but if possible we will perform a sub analysis to determine homogeneity in paired couples, to see if there is an association between PTSD in patients and their partners.

2.6. Data storage

All data will be made anonymous and stored in SPSS documents. Anonymizing is done by assigning all test subjects to numbers. The personal details are connected to a number in a secured document, which is only accessible to the investigators. All data is stored on secured computers.

2.7. Statistical analysis

2.7.1. Sample size

We are planning two studies of independent cases and controls with one to two controls per case. The same analysis is done for both the patient and partner groups. We hypothesize a 10% increase of prevalence in both patient and partner group compared to controls, based on numbers of other risk factors such as PE and PPROM, since these are unknown for PPH. We will use the same number for the partner group. The prevalence of PTSD in the general population is 1.2% in the Netherlands. This prior data indicates that the failure rate among controls is 0.012. If the true failure rate for patients is 0.087, we will need to study 130 patients and 130 control subjects to be able to reject the

null hypothesis, that the failure rates for patients and control subjects are equal with probability (power) 0.8. The Type I error probability associated with this null hypothesis test is 0.05.

2.7.2. Data analysis

We will use an uncorrected χ^2 statistic to evaluate this null hypothesis, or a Fisher's exact test in the case of smaller numbers. All categorical data will be reported in number (%) and analyzed with a χ^2 analysis. All continuous data will be reported in mean \pm SD and analyzed with t-test, or median (interquartile range 25–75%) and analyzed with Mann-Whitney U test when appropriate. We choose to measure association between severe PPH and PTSD. The goal is not to predict, but to answer association. For the primary outcome, a multivariable analysis is not possible due to the small number of expected PTSD patients and the number of confounders. For the secondary outcome, prevalence is expected to be higher. A multiple logistic regression-analysis is used to correct for potential risk factors. For both outcomes, a McNemar's test is done on the paired (women and partners) nominal data, to determine marginal homogeneity.

2.8. Ethical considerations

This research has ethical approval of the VCMO, the Netherlands. It is registered in the Dutch Trial Register under registration number NL50273.100.14. The risks of participating in this research are estimated very low. Serious adverse events are not expected. For anonymous questions or remarks, participants have the possibility to consult an independent doctor.

3. Discussion

There is some evidence suggesting that severe PPH is a risk factor for the development of PTSD. However, proper quantitative and qualitative studies on this topic are lacking, especially concerning partner groups. This study is designed to give insight into the frequency of PTSD and PTS symptoms following a severe PPH, both in patients as well as in their partners. Through this study, we hope to contribute to the development of an evidence-based risk profile, in order to establish adequate screening and follow-up after traumatic childbirth.

A methodical point of discussion in this type of research is the low response rate, due to the avoiding nature of PTSD patients. Our experience is that personally informing the patient early after delivery about participation, helps increasing the response rate. Obviously, the response rate is important in all types of research, but crucial in this field, due the large non-response bias.

List of abbreviations

CRF	Case report form
CAPS-5	Clinician Administered PTSD Scale for the DSM-5
DSM-5	Diagnostic and Statistical Manual of Mental Disorders 5th Edition
EMDR	Eye movement desensitization and reprocessing
GP	General practitioner
MEC-U	Medical research Ethics Committees United

OLVG

PCL-5	PTSD CheckList for the DSM-5
PE	Pre-eclampsia
PPH	Post-partum hemorrhage
PPROM	Preterm premature rupture of membranes
PTSD	Post-traumatic stress disorder
PTS	Post-traumatic stress

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Authors' contributions

K.W.F. Scheepstra and M.E. van Steijn designed this study and will collect data. All authors were involved in writing the protocol and had final approval of the submitted and published versions.

Competing Interests

The authors declare no competing interest.

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Addendum 1

Extra questions added to digital questionnaire:

Patiënt questionnaire:

- (1) What is your highest education level?
 - (a) Lower school
 - (b) High school
 - (c) College
 - (d) University

- (2) Do you have a psychiatric medical history (for example a post-traumatic stress disorder or a depression)?
 - (a) Yes, please specify:
 - (b) No

- (3) Were you diagnosed with a depression during your pregnancy?
 - (a) Yes
 - (b) No

- (4) Did you use antidepressants during your pregnancy?
 - (a) Yes, please specify
 - (b) No

- (5) Do you currently drink alcohol?
 - (a) Yes, please specify:
 - (b) No

- (6) Do you currently use illegal drugs?
 - (a) Yes, please specify:
 - (b) No

- (7) Did you have the feeling you were bleeding to death during your delivery (for example because u almost fainted, became dizzy, lightheadedness or had shortness of breath)?
 - (a) Not at all
 - (b) A little bit
 - (c) Moderately
 - (d) Quite a bit
 - (e) Extremely
 - (f) I can't remember

- (8) How did you experience this?

Partner questionnaire:

- (1) What is your highest education level?
 - (a) Lower school
 - (b) High school
 - (c) College
 - (d) University
- (2) Do you have a psychiatric medical history (for example a post-traumatic stress disorder or a depression)?
 - (a) Yes, please specify:
 - (b) No
- (3) Were you diagnosed with a depression during the pregnancy of your partner?
 - (a) Yes
 - (b) No
- (4) Did you use antidepressants during the pregnancy of your partner?
 - (a) Yes, please specify
 - (b) No
- (5) Do you currently drink alcohol?
 - (a) Yes, please specify:
 - (b) No
- (6) Do you currently use illegal drugs?
 - (a) Yes, please specify:
 - (b) No

Current knowledge on the subject

- The incidence rate of post-traumatic stress disorder as a result of childbirth in women in Western countries is estimated between 1 and 3%.
- Post-traumatic stress disorder as a result of a severe post-partum hemorrhage of 2 l or more, has not been extensively researched, but is often described as psychotraumatic.
- Partners can also develop a post-traumatic stress disorder after childbirth, but most risk factors are not yet identified.

What this study adds

- A study method to investigate avoidant PTSD patients to maximize response rate.
- Background on post-traumatic stress after severe post-partum hemorrhages.



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