Feasibility of a RCT of techniques for managing an impacted fetal head during emergency caesarean section: the MIDAS scoping study

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Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/KUYP6832.

Primary conflicts of interest: Susan Ayers reports grants from the National Institute for Health and Care Research (NIHR) outside the submitted work. Nia W Jones reports grants from NIHR Health Technology Assessment (HTA) during the conduct of the study. Jon Dorling reports grants from NIHR during the conduct of the study, and grants from NIHR, Canadian Institute of Health Research, Izaak Walton Killam and Nova Scotia Research outside the submitted work. Jon Dorling also reports membership of the following committees: HTA Efficient Study Designs (2015–16), HTA Maternal, Neonatal and Child Health Panel (2013–18) and HTA General Committee (2016–18). Rachel Plachcinski reports personal fees from University of Nottingham, outside the submitted work. Marian Knight reports grants from NIHR during the conduct of the study and membership of the following committees: HTA Remit and Competitiveness Group (2021 to present), HTA Prioritisation Committee B Methods

Group (January 2021 to March 2022), HTA Funding Committee Policy Group (formerly Clinical Studies Group) (2021 to present), HTA Commissioning Committee (2021 to present) and HTA Programme Oversight Committee (2021 to present). Jim G Thornton reports membership of the NIHR HTA and Efficacy and Mechanism Evaluation (EME) Editorial Board (2016–21).

Published March 2023
DOI: 10.3310/KUYP6832

Scientific summary

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Health Technology Assessment 2023; Vol. 27: No. 6
DOI: 10.3310/KUYP6832

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

Emergency caesarean section (CS) performed in the second stage of labour, which occurs in 34,000 births per annum in the United Kingdom (UK), has greater perinatal and maternal morbidity than CS performed in the first stage.

Second-stage CS may be complicated by the fetal head being deeply impacted in the maternal pelvis, which occurs in 1.5% of all emergency CSs. Complications include longer delivery times, uterine tears, injury to the baby and even, albeit rarely, death.

Numerous techniques to assist in delivery of an impacted fetal head (IFH) are reported. The superiority of one technique over another is contentious. At present, there is no national guidance on what techniques to employ.

Research questions

What are the current practice, level of experience and training requirements for managing an IFH during emergency CS among UK obstetricians, obstetric anaesthetists and midwives?

What are the views of pregnant women and their partners on research in this area?

How acceptable is a randomised trial in this area to women who have experienced a second-stage caesarean birth, and what are their views on the different proposed techniques for managing an IFH?

What is the incidence of IFH and maternal and neonatal complications arising from IFH in the UK?

What techniques and outcomes do health-care professionals and parents think should be included in a randomised trial in IFH?

What should the design be for a randomised trial in IFH?

How acceptable is the randomised trial we have designed to health-care professionals, women who have experienced a second-stage caesarean birth and pregnant women?

Methods

We undertook a national survey of obstetricians, trainee obstetricians, obstetric anaesthetists and midwives to determine current practice, level of experience and training requirements for managing IFH during emergency CS. We also undertook a national survey of parents to determine their views on this topic.

Individual face-to-face interviews with women who have experienced a second-stage CS were carried out to determine the acceptability of a randomised trial in this area and their views on the different proposed techniques for managing IFH.

A national, prospective UK Obstetric Surveillance System (UKOSS) surveillance study was undertaken to determine the incidence and consequences of IFH in the UK.

Based on the findings of previous work packages, we conducted a Delphi survey followed by a virtual consensus meeting of experts and important stakeholders to decide which techniques should be tested in any trial and which outcomes should be included.

A randomised trial of different techniques for managing IFH during emergency CS was designed.

We undertook a national survey of lead obstetricians, pregnant women and midwives to determine the feasibility and acceptability of the randomised trial designed.

Three sets of individual telephone or video interviews were carried out with lead obstetricians/senior obstetric trainees, women who have experienced a second-stage CS and primiparous women to determine the acceptability and feasibility of the planned trial.

Results

The majority (89%) of health-care professionals stated that a clinical trial in this area would help to guide their clinical practice, and 87% would be willing to participate in such a trial. In addition, 37% of parents reported that they would be either likely or very likely to take part, or neutral.

Women varied in which technique they thought was most acceptable, and their trust in medical expertise and prioritising the safety of the baby were important moderators of acceptability.

Our national prospective observational study found that impacted head is common, occurring in 16% of second-stage caesarean births in the UK, and leads to both maternal and neonatal complications. Overall, 230 (41%) women and 20 babies (3.5%) experienced complications. Thirteen babies (2%) died or sustained severe injury. Seven suffered bony fracture, two brachial plexus injury and one facial palsy. Three had moderate or severe hypoxic ischaemic encephalopathy, and seven were cooled. Four babies died: one prior to the caesarean, one with multiple abnormalities and two as a direct result of complications caused by IFH. IFH is currently most often treated by an assistant pushing the head up vaginally during the CS.

Data from earlier work packages were used throughout the project, culminating in the design of a randomised clinical trial. Our proposed trial would compare a new device, the fetal pillow, with a procedure used for many years, the vaginal push technique, for preventing IFH. Most doctors and midwives believed that such a trial would be important and were willing to recruit participants to one. About one in three women said that they would be willing to join such a trial.

The only interventions that were more popular with patients were tocolysis and the head-down technique. Both of these are adjunct techniques used by all obstetricians and, therefore, are not suitable for evaluation in a trial.

The required sample size of such a trial depends on whether it is powered to show a difference in severe maternal morbidity (control event rate 2.3%, 4698 participants per group), a difference in fetal short-term morbidity (control event rate 13.7%, 754 participants per group) or only a difference in less severe maternal events, including haemorrhage over 1000 ml (control event rate 27%, 322 participants per group).

We believe that it is not feasible to conduct the trial powered on severe maternal morbidity. However, parents and doctors believe that a trial to test the effect of different procedures on meaningful baby outcomes is important. We therefore recommend that the required sample size would be 754 per group.

The vast majority of midwives (83%) and obstetricians (88%) would be willing to participate in the clinical trial proposed. In addition, 37% of parents reported that they would be either likely or very likely to take part, or neutral. Our qualitative study found that most participants thought that the trial would be feasible and acceptable.

Conclusions

We recommend that a randomised trial with an internal pilot phase comparing a new device, the fetal pillow, with a procedure used for many years, the vaginal push technique, for managing IFH be conducted.

This trial is widely supported by health-care professionals.

We recommend that the definitive trial be powered to test an effect on important short-term maternal and baby outcomes, which would require 754 participants per group. A sufficient number of women would be willing to be join such a trial to make it likely to be feasible in the UK.

Study registration

This study is registered as Research Registry 4942.

Funding

This project was funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme and will be published in full in *Health Technology Assessment*; Vol. 27, No. 6. See the NIHR Journals Library website for further project information.

Health Technology Assessment

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 4.014

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This report

The research reported in this issue of the journal was funded by the HTA programme as project number 17/75/09. The contractual start date was in February 2019. The draft report began editorial review in July 2021 and was accepted for publication in May 2022. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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