

Randomised trial for impacted fetal head at caesarean: acceptability and feasibility

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Background: In the UK 26% of all births are performed by caesarean section (CS) (1). 5% of all CS are performed in the second stage of labour (2). In some cases, second stage CS can be made more difficult due to the fetal head being deeply impacted in the maternal pelvis, known as ‘impacted fetal head’ and requires action to deliver the baby safely. The risks associated with this include; major haemorrhage; longer hospital stay and delivery times; greater risk of bladder trauma, uterine tears and or injury to the baby (3). While there are a number of techniques used to manage impacted fetal head, there is no national guidance on managing this issue in the UK.

Aim: To explore health professionals’ and women’s views on the acceptability and feasibility of a randomised controlled trial (RCT) designed to determine the most effective technique for managing an impacted fetal head during emergency CS.

Methods: Semi-structured interviews with 10 obstetricians and 16 women (6 were primiparous or pregnant and 10 had experienced an emergency second stage CS) were carried out. These interviews explored;

- (i) the acceptability of different techniques;
- (ii) willingness to be involved in a trial of this type
- (iii) views on two different RCTs designed to examine the effectiveness of techniques for managing impacted fetal head.

Different trial designs: Participants were shown two trial designs which had been proposed from previous work in the MIDAS study. A visual guide was used during interviews to help them consider the different designs.

- The **first** is a randomised trial with two groups to compare the use of the push technique with the fetal pillow. Women would be randomised when a decision was made to perform an emergency CS and an impacted fetal head was anticipated
- The **second** trial design has three groups which compare prophylactic use of the push technique or fetal pillow prior to CS or waiting until during the CS when it can be established whether the fetal head is impacted or not.

Analysis: Interviews were transcribed and analysed using systematic thematic analysis (4).

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Results: Most participants thought the RCT would be feasible and acceptable. Four main themes were identified:

Recruitment and consent included consideration of the time at which you obtain consent, how and when information about the RCT is presented, and barriers and facilitators to recruiting health professionals and women into the RCT.

Feasibility and acceptability

Obstetricians emphasised the importance of training in the techniques, as well as the potential conflict between the RCT protocol and current site or individual practices. Women said they would trust health professionals’ to use the most appropriate technique and abandon the trial protocol if necessary.

Design considerations

Similarly, obstetricians raised the tension between the trial protocol versus safety in reverting to what they knew under emergency situations. Both groups reflected on how this might affect the results. There were varying views on which of the two trial designs presented to participants would be preferred.

Outcomes

A range of important maternal, infant and clinical outcomes were raised by women and obstetricians.

Conclusions: The views of women and obstetricians were elicited in this study to examine specific trial designs to evaluate the effectiveness of different techniques for managing impacted fetal head. This study highlights the complexities involved in conducting research in this area, particularly those which involve obstetric emergencies. This research suggests a randomised trial designed to determine the most effective techniques for managing an impacted fetal head would be feasible and acceptable to both women and health care professionals (HCP). It highlights a number of considerations that are important when designing such a trial. Women and HCPs discussed safety and reverting to HCP preferred technique in an emergency. Finally, women and HCPs indicated important outcomes (maternal, infant and clinical) for the trial. Results can be used to inform the design and conduct of a definitive trial in this area.

References:

1. Office for National Statistics, NHS Maternity Statistics 2013-14 (2015)
2. Untersheider J, McMenemy M, Cullinane F. Rising rates of caesarean deliveries at full cervical dilatation: a concerning trend. European J Obstet Gynaecol Reprod Biol. 2011;157(2):141
3. Allen VM, O’Connell CM, Baskett TF. Maternal and perinatal morbidity of caesarean delivery at full cervical dilatation compared with caesarean delivery in the first stage of labour. BJOG. 2005;112(7):986-990.
4. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative Research in Psychology. 2006;3(2):77-101.



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