Midwives' contribution to normal childbirth care: Cross-sectional study in public-health settings, the MidconBirth Study protocol

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ABSTRACT

This paper presents the Protocol for a multicentre study that seeks to analyse the relationship between midwife care during childbirth and spontaneous vaginal birth. Each participating hospital collects outcome data from a sample of all women birthing, determined according to the number of annual births attended by midwives, in each hospital.

Data collected are sociodemographic variables (age, nationality, level of education). Clinical variables collected are onset of labour, augmentation of labour, professional (midwife or obstetrician) providing care in the first and second stage of labour, transfer of care between professionals, mobility during labour, pharmacological and non-pharmacological pain-management methods used, if any, position for birth, mode of birth outcomes, Apgar score at 1 and 5 minutes, birth weight, timing of breastfeeding initiation and breastfeeding rates. The Bologna Score scale items, are evaluated also.

The midwife's contribution in the care of normal birth, and the relationship with spontaneous birth (i.e. vaginal birth without the use of instruments) will serve as a basis for further improving the quality of care provided to pregnant women and their families. Phase I of the study ended in January 2017.

INTRODUCTION

Many recent studies have demonstrated the benefits of midwife care during labour and birth[1, 2] and recommend that healthy women in spontaneous labour should be attended by midwives[3]. The American College of Obstetricians and Gynecologists, in 2017, recommends using low-interventional approaches, when appropriate, for the intrapartum care of low-risk women in spontaneous labour; these include intermittent auscultation and non-pharmacologic methods of pain relief, positions of comfort and massage or water immersion. They conclude that obstetric-care providers should be familiar with, and consider using, low-interventional approaches for the intrapartum care of low risk women in spontaneous labour[4].

It has been demonstrated that many common obstetric practices such as rupture of membranes for induction of labour, routine intrapartum amniotomy, continuous electronic foetal heart-rate monitoring or routine continuous infusion of intravenous fluids and oxytocin augmentation, are of limited benefit[5-6]. The range of and variation in the use of interventions in healthy low-risk women who are cared for in highly-technological birth environments have implications both in economic and health terms[7-12].

Study Protocols

In the Spanish Health System, midwives provide care to women with normal, low-risk or medium-risk pregnancies. However, the exact overall proportion of births attended by midwives in public hospitals in Spain and other European countries is unknown. This study aims to explore the proportion of births in healthy women, who are low or medium risk that are attended by midwives and the outcomes of these births. The findings will form the basis for future research exploring economic, organisational and health aspects related to the intrapartum care of this group of pregnant women.

Our study hypothesis is that pregnant women that are attended by midwives during labour and birth are more likely to have a normal vaginal birth (birth without use of instruments).

Our study objective is to estimate the proportion of and outcomes for low- or medium-risk births attended by midwives in public-health settings and publicly-funded home births during the study period (2016-2019).

METHODS

We begin by specifying the type, design and settings of our study, then we list, in Table 1, the inclusion and exclusion criteria algorithm of the MidconBirth Study.

Study type: Observational

Study design: prospective multicentre cross-sectional study

Study settings: these are public obstetric units in hospitals; public birth-centres separated from obstetric units; and individual midwives attending publicly-funded homebirths in Spain, and in another 5 participating countries – Ireland, Iceland, Italy, Belgium and Switzerland.

Table 1. The inclusion and exclusion criteria algorithm of the MidconBirth Study.

Inclusion criteria
1. Women aged 18 years or older
2. Women aged 40 years or younger
3. Singleton pregnancy
4. Cephalic presentation of the foetus
5. Not classified as women at high or very high risk during pregnancy
6. Starting labour from 37 (first day) weeks of pregnancy and before 41 (last day) weeks ofv pregnancy

Exclusion criteria
1. Women aged 17 years or younger
2. Women aged 41 years or older
3. Multiple pregnancy
4. Non-cephalic presentation of the foetus
5. Classified as women at high or very high risk during pregnancy
6. Starting labour before 37 weeks (last day: [36 weeks + 6 days]) of pregnancy and at or after 42 weeks of pregnancy
7. Congenital disease of the new-born, detected during pregnancy or after birth

Intervention and participant recruitment timeline

In this study, the intervention is the care provided to low-risk women during labour and birth, and includes all procedures performed during the intrapartum-care process. For that purpose, the health professional attending the woman, and data related to diagnoses and procedures performed to each woman who meets the inclusion criteria, will be registered. Each participating setting or midwife will register data from all low-risk women admitted for labour during a 4-month period or until a representative sample is achieved for each setting (hospital, birth centre or home-birth midwife). Participating settings and midwives will be progressively included during the study period until June 2019. In Phase 1, recruitment started in June 2016 and ended in January 2017, while in Phase 2, recruitment started in October 2016 and will end in June 2019.

Primary and secondary outcomes

Primary outcomes include the proportion of low-risk women attended by midwives in public- health settings, birth centres and publicly-funded home births, during the study period. Secondary outcomes include the outcomes of births attended by midwives, measured using the Bologna Score within the 24 hours after birth and before discharge from the maternity ward; and transfer rates within obstetric units and from public-birth centres and home births attended to by midwives to obstetric units.

Ethics approval

Ethics-committee approval is required for each participating setting or birth centre. Individual midwives will apply for ethics-committee approval from their organisation.

The first phase of the study has been approved by the ethics committee of the coordinating centre (Consorci Sanitari Integral 15/74) and by the ethics committee of each participating centre. The second phase of the study has been approved by the ethics committee of the coordinating centre (Clinical Research Ethics Committee of Parc de Salut Mar 2016/6785/I)

Data Collection

Independent variables include:

1) Hospital identification: stratified in four strata according to the number of births per year.

2) Case identification: each case (woman) will be assigned a numerical random code.

3) Investigator identification: each research collaborator's code is linked with the participating hospital/centre.

4) Mother´s socio-demographic and clinical variables: age; nationality; level of education (primary, secondary school, university, professional qualifications, unknown); gestational age (between 37 and 41,6 weeks' gestation); parity (nulliparous or multiparous).

5) New-born weight (less than 2500 g; between 2501 and 3000 g; between 3001 and 3500 g; more than 4001 g)

Dependent variables include:

Labour and birth care

Labour start type:

1) spontaneous, 2) induction with pharmacological or mechanical methods, 3) induction by homeopathic methods, 4) admitted to the hospital for elective caesarean section without medical indications, 5) admitted to the hospital for elective caesarean section with medical indications.

Professional providing care at the beginning of labour:

1) midwife, 2) midwifery student, 3) obstetrician, 4) obstetrician resident, 5) other professional.

Transfer of care between professionals:

This happens when the professional who is looking after the woman at the start of her labour transfers the responsibility for care to

another professional; 1) no transfer, 2) midwifery resident to midwife transfer, 3) midwife to obstetrician resident transfer, 4) midwife to obstetrician transfer, 5) obstetrician resident to obstetrician transfer, 6) obstetrician resident to midwife or midwifery student transfer, 7) other transfers.

Only for birthing centres or home births variables:
1) transfer to another unit because of no or slow labour progress, 2) transfer to another unit for other complications, 3) other.

Professional profile of who attends the delivery (during the second stage of labour):
1) qualified midwife, 2) midwifery resident, 3) qualified obstetrician 4) obstetrician resident, 5) other professional, 6) another qualified professional or student.

Presence of companion throughout the process (Bologna Score I):
1) Yes, the companion is present throughout the process (Bologna Score 1).
2) No, the companion is not present throughout the process (Bologna Score 0).

Use of partograph (Bologna Score II):
1) Yes, use of partograph (Bologna Score 1).
2) No, use of partograph (Bologna Score 0).

Pharmacology stimulation during labour (Bologna Score III):
1) Non-pharmacological stimulation during labour (Bologna Score 1). This variable does not consider the use of oxytocin/ergometrine in Phase III of labour.
2) Non-pharmacological methods to stimulate or induce labour (Bologna Score 0). Examples include artificial rupture of membranes, dilatation cervix, uterine fundal pressure, homeopathy, and other alternative methods.

Pharmacological stimulation during labour (Bologna Score 0): Use of some type of medications to induce or stimulate labour. This variable does not consider the use of Oxytocin/Ergometrine in Phase III of labour.

Pharmacological stimulation plus Non-pharmacological methods: to stimulate or induce labour.

Analgesia

No use of analgesia. When no pharmacological analgesia is used during the labour. In this variable, the use of local anaesthetic in case of need of perineal suture is permitted.

Use of epidural analgesia. The use of epidural analgesia at some point of labour process, including the third phase of labour using this analgesia for any procedure (e.g. to repair major perineal injury, manual removal of the placenta).

Use of general anaesthesia. The use of general anaesthetic at some point of labour process to perform any intervention.

Use of other pharmacological methods for pain relief. This includes the use of some medication for pain relief between labour and the birth of the baby. Pharmacological pain-management methods are registered when they are used on their own, but not when used before epidural analgesia or general anaesthesia.

Use of alternative methods for pain relief. When any other non-pharmacological method is used to relieve pain during the labour process. Homeopathy is included in this variable (as well the use of water, massage, movement, acupuncture, autohypnosis, other). Use of alternative methods for pain relief plus use of epidural analgesia.

Mobility during labour

Freedom of movement during labour. Walking-epidural is included in this variable.

No freedom of movement during labour. When woman does not have freedom of movement during the greater part of the labour, regardless of the reason.

Position of the body during delivery chosen

Freedom to choose position during birth. When the woman can choose her position during birth.

No Freedom to choose position during birth. When the woman is not permitted to choose her position for birth.

Adopted position by the woman during her baby's birth (Bologna Score IV): Different position from the lithotomy during the baby's birth (Bologna Score 1); Use of lithotomy position during the baby's birth (Bologna Score 0).

Delivery of the placenta

Active management of stage III of labour. The use of some pharmacological or mechanical method for the delivery of the placenta.
Physiological management of stage III of labour.

Delivery results
Type of birth:
1) normal vaginal birth - no use of any instruments needed.
2) instrumental vaginal birth - vacuum, spatulas, forceps, caesarean section.

Perineum: Intact perineum - no lesion is seen; 1-2nd degree perineal tear; episiotomy; episiotomy plus extended tear 1-2nd degree perineal tear; episiotomy plus extended 3-4th degree perineal tear; 3-4th degree perineal tear.

Postpartum haemorrhage (PPH): no postpartum haemorrhage; immediate post-partum haemorrhage - more than 1000 mL of blood loss in the first two hours after birth; late postpartum haemorrhage - more than 1000 mL of blood loss after two hours after birth.

Admission to ICU: woman not admitted to intensive care unit (ICU); woman admitted to ICU (will be considered when there is mother admission to ICU during postpartum hospital stay, regardless of the reason for the admission).

Mother´s postnatal ward discharge: discharge without complications during the postpartum hospital stay; discharge of the mother, with complications during the hospital stay (it is assumed that complications have been resolved at the time of discharge).

New-born results
New-born Apgar Score: Apgar Score equal or greater than 7 at 5 minutes; Apgar Score less than 7 at 5 minutes.

Neonatal resuscitation manoeuvres: no neonatal resuscitation manoeuvres needed. No cardio-respiratory resuscitation manoeuvres needed after birth; need of neonatal resuscitation manoeuvres. This variable is not considered in case the baby needs resuscitation manoeuvres beyond two hours after birth.

New-born admission to ICU: admission of the new-born to ICU, either immediately after birth or at any time during the hospital stay the new-born is admitted in ICU regardless of the reason for admission; no admission of the new-born to ICU.

Study Protocols

Early skin-to-skin contact (Bologna Score V):
1) Early skin-to-skin contact with the mother (Bologna Score 1). When early skin-to-skin contact between the mother and new-born is started immediately after birth and uninterruptedly for at least 30 minutes.
2) Early skin-to-skin contact with father because of the woman's condition (Bologna Score 0). This variable only is considering when the woman's clinical condition does not allow the skin-to-skin contact.
3) Early skin-to-skin contact with father and good maternal condition (Bologna Score 0). This variable is considered only when the clinical conditions of the woman permits skin-to-skin contact, but the woman/couple opts for the father to perform it.
4) No early skin-to-skin contact with mother (Bologna Score 0)., Wwhen early skin-to-skin contact between mother and new-born is not started immediately after birth and/or uninterrupted during the first 30 minutes.

New-born hospital discharge: new-born hospital discharge without complications during the hospital stay. This is considered when a baby is born without any congenital conditions or malformations, and when no complications were detected during the hospital stay; new-born hospital discharge with complications during the hospital stay. This is considered when a baby is born without any congenital conditions or malformations, and when any complications were detected during the hospital stay.

Dissemination policy

The principal investigator (PI) and the team will publish and disseminate global and grouped results. Collaborator researchers from participating settings may disseminate their own results. Collaboration among researchers to combine results is encouraged. A dissemination report will be delivered to the main sponsor of the first phase, and several scientific papers are expected to be published by the principal investigator and team.

Sample size calculations

The sample size is calculated on the annual number of births of each participating centre or midwife. To calculate the sample size (95% level of confidence) it is assumed an unknown proportion of births attended by midwives for each estimated population (50%) in each setting, with a (+/-) 5% precision and a reposition proportion of 10%.
Hospital settings will be stratified into four strata according to annual number of births. Birth centres and individual midwives will be analysed by Group:
Hospital settings based on births/year:
Group 1 - less than 600
Group 2 - from 601 to 1200
Group 3 - from 1201 to 2400
Group 4 - more than 2400

A minimum sample size was calculated to achieve a representative sample for the first phase in Catalonia and for each group of hospitals. Target sample size in Phase 1 was 1500 and has been achieved already (January 2017), as depicted in Table 2. For Phase 1, to achieve a representative sample size for Catalonia and for each group of hospitals, we considered the available data of births attended in each hospital/centre group in 2012.

Table 2. Sample size for Catalonia within the MidconBirth Study

Group	Number of hospital settings (obstetric units)	Reference population* [4 months] (estimated recruiting period)	Minimum sample size
Group 1	11	1000	300
Group 2	10	2850	372
Group 3	17	4500	390
Group 4	5	2000	372

* Reference population in each group according to Minimum Basic Data Set registered births in 2012

For the second phase, a representative sample size is calculated according to each setting, birth centre or volume of births attended to by a midwife.

Recruitment

Births are registered consecutively for each woman meeting the inclusion criteria, admitted in labour during a 4-month period or until the representative sample is achieved. Informed consent from women is not required because no intervention other than usual care is performed, and only anonymised data are collected. However, settings may decide to ask for informed consent from women, prior to being included in the study.

To ensure accuracy of data recording, an information session will be provided to all participants (i.e. midwives) before being included in the study and registering the data in the web-based data set (Midconbirth platform). A research group in each participant setting will be set up to agree on the data-management processes.

Each registered case will be allocated a random identification numeric code to ensure anonymisation. Each participant investigator registering data will have a personal password to access the Midconbirth platform and will have access to all data from own setting, but not to data from other settings. Once the target sample is achieved, the participant investigator may download all registered data from own hospital/centre.

Data may be modified by the registering person during the first fifteen days following case registration, after which the case will be definitively closed and stored in the web-data set.

Access to data

The principal investigator (PI) will have access to all the data. Researcher collaborators from participant settings, including birth centres and midwives will have access to data from their settings.

Statistical analysis

Descriptive analyses of the variables for each group, birth centre and midwives who attended homebirths, will be performed and the mean and the confidence interval (95%) of each dependent variable will be presented. Bivariate analyses will be conducted to obtain the intervention provability or related events.

The relationship between qualitative variables will be analysed using a chi-square test (X^2) and the Student t-test will be used for quantitative variables; a p value equal to or lower than 0.005 will be considered significant. Finally, a logistic regression model will be used

Study Protocols

to analyse the relationship between type of professional attending to the woman during labour and birth, type of birth and Bologna Score average. The PASSW 21 Statistical Package will be used for the analysis.

DISCUSSION

The study will show the outcomes of all deliveries attended to by midwives in participating birth settings, and will allow comparison of these outcomes among all participants in the study. The findings of this study will be important for the health-service organisation responsible, especially in settings where midwives still have a wide range for competence development. The study records all the interventions performed on women with low risk during delivery. This will allow one, on the one hand, to compare the intervention rates between the participating centres, and on the other hand, will show the potential relation between intervention rates and birth outcomes in low-risk women.

The study includes the necessary items to assess the quality of birth care through the Bologna Score[10] in each birth setting. Results obtained with Bologna Score will help to identify those aspects that need to be improved during childbirth care in each participating setting.

One important contribution of this study will be to highlight the importance of having common criteria for the quality assessment of birth care and the need for valid and reliable indicators for the birth-care assessment.

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