ROYAL
COLLEGE
OF MIDWIVES

ISSN: 1479-4489 December 2019 Vol.17 No.4

EVIDENCE BASED MIDWIFERY

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OF MIDWIVES

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December 2019
Volume 17 Issue 4

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EVIDENCE BASED MIDWIFERY IS A STANDALONE PEER-REVIEWED JOURNAL PRODUCED BY THE ROYAL COLLEGE OF MIDWIVES

Evidence Based Midwifery
Royal College of Midwives
15 Mansfield Street
London W1G 9NH
United Kingdom

Publishers:
Redactive Media Group

What is DORA?

Key words: DORA, research assessment, REF2021, PLAN S, evidence-based midwifery

You are probably thinking: "Oh dear! What have we here, not another acronym?" Yes, it is indeed. But please note, this one is of great importance for you as an individual, if you are chasing promotion and your publication profile is under scrutiny. DORA stands for Declaration of Research Assessment and emerged in 2012 following the annual meeting of the American Society for Cell Biology (ASCB) in San Francisco. At that time, the research community was greatly concerned about the fact that, for many scientists, promotion was based on the correlation between the contributions of the scientist and the impact factor (IF) of the journal(s) in which their work was published.

ASCB members signed up to DORA and made it clear that their intent was to improve the ways in which all of the outputs for research (not just publications) were assessed and they highlighted the need to be judicious in the use of metrics for evaluation and promotions. *Their vision was to advance practical and robust approaches to research assessment globally and across all scholarly disciplines.*

The DORA principles apply to all research, including arts, humanities and social sciences. When I heard the word 'declaration' my mind automatically leapt to the famous Declaration of Helsinki 1975 (emanating from the Nuremberg Code 1947) that set out to regulate ethical behaviour in medical research practices following the inhumane treatment of people in concentration camps by the Nazis during World War Two.

Therefore, when I first heard my colleagues talking about DORA, I presumed this was an important document that required detailed review and a conscientious response. Obviously, I hope you will take time to read it in full and make up your own mind. But before you read the Declaration, ask yourself these questions: Is the research publication system ethical and equitable? And are researchers treated with respect regardless of the journal in which they have published their research?

Take time to log-on to the DORA website and view the presentation that highlights the problems with skewed results from impact factors (IFs) and journal-based metrics and the lack of transparency in compilation of IFs.

Let me share with you my simple understanding of DORA. To me, the DORA team are research activists who are online seeking subscribers to sign their Declaration to ensure institutions, publishers, professional societies and individual researchers across the world to agree to changing their research practices. The team spirit seeks to find consensus on the value and need for a unified approach to achieving the best possible research based on achieving a level of agreement and compliance across institutions and organisations. The movement appears to have started because of visible inequities in the research business, unfair treatment of researchers and over reliance on IFs and metrics for promotion.

The team at DORA has outlined 18 principles that target: **funding agencies, institutions, publishers and organisations that supply metrics for researchers.** In my opinion, the message is calling for an end to the brain drain from broken and lost researchers, stopping the inequity to accessing research data, curbing the power of the money making publishing companies to dictate citations and IFs and a challenge to all to do what is just and ethical!

DORA has recently published its two-year Road Map (DORA Road Map 2018) which focused on three main objectives:

1. To increase awareness of the need to develop credible alternatives to the inappropriate uses of metrics in research assessment.
2. To research and promote tools and processes that facilitate best practice in research assessment.
3. To extend the reach and impact of DORA's work across scholarly disciplines and in new areas of the world.

DORA's overall recommendation states: *Do not use journal-based metrics, such as journal IFs, as a surrogate measure of the quality of individual research articles, to assess an individual scientist's contributions, or in hiring, promotion, or funding decisions.*

The full content of the Declaration can be accessed from https://sfdora.org/read/ and you can check their website for evidence of sign up by key organisations across the world. You will see 1,595 organisations and 15,336 individuals have signed the Declaration (accessed 10 December 2019).

Taking a step back into history, it is important to note what was happening in the UK in 2012 when DORA was activated. This was a critical point in time for the Research Excellence Framework (REF2014). As a member of the panel judging the submissions for midwives and nurses I can assure you that we were not permitted to use the IF of the journals to rate the papers we were assessing.

Metrics were only permitted to be used when a team reached deadlock and could not agree on the rating of a particular paper. I can only remember this happening on one occasion and we made reference to the citations for the paper. REF2014 and REF2021 are important for midwifery in the UK and all of those who publish their research in *Evidence Based Midwifery*.

I have been struggling for 10 years to get our IF measured and now I am not so sure of the perceived value based on DORA for *Evidence Based Midwifery*. We do have a challenge ahead of us, however. To be REF2021 compliant, all journals must follow certain rules and produce information about the journal publication timing, open access etc, and follow SHERPA ROMEO REF guidelines (https://www.jisc.ac.uk/rd/projects/sherpa-).

According to the DORA website, discussions with HEFCE on the REF2021 are in progress and we need to watch the space as updates are likely to materialise.

Many UK universities are currently engaged in discussions

about what to do about DORA. The DORA website has the name of every institution that has signed up. Adding a signature is a decision that requires consideration of many factors including REF2021 Code of Practice statement: '*Where there is no distinction in terms of quality between two outputs additional metrics will be brought into play...*'

This statement is a challenge to DORA recruits. In June 2019, UKRI signed the Dora declaration. It is important to note that in 2018 all of the seven UK Research Councils, now under the umbrella term of the UKRI, signed the Declaration. The UKRI is also a member of the newly formed 'cOALition S', set up by the European Commission and the European Research Council, in which the S stands for shock!

This lesser known but important initiative is labelled PLAN S and operates on 10 principles including author ownership of their outputs, prohibition of publication in hybrid or subscription journals and standardisation of article publication charges (APCs). PLAN S has the backing of 12 EU countries and they have all signed up to publish their research in open journals or repositories that can be accessed by all by 2021 (Wikipedia 2019). This important factor will affect dissemination of research findings.

There are many changes afoot and as we prepare for 2020 and the final REF submissions it is important for all research active midwives to have a basic understanding of major initiatives such as these because they will have a major impact on the selection of a journal for publication of key research. Naturally, you know and expect me to point out to you how lucky you are today to be reading this editorial in *Evidence Based Midwifery*, your RCM journal that has always promoted midwifery research and strived to provide the label free platform for dissemination of research.

In the last REF2014 and in REF2021, your papers published in *EBM* were and will continue to be eligible for review. The *EBM* papers in the last REF scored well and in REF 2021 they can score even more highly and, more importantly, you still have time to get that publication into print.

I am continuing to encourage you to select *EBM* for publication of your major research regardless of IF. The IF is secondary with regard to the quality of your research that ought to stand alone. All papers submitted to *EBM* are and will be subject to double blind peer review and we process and publish most of our papers within six months. Three months after publication, all papers are fully open-access and free to all and this is in keeping with SHERPA REF.

This is an exceptional gift to UK midwifery researchers and to the world of childbirth researchers and is under sold and under-estimated as a truly generous Christmas gift given to you and I every year from the RCM. Please let me encourage you this year to open this Christmas gift and use it in 2020 to submit your paper for publication in EBM.

I also need to leave you with an important reminder about the next REF 2021 assessment: Research Excellence Framework (REF) panels are briefed on DORA, and the REF2021 guidance (https://www.ref.ac.uk/publications/guidance-on-submissions-201901/) for submitting institutions states that **journal impact factors or hierarchy of journals will not be used in the assessment of outputs** (UKRI 2019).

Finally, before I wish you all the best for Christmas and 2020, I need to take this important time to thank all of you who have given us gifts of excellent peer reviews and sound advice during 2019, all of which have made a major contribution to the quality of our EBM papers.

Thank you!

Professor Marlene Sinclair (editor)

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Assessing the inter-rater reliability of (Uscan) bladder scanner during pregnancy and following childbirth

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Date submitted: 15/09/2019 Date accepted: 18/11/2019 Date published: 20/12/2019 Date open access: 20/03/2020

Abstract

Study background. Evidence suggests that bladder-scanner findings used for maternity care can be inaccurate. Therefore, to address the inaccuracies reported, a newly designed scanner (Uscan) with real-time ultrasound and editing functions has been developed. This article will describe and discuss the inter-rater reliability of this bladder scanner during late pregnancy and the early postnatal period. It is essential to assess its accuracy, reliability and usability as there are potential benefits to women, such as a reduction in the number of urinary catheters inserted and then the avoidance of the negative sequela that often follows. Research to test the latest technology in bladder scanners and scanning is urgently required.

Objective. To assess inter-rater reliability of a bladder scanner (Uscan) during late pregnancy and the early postnatal period.

Method. Following ethical approval, inter-rater reliability testing of the (Uscan) bladder scanner commenced at the Women's and Children's hospital in Adelaide, South Australia. It took place in July 2016 (antenatal), January 2017 (postnatal) and June 2017 (antenatal). The testing involved two midwives scanning pregnant and newly birthed women to compare urine volumes measured using the Uscan bladder scanner. The results were compared for inter-rater reliability between two midwives/assessors.

Findings. Initially, the inter-rater reliability testing was conducted on 12 pregnant women, and these preliminary results demonstrated that the (Uscan) bladder scanner was unreliable. This instigated further technology development and technicians altered the algorithms and improved the editing function to combat the problems identified. The bladder scanner was then re-tested on pregnant women and the results showed an intraclass correlation coefficient (ICC) of 0.98 (95% CI 0.94-0.99). The bladder scanner was then tested for inter-rater reliability on 12 newly birthed mothers and results demonstrated that the scanner was also reliable for use postnatally. The ICC between two raters was found to be 0.97 (95% confidence interval 0.833-1.00).

Conclusion. A high inter-rater reliability score was achieved both antenatally and postnatally after learning from initial reliability testing of the (Uscan) bladder scanner, which prompted further development work that involved altered algorithms and improved editing functions. There is potential to use the (Uscan) bladder scanner in midwifery clinical practice to assess bladder volume. Using the scanner may lead to a decrease in the number of urinary catheters used during the childbirth continuum. A decrease in use of urinary catheters will reduce the associated risk of urinary tract infections (UTIs), urethral trauma, uncomfortable sensation and embarrassment for women, which collectively has an impact upon healthcare costs, length of hospital stay and family separation. Further research is indicated to assess the impact of utilising the Uscan bladder scanner in a clinical trial.

Keywords. Bladder scanner, pregnancy, postnatal care, reliability, ultrasonography, bladder volume, urinary retention, midwives, evidence-based midwifery

Introduction

Bladder care during pregnancy, labour and following birth is an important aspect of women's health care (Lovell and Steen, 2016). Urinary problems can have numerous negative physical and psychological consequences for women in the short and long term following birth; yet women may be too embarrassed to seek help as it is often a taboo subject (Steen, 2013). Ultrasound is a low risk intervention that can be conducted by midwives and devices can be portable. Bladder ultrasound scanning is often used in general nursing care, but evidence suggests that bladder scanning in maternity care is not commonly performed as inaccurate measurements of bladder volume have been reported (Pallis and Wilson, 2003; Mathew et al, 2007). Difficulties differentiating between a full bladder and a developing uterus containing amniotic fluid have been specifically highlighted as an issue (Lee et al, 2008). Therefore, to address inaccurate measurements of bladder volume, a newly designed scanner (Uscan) with real-time ultrasound and editing functions has been developed (See figure 1). It is, however, essential to assess the inter-rater reliability of this newly designed bladder scanner as this will provide evidence of effective measurement of bladder volume between assessors.

Background

During labour and following birth some women will be catheterised. However, there is potential to use a bladder scanner to determine bladder volume as an alternative to catheterisation (Lovell and Steen, 2017). Bladder scanners are used to detect the volume of urine in the bladder of a person unable to void, showing signs of voiding dysfunction or urinary retention. Catheterisation has remained a standard treatment

for voiding dysfunction in pregnancy, labour and for newly birthed mothers with urinary retention or dysfunction. There are several risk factors associated with catheterisation, such as: UTIs, urethral trauma, discomfort, negative psychological effects and unnecessary catheter insertion. The use of bladder scanners has the potential to reduce these associated risks. Therefore, research using the latest technology for bladder care is urgently required (Lovell and Steen, 2017).

The Australian Government National Medical Research Council website states that 20% of hospital-acquired infections are UTIs. This percentage is derived from a study involving 75,694 participants, undertaken in England, Wales, Northern Ireland and the Republic of Ireland. Of the reported UTIs, it is estimated that between 40-57% are caused by urinary catheters (Smyth et al, 2008).

Figure 1. Uscan bladder scanner.

A scoping review conducted by Lovell et al (2017) to determine the current evidence on the accuracy of bladder scanning in maternity care reported that eight out of 11 studies found bladder scanning to be accurate when used for postnatal women and one study concluded that bladder scanners were beneficial during labour with ruptured membranes.

However, results were inaccurate when membranes were intact and eight of the studies reported cases where the bladder scanner differed considerably to the actual bladder volume (Barrington et al, 2001; Pallis and Wilson, 2003; Demaria et al, 2004; Van Os and Van Der Linden, 2006; Lee et al, 2008; Mathew et al, 2007; Nusee et al, 2014 and Blomstrand et al, 2015). These inaccuracies can be caused by fluid in the uterus; fibroids; irregular shaped bladder; ovarian cysts; increased adipose tissue; retropubic haematoma; bladder oedema (Lee et al, 2008); scar tissue; uterine prolapse; pregnancy; and pelvic mass (Nusee et al, 2014). The bladder scanners used in these studies did not have the ability to view the bladder.

A bladder care study was funded by an Industrial Commonwealth Grant and matched funding by Signostics, the South Australian company that designed and developed the Uscan bladder scanner (Australian Government DIIS, 2016). The research was undertaken independently by the University of South Australia. The Uscan bladder scanner has a touch screen where anatomy by ultrasound can be viewed (See figure 1). This scanner also allows a health professional to manually edit the outline of a bladder, which can override the scanner measurements if these are seen to be inaccurate. For example, if a pregnant woman is scanned and the outline is seen to be measuring amniotic fluid in the uterus, the outline can be deleted or adjusted to capture the bladder.

Objectives

The purpose of this initial phase of a study was to assess the inter-rater reliability between two midwives/assessors in performing bladder scans using a newly designed (Uscan) bladder scanner during late pregnancy and the early postnatal period.

Method

The inter-rater reliability of the Uscan bladder scanner involved two midwives scanning pregnant and newly birthed women to compare bladder volumes. The results were compared for inter-rater reliability. The two midwives were trained to use the Uscan bladder scanner by technicians at Signostics and undertook basic education and training in ultrasound by an ultrasonographer. Ethical approval was granted by the Women's and Children's Hospital Network Human Research Ethics Committee (HREC/16/WCHN/5) and University of South Australia Human Research Ethics committee (Uni SA HREC, 0000035628).

Recruitment and setting

Initially, 12 pregnant women were recruited while attending the antenatal clinic at the Women's and Children's Hospital in Adelaide, during July 2016 and then a further 12 pregnant women were recruited in June 2017. Medical and midwifery

staff were fully aware of the study criteria and assisted to identify potential participants. Women were eligible to participate and have a bladder scan if they were over 18 years of age, 36 weeks gestation or more, and able to speak and read English. An information sheet was given to eligible women by antenatal clinic staff; if they agreed to participate, the study was explained further by the midwifery researchers and informed consent gained before scanning commenced. The data collected from antenatal women participants included: age, parity, gestation, uterine fibroids, previous caesarean, body mass index, booking weight, membranes intact or ruptured, time since last void, as well as the time of the bladder scans and the results.

Newly birthed mothers were recruited from the postnatal ward during January 2017. Midwives providing postnatal care to eligible women acted as a gatekeeper. They discussed the study requirements with women and asked permission for the second author (BL) to explain the study in greater detail before gaining written consent. The eligibility criteria used was the same as for pregnant women, except that the women were post-vaginal birth. The data collected for the postnatal women included: age, parity, booking weight, body mass index, number of hours since birth, birth weight, length of first and second stage, syntocinon, epidural, spinal, previous caesarean, uterine fibroids, perineal status and hours since last void.

The scanning procedure:

The women were scanned by one midwife/researcher and then immediately scanned again by another midwife to limit the time lapse between the scans. Limiting the time lapse ensured that a very similar bladder volume was measured due to the nature of ongoing diuresis. The midwives also alternated who performed the first scan. Women were positioned on the bed or examination table in a semi-recumbent position. Once the scans were completed, the midwives could edit the results if necessary, using the editing function on the scanner. Antenatal scans to assess inter-rater reliability were repeated in January 2017, after alterations to algorithms were made to the scanner and improvements to the editing functions by technicians at Signostics.

Inter-rater reliability analysis:

Inter-rater reliability was measured using the intraclass correlation coefficient (ICC); a two-way mixed model, single measure for absolute agreement was used. Cicchetti (1994) has suggested inter-rater reliability to be good for values between .60 and .74, and excellent for values between .75 and 1.0. Usually for inter-rater reliability, 0.7 is considered acceptable. Therefore, a sample of 12 is sufficient to find an ICC of 0.7 to be statistically significant with 80% power and alpha=0.05. An intraclass correlation coefficient (ICC) greater than 0.7 was used as a cut off to determine reliability between midwives/assessors. A sample size of 12 women and two raters achieves 83% power to detect an intraclass correlation of 0.8 with a null hypothesis intraclass correlation of 0.3, using an F-test with a significance level of 0.05.

Results

The first inter-rater reliability phase was undertaken on pregnant women between 36 and 40.5 weeks gestation attending an antenatal clinic. The average age of the women was 30 years. There were seven primiparous and five multiparous women recruited. Two women had a previous caesarean. The average BMI was 24.5 (range 21-31.9). All women had intact membranes. The average time in between scans was two minutes (range 0-9 minutes). Recruitment did take time and 15 women declined to participate in the study. The main reasons for declining participation were: too tired; not enough time; not interested or did not want to be scanned. The initial scan results were incorrect and recorded an ICC of 0 (see table 1 for data).

The average difference in scan results was 92 ml (range 19-245 ml). These results occurred due to the bladder scanner outlining the baby's head, and detecting the baby's head as the bladder. Although, the bladder could be seen by the midwife/assessors it was not possible to measure the bladder when the baby's head was outlined by the scanner. During this phase the editing program also malfunctioned.

These errors and malfunctions were reported to the technicians who designed the bladder scanner. Following further designing and testing of the scanner, this antenatal testing of inter-rater reliability was repeated with another 12 women who were between 36-38.5 weeks gestation. The average age of these women was 32 years and there were five primiparous and seven multiparous women. Two of these women had fibroids and four had a previous caesarean. The average BMI was 28.6 (range 20-44). The time between scans averaged 1.5 minutes (range 0-4 minutes) A re-tested inter-rater reliability showed an ICC, 0.98 (95% CI 0.94-0.99) (See table 2 for data). This result demonstrated that the scanner was now reliable to detect the bladder correctly and able to edit the bladder volume. The average difference in measurements was 13.5 mls (range 2-34ml).

Some further challenges occurred when recruiting and undertaking bladder scans on women who were newly birthed and admitted to the postnatal ward. During the postnatal recruitment, 10 women declined to participate in the study. The main reasons women gave were: too tired, in pain, had visitors or not interested. A sample of 12 postnatal women were recruited and bladder scan results showed a high inter-rater reliability – ICC 0.97 (95% confidence interval 0.833-1.00) (See table 3 for data). These women's average age was 32 years. There were five primiparous and seven multiparous women in this sample. Nine of the women had a normal vaginal birth and three women had a forceps assisted birth. One woman had small uterine fibroids and one woman had a previous caesarean. The average difference in measurement between the scans was 14.25ml (range 0-34ml).

Discussion

With data collected during this study and valuable feedback from midwives/assessors, technicians were able to alter the algorithms and improve the editing function of the bladder scan device. Improvements to the bladder scanner following

Table 1: Antenatal inter-rater reliability – first attempt

Scan 1	Scan 2
180ml	0ml
24ml	115ml
23ml	90ml
301ml	56ml
>256ml	169ml
171ml	224ml
111ml	46ml
150ml	109ml
88ml	221ml
142ml	123ml
140ml	88ml
75ml	Oml

*These results were unable to be edited due to a malfunction with the scanner.

Table 2: Antenatal inter-rater reliability – second attempt

Scan 1	Scan 2
159ml	169ml
14ml	11ml
278ml	283ml
38ml	35ml
239ml	205ml
124ml	105ml
119ml	122ml
21ml	**33ml**
26ml	28ml
172ml	178ml
307ml	293ml
284ml	232ml

*Results that are bold were not edited – all other results edited by the midwives/researchers to show the edges of the bladder.

the initial inter-rater reliability testing by two midwives resulted in a reliable device and high inter-rater reliability results. The editing function was adjusted by the technicians to enable the midwife assessors to delete the measurement made by the scanner (if necessary) and re-draw the outline using their finger to draw (a blue outline) on the screen where the bladder is located (See figure 2).

The measurement is then recalculated by the scanner based on the new outline. This enabled the midwife assessors to identify the bladder and ensure that the correct fluid-filled area was measured. However, initially the editing function had to be carried out by the two midwife/assessors on multiple screens captured during scanning. This function was adjusted by the technician after further feedback was given about the process being too time-consuming and that midwives in clinical practice would not have time to spend adjusting multiple screens. The new improved editing function allowed the midwives to edit the middle frame and the scanner to recognise and outline the bladder on outlying frames, reducing the amount of required changes for the midwife to perform. However, it still took time and skill to perform. An identified challenge with the editing function was that a midwife assessor needs to be skilled in identifying the bladder on ultrasound and trained in the use of the editing function (See figures 2 and 3).

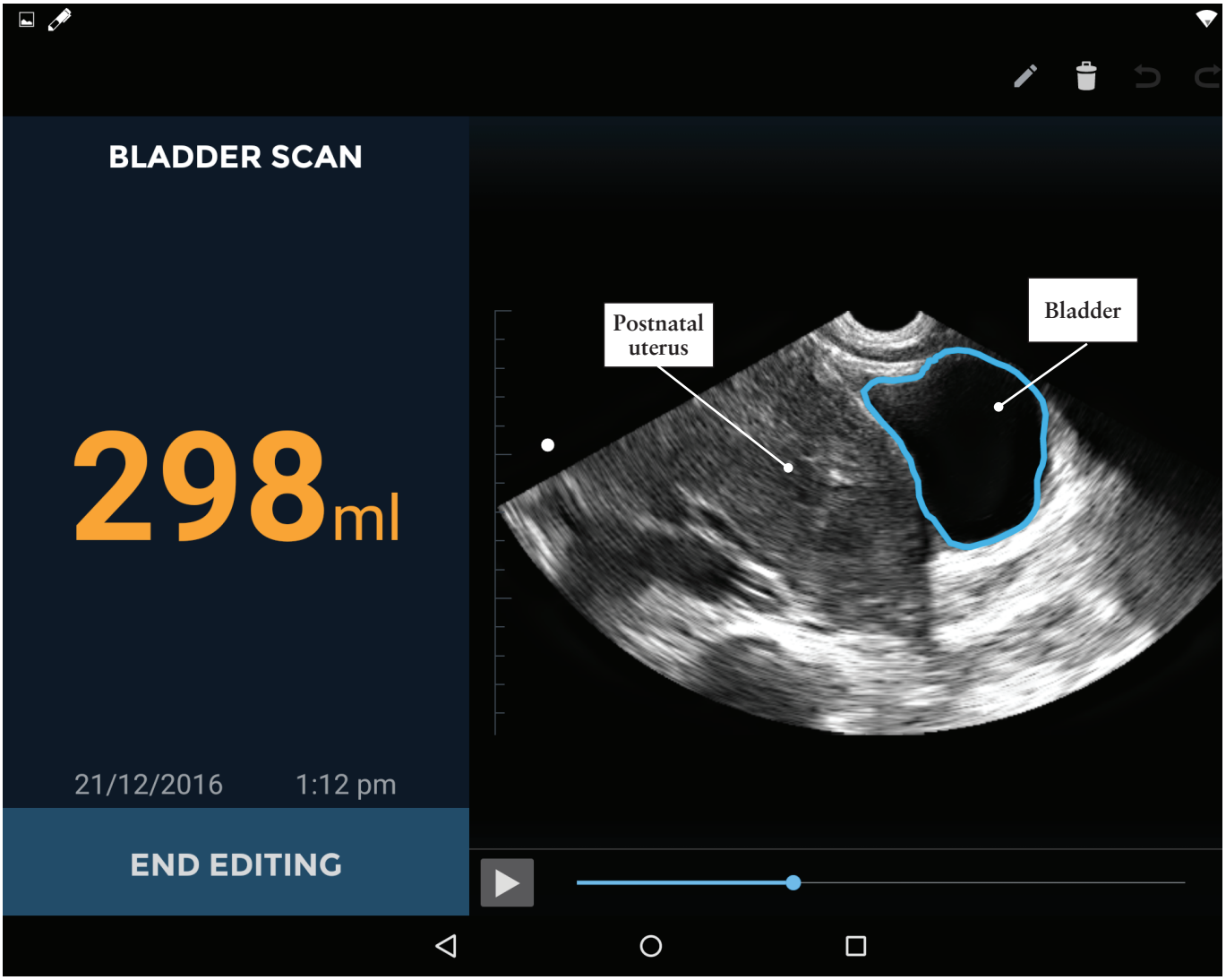
The technique to centre the bladder when scanning requires some practice for a midwife to become proficient. When the antenatal inter-rater reliability testing was repeated the

Table 3: Postnatal inter-rater reliability

Scan 1	Scan 2
18ml	37ml
203ml	202ml
239ml	272ml
98ml	98ml
33ml	67ml
79ml	81ml
64ml	75ml
118ml	100ml
49ml	41ml
70ml	63ml
233ml	205ml
75ml	85ml

*All scans were edited.

Figure 2: Postnatal scan – blue line indicates that the scan has been manually edited.



midwife/assessors were able to manually edit the scan if the baby's head was measured during the scan, as long as the bladder could be visualised on the screen. Interestingly, there were two women in the repeat scans with breech presentations and reliability was still achieved.

It is noteworthy to mention that the Uscan bladder scanner has a unique capability to identify an image and upload images to a secure environment for analysis by artificial intelligence driven computers. These computers can provide feedback for quality control and facilitate decision making which, over time, will assist by recording accurate data as data sets increase.

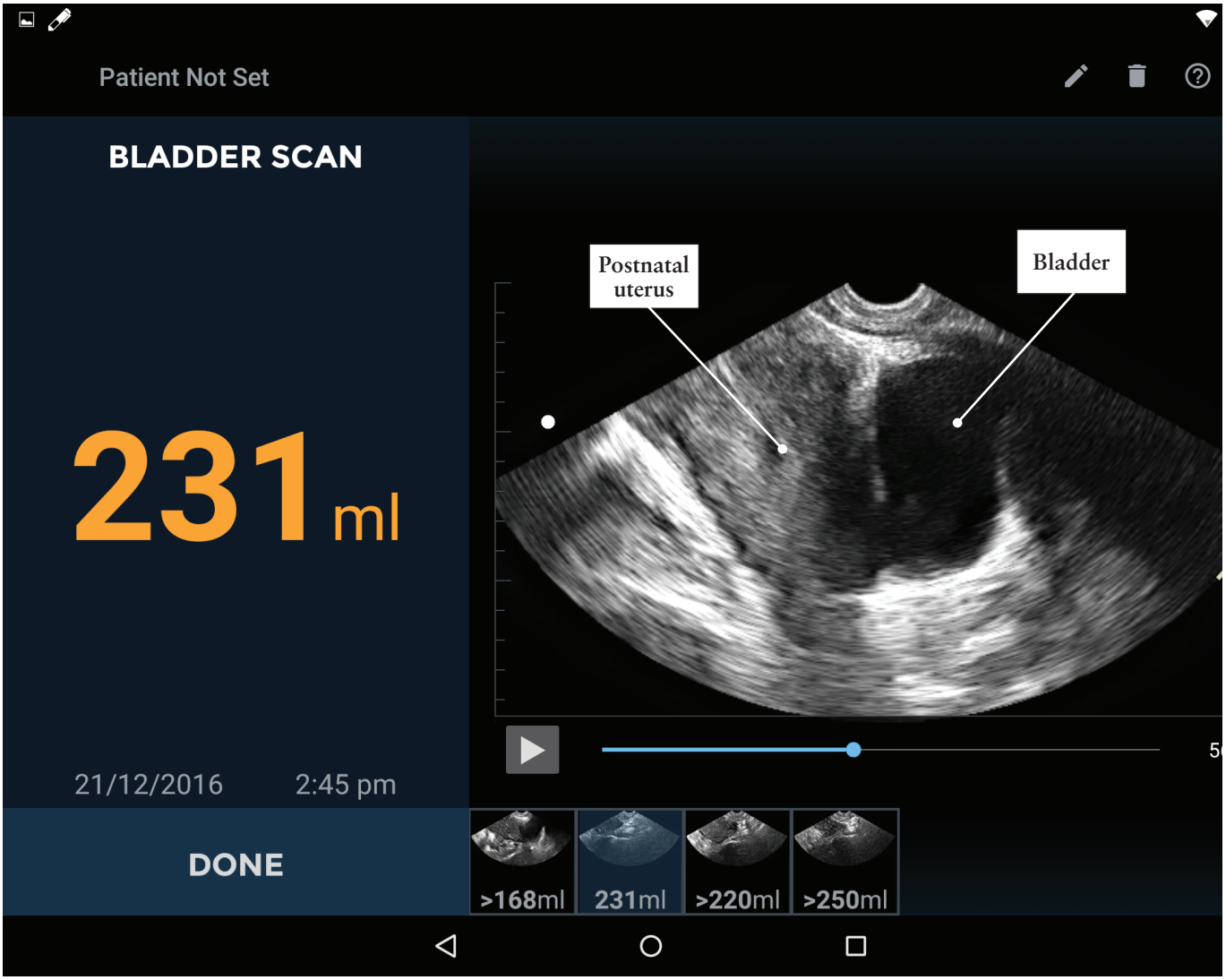
Strengths and limitations

A strength identified while undertaking the initial inter-rater reliability testing performed by two midwives in an antenatal clinic setting was 'learning during the testing phase', on pregnant women and then collaborative working with technicians to instigate further development work that involved altered algorithms and improved editing functions of the Uscan bladder scan. Midwives working collaboratively with a technician and giving valuable feedback led to essential improvements being made to the Uscan bladder scanner. This demonstrates how important it is to report 'trial and error findings'. The improved functioning of the bladder scanner enabled the two midwives to perform accurate bladder scans and achieve a high inter-rater reliability score both antenatally and postnatally. The assessments were undertaken by independent midwife researchers who have no conflict of interests.

The initial inter-rater reliability testing on 12 pregnant women who were more than 36 weeks gestation was the first time that the newly designed Uscan bladder scanner had been used clinically in an antenatal clinic and the first time that the midwives/researchers had scanned pregnant women due to the fact that it was not possible to gain access to this target group before ethical approval had been obtained. Prior bladder scanning practice was conducted with non-maternity volunteers (males and females). Once ethical approval was granted recruitment commenced but some challenges occurred when recruiting participants both antenatally and postnatally.

Women declined to participate due to time constraints after birth, being in pain, having visitors present and not

Figure 3. Postnatal scan – showing the empty uterus and the elongated bladder.



that interested. However, this demonstrates that women who did agree to participate fully understood what the study was about and ethical considerations were adhered to. Antenatally, 12 pregnant women were recruited and all had cephalic presentations. It was found during this initial inter-rater reliability testing that the scanner would often mistake the baby's head for the bladder and the head would be outlined and measured by the scanner.

An editing function was later designed to enable the bladder outline to be moved by dragging the outline on a digital screen and the bladder was seen to be on the maternal left side and was elongated and shaped like a jelly bean or similar (see figure 4).

Conclusion

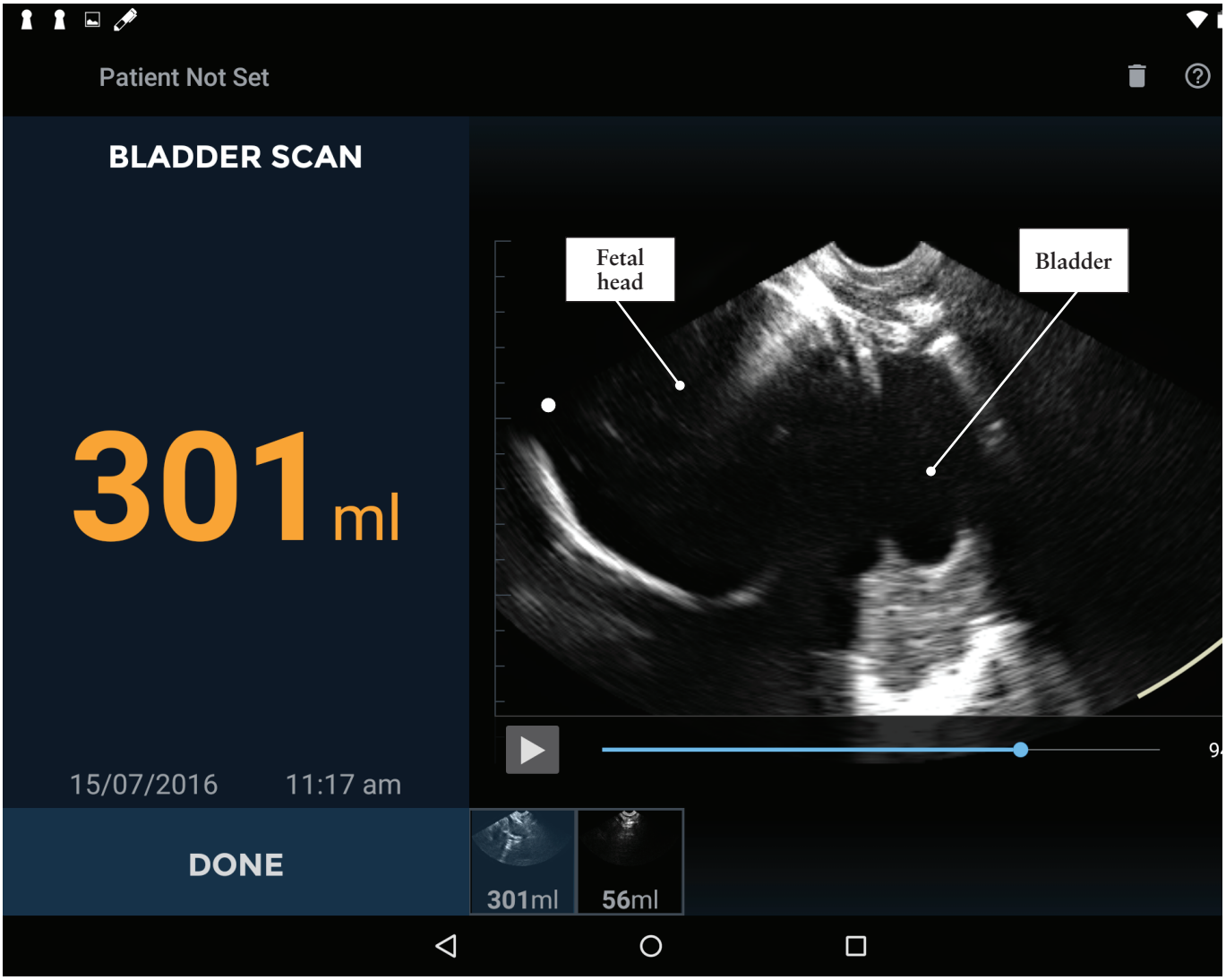
The midwives/assessors during the inter-rater reliability testing were able to give valuable feedback and work closely with technicians to improve the reliability of the bladder scanner. The initial reliability of the scanner to measure bladder volume was found to be inconsistent. Further development work that involved altered algorithms and improved editing functioning of the Uscan bladder scanner enabled the two midwives to perform more accurate bladder scans and achieve high inter-rater reliability scores.

Implications for clinical practice

Bladder scanning may reduce catheterisation rates and also detect bladder problems during the childbirth continuum. Bladder scanning may help midwives and obstetricians to give improved care by providing bladder volume estimates that will then enable them to advise women when there is a clear clinical indication to insert a catheter to prevent bladder trauma. Catheterisation is an intervention used when there is urinary dysfunction or retention detected during the antenatal and postnatal period. Catheterisation is also a procedure often performed on women who have an epidural in labour and increases the risk of a urinary tract infection.

Being educated and trained to perform a bladder scan may assist midwives and obstetricians to detect bladder problems such as urinary retention and to make shared clinical decisions about bladder care with women. Bladder scanning is a non-invasive procedure that may be more accepted by women than the insertion of a urinary catheter

Figure 4. Antenatal scan – showing fetal head and an elongated bladder.



and is, therefore, potentially a useful tool for the midwife to utilise and can give women an alternative option. Further testing needs to be conducted to determine the accuracy of the bladder scanner before it can be recommended to use in clinical practice within a maternity setting.

Acknowledgements

We would like to thank the women who give their consent for us to scan them for this study. Thank you to midwife Monica Diaz, who helped scan women during this phase. We thank Signostics and the Commonwealth for the funding that allowed this research to be undertaken. We would also like to thank Women and Children's Hospital, Adelaide, for supporting this research.

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Can an educational web-intervention, co-created by service users alongside self-efficacy theory, affect nulliparous women's experiences of early labour? A study protocol for a randomised control trial (the L-TEL Trial)

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The authors would like to thank Dr Zoe Sheppard for her support with the sample-size calculation.

Date submitted: 11/09/2019 Date accepted: 18/11/2019 Date published: 20/12/2019 Date open access: 20/03/2020

Abstract

Background. 'Early labour' refers to the beginning phase of a woman's labour. It is the period of time where there are painful contractions and the cervix changes in preparation for active labour and subsequent childbirth. In UK clinical practice, cervical dilatation of four centimetres is commonly accepted as when active labour begins. Low-risk women, with uncomplicated pregnancies, have less unnecessary medical intervention if they remain at home in early labour. Despite recent efforts to improve labour triage, assessment and diagnosis in an attempt to reduce early-labour admission rates, women remain fearful and under-confident to remain at home during this time and continue to seek admission to their birth place. Thus, further research is required to evaluate new interventions aimed at improving women's experiences of remaining at home in early labour.

Methods. This trial is a pragmatic, randomised control trial with mixed-method data collection. The trial will evaluate the effect of a co-created, educational web-intervention on women's early labour experiences. The trial aims to recruit 140 low-risk, pregnant nulliparous women from a single National Health Service (NHS) Hospital Trust in England. Participants randomised to the intervention group will receive a link to the web-intervention, alongside routine maternity care provisions. The control group will receive only routine maternity care provisions. Ethical approval was granted on 15 October 2018 by the local research ethics committee and study approval by the Health Research Authority.

Discussion. It is hypothesised that the group that receive the intervention will score higher in the Early Labour Experience Questionnaire (ELEQ, Janssen and Desmarais, 2013), indicating an improved early labour experience when compared with those in the control group. It is anticipated that findings from this trial will contribute to the knowledge base around how to improve first time mothers' experiences of early labour, particularly the time spent at home prior to admission.

Keywords. Pregnancy, childbirth, early labour, latent, self-efficacy, experience, education, website, online, protocol, randomised control trial, evidence-based midwifery

Background

'Early labour' (used interchangeably in the literature with the 'latent phase') is the term used by health care practitioners to refer to the beginning of labour. Generally, the end of the early labour phase is marked by an increased rate of cervical dilatation; this is also the beginning of the more progressive stage of labour referred to as 'active labour'. However, establishing a specific definition of early labour, in particular the point at which early labour transitions to active labour, that academics and practitioners can unanimously agree on has been challenging (Hanley et al, 2016; Hundley et al, 2017). Much of the existing literature agrees that early labour is the time when a woman has contractions, while her cervix effaces and prepares for childbirth; however the numerical dilatation in centimetres that represents the end of early labour varies between two to five (Friedman, 1954; Albers et al, 1996; Zhang et al, 2002; Zhang et al, 2010; Oladapo et al, 2018). The National Institution for Health and Care Excellence (NICE) defined early labour as "a period of time, not necessarily continuous, when there are painful contractions and there is some cervical change, including cervical effacement and dilatation up to four centimetres," (NICE 2014: p18-19). In spite of recent international guidance that recommends five centimetres of cervical dilatation as a better indication to mark the transition between early and active labour (World Health Organization, 2018), the NICE definition remains the most commonly accepted and practised by midwives currently working within the UK.

Women with low-risk pregnancies are less likely to have unnecessary intervention if they remain at home in early labour, coming to their chosen birth place for admission after this phase has finished (Rota et al, 2018). Admission to hospital in early labour increases the risk of obstetric intervention such as oxytocin augmentation of labour, fetal blood sampling, continuous electronic fetal monitoring, epidural analgesia, infection and caesarean section (Hemminki and Simukka,

1986; Holmes et al, 2001; Bailit et al, 2005; Rahnama et al, 2006 Tilden et al, 2015: Mikolajczyk et al, 2016).

There are a number of theories that seek to provide an explanation for these increased risks of intervention: inherent problems with labour that drive women to seek earlier admission; the impact of the hospital environment on women and their subsequent labour progression; care practitioners' impatience and the notion of predetermined labour timeframes resulting in artificially expedited labour; women's unrealistic expectations once admitted to their birth place; and the challenge of effectively diagnosing the early and active phases of labour (Marowitz, 2014; Hanley et al, 2016).

The complex relationship between the biological, physiological, social, psychological and environmental factors that affect labour progression makes reducing unnecessary interventions after admission challenging. Yet it is widely accepted that avoidable obstetric intervention can have an impact on optimum maternity care and subsequent birth outcomes. This notion is supported by national policy where normalising childbirth, improving outcomes and safety while reducing unnecessary obstetric intervention remains at the forefront of UK maternity care targets (NHS England, 2016). Finding ways to minimise the rates of early labour admission will reduce the number of women at risk of unnecessary obstetric intervention. This is likely to have a positive impact on the provision of optimum maternity care.

A recent evidence review (Kobayashi et al, 2017) concluded that existing assessment and support interventions during early labour have yet to have an impact on mode of birth, a key benchmarker for optimum maternity outcomes and care. So far, research has focused on attempting to improve early labour triage, assessment and diagnosis (McNiven et al, 1998, Janssen et al, 2003; Janssen et al, 2006; Cheyne et al, 2008; Hodnett et al, 2008; Spiby et al, 2008).

McNiven et al (1998) demonstrated that women who were assessed in a separate early labour area (away from the central delivery suite) had less intervention rates and improved satisfaction, confirming that a hospital's delivery suite is not the best place for women in early labour. An algorithm designed to assist midwives' labour assessments did not significantly reduce augmentation or intervention rates but did increase the number of women discharged after assessment (Cheyne et al, 2008).

Spiby et al's (2008) large, multi-centre trial found assessment at home improved maternal satisfaction when compared with telephone triage, but did not reduce obstetric intervention rates. These studies indicate that although early labour assessment should be carried out away from hospital, improving triage methods and midwives' diagnosis of labour has yet to reduce the high rates of intervention associated with early labour admission.

Contrary to improving care, women report that midwives are acting as 'gatekeepers' to their chosen place of birth (Eri et al, 2011) and previous research efforts appear to fall in line with this notion. Many existing studies have primarily focused on developing early labour management pathways that are service-focused, attempting to keep women out of hospital in early labour to improve clinical outcomes. However, qualitative literature in this field indicates that research efforts also need to proactively find woman-centred interventions that aim to meet women's needs in early labour.

Not coping with pain and having low levels of confidence during early labour is cited in the literature as reasons why women seek admission despite professional advice to remain at home (Low and Moffat, 2006; Cheyne et al, 2007). Eri et al's (2015) metasynthesis of women's experiences identified early labour as 'an unknown territory' and concluded women are not having their needs met during this time.

Research efforts may be better focused on improving women's experiences of being at home in early labour as this may aid women to feel more confident to cope and remain out of hospital. Currently, no research has focused on specifically developing and trialling interventions designed to improve women's experiences of this phase. The L-TEL Trial aims to focus on this gap in the literature and offer a woman-focused solution to address the negative experiences associated with being at home in early labour.

Methods

The intervention

The intervention in this trial has been co-created with women who have previously had babies and been cared for within the maternity service. It is a web-based, educational tool developed for use during pregnancy, to provide information about early labour and support for women expecting their first baby.

Antenatal education continues to play a role in how parents prepare for the birth of their baby; participation with antenatal preparation is associated with higher satisfaction and a more positive birth experience (Schrader McMillan et al, 2009). Traditionally, antenatal education is provided by health professionals to groups of pregnant women.

However more recently, women are increasingly accessing and valuing online and digital information during pregnancy (Lupton, 2016). In a recent review, 'delivery stages' was identified as one of the most common topics of interest (Javanmardi et al, 2018). Furthermore, the information women are accessing online can be inaccurate and not discussed with their health professionals; consequently there is a great need to provide more accurate and reliable online education (Sayakhot and Carolan-Olah, 2016; Javanmardi et al, 2018).

The web-intervention's development was in line with existing self-efficacy theory (Bandura, 1977). Self-efficacy is defined as one's belief that one will achieve a desired goal or outcome. The existing qualitative literature suggests that in relation to coping at home during labour, women have low levels of self-efficacy. Self-efficacy has been previously shown to be a powerful predictor of how well women cope with labour (Larsen et al, 2001).

In addition, self-efficacy is an important psychological factor in achieving a positive birth experience (Beebe et al, 2007), particularly for first-time mothers (Berentson-Shaw et al, 2009). According to the theory, self-efficacy can be increased though personal mastery, vicarious experience,

emotional arousal and verbal persuasion (Bandura, 1977).

In line with this theory, to channel other women's vicarious experiences, the web-intervention's content was shaped by previous users of the maternity service. Involving women in this way has been shown to ensure health and social research remains focused on relevant, key priorities identified directly by the public (Stanley, 2009).

Women who had previously had babies were identified via an independent, infant-feeding support group on social media and volunteered to speak about their time at home in early labour. Following the provision of an information sheet and a written consent form, the researcher conducted semi-structured interviews with 10 women who had spent time at home while in early labour with their first baby. These interviews were conducted in a private room in a community centre. The interviews focused on drawing out women's coping mechanisms while remaining at home in early labour.

Interviewees were keen to offer emotional arousal and verbal persuasion to other first-time mothers and this fell in line with existing self-efficacy theory (Bandura, 1977). Some women who volunteered to offer their experiences of being at home in early labour did not wish to be interviewed in person and therefore a further 15 women offered their experiences by written response via an online questionnaire using the same questions as were asked at the interviews. This was to ensure a wide variety of women contributed to the web-intervention's development. The researcher used the interviews and questionnaire responses to identify topics that women had deemed to be important and these formed the development of the web pages (See box 1).

Box 1 Topics identified by previous service users

- What does early labour feel like?
- Being at home
- Preparing
- Eating and drinking
- Positioning
- Breathing techniques
- Using water
- TENS
- Distraction
- Hypnobirthing
- Massage
- Reminders from your birth partners
- Being present
- Positive thinking

With permission and consent, the face-to-face interviews were video recorded and edited together using the same topics of interest that had emerged naturally. These videos were embedded within the website and the topics guided the web-intervention's written content, which offers coping mechanisms and motivational techniques. Those women who had been video recorded were invited to view the edited footage to consent to the publication of the videos online and to confirm that the final, edited footage was representative of their original views and experiences.

The existing evidence base, as well as national and local clinical guidelines, supported the written content of the web-intervention. This was reviewed by the Trust's consultant midwife to ensure safe advice was being provided. Furthermore, an independent panel of academics, known for their work in the field of early labour research, peer-reviewed the web-intervention and provided feedback to ensure the provision of safe, credible and evidence-based information.

The web-intervention was then reviewed by an independent group of previous maternity service users to ensure it provided clear information accessible to a wide variety of women. From this review, some adjustments were made to the use of specific words, and definitions of certain terms were added to ensure clarity for the user group.

Research design

This web-intervention will be trialled in a pragmatic randomised control trial (RCT) in a single NHS Trust. The intervention group will receive the link to the web-intervention alongside routine maternity care and the control group will receive only the routine maternity care.

Outcomes and hypothesis

This trial's primary outcome is women's affective experience determined by the total score of the pre-existing, validated, self-report ELEQ (Janssen and Desmarais, 2013). It is hypothesised that on average those in the intervention group will score higher than the control group. If shown to be true, this will illustrate the intervention's likely positive impact on improving women's experiences of remaining at home in early labour. A number of secondary, maternal and neonatal clinical outcomes will also be collected from the hospital's centralised computer system (See box 2).

This trial is not aiming to demonstrate statistical differences in clinical outcomes between the intervention and control group. Instead, it is anticipated that collecting these secondary outcomes may offer context and depth to any findings from this trial. Furthermore, these data may offer insight as to whether a future, larger trial, with higher target recruitment, would be feasible and valuable for measuring clinical outcomes between the trial groups.

Sample Size

The primary outcome for this trial is the total, ELEQ average score. In relation to improving women's experiences, a 10% difference in scores is documented to be clinically important for a similar scale, the Labour and Delivery Satisfaction Index

Box 2 – Secondary outcomes

- Labour phase (as defined by NICE 2014 guidelines) on admission
- Place of birth
- Birth mode (i.e. spontaneous vaginal birth, instrumental assisted birth or operative caesarean section birth)
- Analgesia use
- Spontaneous or induction of labour
- If spontaneous: any augmentation of labour (artificial rupture of membranes, intrapartum oxytocin infusion use)
- Neonatal Apgar scores as assessed at one minute and five minutes of age
- Neonatal resuscitation required
- Feeding at discharge from place of birth

Box 3 – Eligibility criteria

- Pregnant with a live, healthy, single foetus without known complications
- Nulliparous (no previous pregnancy >24 weeks gestation)
- At least 16 years of age at the point of consent
- Planning and professionally assessed as suitable for a spontaneous, vaginal birth at a midwifery-led unit at the specified site
- Able to speak and read English for the purpose of informed consent and access to the intervention
- Not requiring antenatal care from a specialist, case-loading midwifery team (a team specifically available for women with complex social needs)
- Able to access the internet without any inappropriate costs for the research participant

(Lomas et al, 1987). Treating the data as normally distributed (as done so by Janssen and Desmarais, 2013), an independent samples t-test will be used to investigate the difference in score by the two groups. Assuming a two-sided significance level of 0.05 and 90% power, a sample size of 70 (35 in each group) is required. An increasing number of women are having their labours started artificially; this is referred to as an induction of labour (IOL). It is reported that 33% of labours in England between April 2018 and March 2019 were induced (NHS Digital 2019). The majority of participants who will undergo an IOL will not be able to provide an evaluation of their early labour experiences at home, nor an ELEQ response. Furthermore, it is acknowledged that a number of participants will be lost to follow-up and therefore the L-TEL Trial aims to recruit 140 women (70 per group) to ensure there are adequate ELEQ responses to contribute to the primary analysis. Participants will need to meet the eligibility criteria (See box 3) and recruitment will take place over a 12-month period.

Recruitment Process

Eligible women will be identified by their community midwives and will be provided with a Participant Information Sheet (PIS). If the potential participant agrees, the midwives will pass their contact details to the researcher via an online, secure form. Midwives reported that an online platform for providing these details would have the least impact on their regular work duties. Those midwives involved will receive a short, online training package about this trial and their involvement in the recruitment process.

Eligible participants will also be able to self-identify, via email, to the researcher as trial posters will be visible at the NHS trust and at their antenatal clinics. The researcher will not contact potential participants for at least 24 hours after they have received the PIS to ensure participants can make an informed, voluntary decision about their involvement. A secure, uniquely password-protected, online consent form will be emailed to participants.

On completion of consent, participants will be provided with an electronic copy of their consent form and asked to fill out the Childbirth Self-Efficacy Inventory (CBSEI, Lowe, 1993). This will give an average, self-efficacy score for both the intervention and control group to determine how group characteristics differ prior to the intervention. Participants will then be randomised via an online randomisation service using randomisation in permuted blocks of four, six and eight to ensure groups are balanced periodically in the relatively small sample group required for this trial. The computerised, randomisation service does not let the researcher know of the details of these blocks. Participants will be notified of their allocation via email.

The intervention group will receive a link to the web-intervention and will be able to use this freely throughout the remainder of their pregnancies. Although forming part of the referral process, individual midwives will not be made aware of a specific participant's involvement or allocation. For safety, midwives providing acute clinical care in the hospital can access information about women's involvement in research without specific detail.

Due to the nature of this intervention, neither women nor health care providers will be blinded and some participants may choose to speak to their midwives about their participation in this trial. This is anticipated in both the intervention and control group. As both groups will have continued access to routine maternity care, this is not anticipated to have an impact on the research findings.

Data collection

Between seven and 28 days postnatally, participants will receive a modified, online version of the ELEQ to complete and data analysis will be by intention to treat (ITT) to maintain the balance and advantages generated from the original random allocation (Gupta, 2011). An online version of this questionnaire was deemed by a public involvement group to be the best method for promoting follow-up and minimising the impact on the study population who will be mothers caring for their new-born baby. Additional qualitative questions around both groups' early labour experiences will be collected and descriptively analysed to add context and depth to the quantitative data.

Secondary, clinical outcomes will be collected by the researcher from the existing, centralised hospital system, coded and descriptively analysed. All raw data collected will be anonymised by the researcher before analysis to maintain participant confidentiality. Data sets will be made public after the final data have been collected. Details of where this will be accessible will be available from the corresponding author after data collection has finished. Participants will be made aware of any findings from this trial and where they can access the data.

Adherence to protocol / Contamination bias

Password protecting the web-intervention was considered to minimise contamination bias but after feedback from a public involvement group, it was felt this was more likely to prevent the intervention group successfully accessing the intervention (due to loss of password etc.). Instead, the participants are asked to agree to the trial's terms by not sharing the web-intervention link. Adherence to protocol will be measured as those in the intervention group will be asked how often they accessed the web-intervention. Additionally, contamination bias will be measured as the control group will be asked if they accessed the intervention, despite not being given the link.

Safety

The web-intervention promotes safety and encourages women to call the midwives if they have any concerns. This phone number is clearly displayed on all of the web pages. The web-intervention is a low-risk, educational intervention. However, if during data collection, severe adverse outcomes are noted, a committee made up of risk specialists on the maternity site, will review the case to make a decision about suspension or termination of the trial. Any of these adverse events will be recorded in a confidential incident form and kept in the site file, which is in a locked office on site.

Discussion

More than 600,000 women give birth each year in the UK, of which about 40% are first time mothers (NHS Digital, 2019). The advice offered to many of these mothers when they first commence labour will be to remain at home to minimise the unnecessary intervention associated with early labour admission.

Previous research efforts have focused on improving the diagnostic methods associated with early labour service provision. Currently, there is a lack of research trialling interventions that have been developed specifically to improve women's experiences of the early labour phase at home. This gap in the literature is evident from the dissatisfaction women report with this phase of their labour.

To conclude, it is anticipated that the new educational web-intervention, which has been developed by previous maternity service users in line with self-efficacy theory, may offer a way to improve women's experiences of this phase of labour. Any results from the L-TEL Trial will be published in peer-review journals as well as specifically disseminated to the research participants involved.

Declarations

Registration: Prospectively registered on ISRCTN registry on 22 October 2018: ISRCTN69770712.

Funding: This research is output of the Wessex Clinical Academic Training Programme funded by the Wessex Partnership Scheme.

Ethics approval and consent to participate: Ethical approval was granted on 15 October 2018 by the local research ethics committee and study approval by the Health Research Authority. Any protocol amendments will warrant notification to both these ethical bodies. Fully informed, voluntary consent will be sought and electronically stored securely for each research participant. Blank copies of the PIS, consent forms and data collection forms can be sought on request from the corresponding author.

Research participants will be able to withdraw their consent,

until the point at which data is anonymised, without reason, and this will not affect any aspect of the usual care they receive. While collecting the primary outcome, participants will be supplied with the details for an existing, post-birth aftercare service offered at the site in case participants require any post-trial care.

Data will be kept securely and confidentially on a University approved, password-protected device for five years following the end of the trial, as per University guidelines. Participants are made aware of how the data they provided will be used and stored, in line with General Data Protection Regulations (European Union, 2018), during the consent process.

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In the wilderness: an action-research study to explore the transition from student to newly qualified midwife

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Date submitted: 28/02/2019 Date accepted: 22/11/2019 Date published: 20/12/2019 Date open access: 20/03/2020-

Abstract

Background. This study, funded by the RCM Ruth Davies Award, explores the experiences of newly qualified midwives (NQMs) in practice. A review of the literature revealed that the experiences of professional healthcare students moving into their qualified status can be uncomfortable, stressful and, for some, traumatic.

Aim. The aim of the study was to explore the experience of NQMs in an identified area and to evaluate a preceptorship programme in Wales.

Method. The research design was based on a qualitative action-research approach. Action research, using focus groups, was chosen to gain a greater understanding of the experiences of the midwives in a participatory way, whereby they were involved actively in the data collection, data analysis and conclusions drawn, which informed the recommendations for future practice. Reflective diaries were also used to gather additional data. The objectives were to explore the context and experience of practice and to gain an understanding of what constitutes a supportive preceptorship programme. Following ethical approval, 30 NQMs in one maternity unit were approached during their induction programme to participate in a series of three focus groups. Thematic analysis was used to identify key themes from the transcripts of audio recordings of each focus group. These were then fed back to the participants in each subsequent focus group where they were invited to comment and provide further clarification, which led to further discussion and the development of recommendations. Additional participants were then recruited to form a secondary focus group that considered and validated the recommendations of the primary group.

Findings. The key themes that were identified were fed back to the participants in a final workshop and the participants used these to develop recommendations for practice. These themes were as follows: 'Early days', 'A time of transition', 'Relationships with colleagues', 'Relationships with women', and 'A new beginning'. Overall, the findings of the study resonated with themes from the literature, highlighting that the participants' emotional responses to their experiences were comparable in different organisations and usually dependent on familiarity and acceptance within the environment, the quality of relationships with professional colleagues, and women's confidence in them. Participants recognised the need to develop inner strength and confidence in themselves. The recommendations that they developed reflected this.

Conclusion. The NQMs' responses resonate with theories of rites of passage and transition. In the process of change from one status to another there are emotional consequences and loss of performance. The recommendations from the findings suggest ways in which support in this preceptorship period could be improved.

Keywords: newly qualified midwife, student midwife, transition, mentorship, preceptorship, rites of passage, evidence-based midwifery

Background

The plight of newly qualified midwives (NQM) has undergone increasing scrutiny in the literature in recent years (Kitson-Reynolds et al, 2014; Avis et al, 2013; Hobbs, 2012; Skirton et al, 2012; Hughes and Fraser, 2011). It has been recognised over time that the dissonance and stress associated with this time of transition (Fenwick et al, 2012; Hobbs and Green, 2003) may result in an individual leaving the profession altogether (Curtis et al, 2006).

Literature review

The review of the literature identified key factors in relation to the causes of discomfort and distress. One theme identified by Hughes and Fraser (2011), was the delay between the time of qualification and the commencement of employment. They undertook a qualitative study employing focus groups of NQMs, preceptors and practice-development midwives. The focus of the study was on the NQMs' feelings about their experience, rather than a measure of their competence. They found that some NQMs had waited 12 weeks between qualifying and commencing employment, and identified this as a significant problem in maintaining levels of confidence (Hughes and Fraser, 2011).

Other studies have found that distress was related to poor staffing levels and subsequent inadequacy of support (Kitson-Reynolds et al, 2014; Avis et al, 2013; Skirton et al, 2012; Fenwick et al, 2012; Davis et al, 2011) as well as the rotational nature of the preceptorship period (Clements et al, 2012).

Kitson-Reynolds, Ferns and Trenerry (2015) designed a project where the university and practice partners worked together to ease the transition of student midwives to NQMs. This included facilitating opportunities for students to practice more independently and to gain an insight into management. It also involved a structured and individualised approach to

the induction and preceptorship periods once qualified. The evaluation of the project demonstrated that this approach was successful in reducing anxiety and easing the change of role. Although the authors recognised the resource implications, it could be argued that the long-term benefits in relation to reducing attrition and enhancing the wellbeing of the NQMs can justify the cost.

Hobbs (2012) also identified NQMs' struggle in making the transition from their student status. She undertook a qualitative, ethnographic study to explore the experience of seven NQMs in their first year of practice. From the findings a model of 'cultural re-creation for midwifery' (p396) was proposed, drawing on theories of transition that recognises three distinct phases. Such theories are based on the original work of Van Gennep (1960) who classified the stages that individuals pass through during rites of passage. Hobbs identified the dissonance experienced by these NQMs as they were expected to fit in with 'old-school' ways, versus their 'new-school' ways (p398) based on the learning acquired in the university. This study is particularly insightful in its analysis of the reasons underpinning the difficulties as experienced by these midwives

Similar themes emerge from studies concerned with newly qualified nurses and midwives, as well as junior doctors (Bere, 2010). The literature suggests that newly qualified professionals will still experience negative feelings that impede their development and performance for a period of time. This is despite preparation at the end of their programmes of education, as well as the provision of frameworks of support in place during the transition into their new roles (Boakes and Shah, 2017; Pezaro et al, 2017; Gray et al, 2016; Whitehead et al, 2016; Kitson-Reynolds et al, 2015). Therefore, it was important to explore what the NQMs' views were on the current programmes of support and what they would regard as effective support mechanisms for the future. This study was expected to shed additional light on ways in which student midwives can be prepared for qualification, how they can develop the ability to take responsibility for themselves, and also to highlight where employers can evaluate the support mechanisms that are in play at the present time.

Research design

The study design was a qualitative approach based on the principles of action research. It is an appropriate method to use when planning a quality improvement as, by gaining a greater understanding of the midwives' views on their experience, it then helps to ensure a collaborative approach to recommendations that result from the findings and inform future practice (Stringer, 2014). The methodology of action research is emancipatory; it recognises knowledge as a living and evolving process, documents everyday experience (Reason and Bradbury, 2008) and involves doing research with and for people rather than on people (Meyer and Cooper, 2015).

The aim of this study was to explore the experience of NQMs in Wales, and to evaluate a current preceptorship programme in order to inform the development of a new All Wales preceptorship programme. The following objectives were determined:

- To explore the context of practice for the participants;
- To identify experiences in practice that were particularly challenging or supportive;
- To explore the participants' views on what constitutes a supportive preceptorship programme; and
- To evaluate a preceptorship programme in Wales to inform future development of an All Wales approach.

Recruitment

Access to NQMs in a maternity unit was sought where the researcher was not well known, thus minimising the impact that a researcher known to the participants might have on their willingness to speak freely. Permission was gained from the Head of Midwifery, and ethical approval was sought and given from the appropriate committees. Information sheets were given and consent forms included notification that participants could withdraw from the study at any time.

From a population of 30 NQMs, a convenience sample was sought to participate in a series of focus groups, and to volunteer to keep a reflective diary. The aims and objectives of the study were presented to the midwives and information sheets were handed out. Five midwives came forward to participate in a series of three focus groups and three of these agreed to keep a reflective diary.

In view of the small number of participants in the first stage of data collection, additional midwives were approached through a social media group and invited to participate in a validation focus group. Thus, a different group of midwives evaluated the findings of the primary focus group and commented on the recommendations made, thereby ensuring a broader viewpoint was heard.

Data collection

Action research involves a flexible approach to data collection and analysis (Meyer and Cooper, 2015). The data were collected through a series of three focus groups attended by the first group of five participants over a period of four months. A fourth group with additional participants became a validation group for the data already collected, as well as generating new data of its own. The use of focus groups is a recognised form of data collection in action research (Stringer, 2014; McNiff, 2002). It was also the means for group work to take place that resulted in the recommendations proposed by the participants. Reflective diaries were used as an additional source of data to add depth and richness from an individual reflective perspective

Data analysis

Data analysis in action research is characterised by reflection, analysis and data driven action (Ferrance, 2000). Its purpose is to uncover the dynamic nature of the elements and phenomena that are revealed, in this case the midwives' responses to their newfound status as registered midwives, and how the environment and culture influenced their experience.

The analysis of the data was integrated with the data collection process. Action research tends to be represented by a cyclical or spiral process (McNiff, 2002) involving

planning, action, observing and monitoring, and reflection. This is a dynamic process that comprises 'knowing in action' as described by Schön (1981) so that the researcher is reflecting and monitoring as the action proceeds.

An ongoing process of consultation and negotiation gives a democratic voice to the participants (Meyer and Cooper, 2015) and is an ideal way through which to explore an everyday problem, with the potential for quality improvement. During each focus group, in addition to the recording of the data, field notes were taken to highlight key points as they arose for cross-referencing. Following transcription of the recordings, thematic analysis identified themes that were coded and further refined using the 'one sheet of paper' (OSOP) approach advocated by Ziebland and McPherson (2006). The key themes were fed back to a secondary focus group.

The second group of participants were invited to comment on and provide further clarification, which led to further discussion. This process is in keeping with the spiral analysis aligned with action research (Stringer, 2014). The final exercise of answering questions raised by the data analysis, independent thought and innovative engagement encouraged a synthesis of ideas that identified priorities for action and recommendations for the research report (McNiff, 2002).

Findings and discussion

In this section, the analysis and discussion of the findings is brought together due to the spiral nature of data analysis in action research and the flexibility of the process. During the analysis, the identification of themes from the data and the emergence of theory from the findings was fluid, a combined process that fed back into the data analysis and supported the identification and development of the themes. This process was in keeping with the spiral analysis aligned with action research (Stringer, 2014). The final exercise of answering questions raised by the data analysis, independent thought, and innovative engagement encouraged a synthesis of ideas that identified priorities for action and recommendations for the research report.

The themes identified from the focus groups and reflective diaries were coded as follows: 'Early days', 'A time of transition', 'Relationships with colleagues', 'Relationships with women' and 'A new beginning'.

What emerged stongly from the data collected by the focus groups was the stength of the participants' feelings as they began their role as NQMs. How they felt was directly influenced by their relationships with their colleagues and their relationships with the women in their care. Underpinning and affecting the whole experience was their experience related to preceptorship, training and the processes within the organisation

Early days

In the primary focus group, the midwives' feelings were overwhelmingly emotive and they said they felt traumatised and angry in describing their initial experiences as NQMs.

It is important to recognise from the start that the strength of their emotion changed and became less intense as time passed and they became more socialised to the workplace:

"If I'm completely honest, my feelings from when I first started are just completely vulnerable and on my own and really unsupported on the ward. In fact, I've really struggled to kind of have any issues or anything I've had to be recognised, and any note taken of how difficult it is." (FG1.1)

"You need to know how to look after yourself because no one else looks after you. It's hard, I mean they talk about it but the actual doing after that, well how do I? It builds resentment. It's really difficult." (FG1.3)

Much of the early discussion in the first focus group concerned feeling overwhelmed, vulnerable and a perception of being unsupported. One of the reflective diary entries gave more detail about how that impacted on life:

"I find that I'm exhausted and tired nearly all the time especially when I have both day and night shifts in the same week… I have tried to make sure I have plenty of healthy food in the house and try to go out. However, I still sleep uneasily before a day shift, I have to solve that one." (P010)

It was clear from all the participants that their new role affected their whole life, it was not just during work time. Sleeplessness, counting down the days until the next shift and anxiety about what might happen were found across the groups.

A time of transition

The early data reflected the midwives' feelings of powerlessness and self-worth. They struggled to make sense of these feelings, compared with their feelings of confidence and competence at the point of qualification. Their perception was that they felt completely unsupported. However, it could be suggested that these feelings were influenced by an inner sense of dissonance, caused by feelings they had not anticipated, compared with previously held expectations (Carolan, 2013).

Drawing on Van Gennep's (1960) theory, models of transition usually refer to recognised stages which individuals will move through to achieve 'membership' of their new place. There is evidence to suggest that the reason or motivation underpinning a life transition will ease the process of transition (Bauer and McAdams, 2004). This is indeed true for these NQMs. They had worked tirelessly towards the goal of qualification for three years and now found themselves without that end goal. Even for the most motivated, it is recognised that the change from a place which is familiar, to one which is unknown, can cause a sense of disequilibrium (QAA, 2015).

Hobbs (2012) has also explored models of transition and recognised how NQMs' experience dissonance because they aspire to remain faithful to the ideals espoused by the university which might be at odds with the culture of their workplace. In taking this observation one step further, a number of models of student transition which analyse the experience of moving from school to university were explored. It seemed reasonable that these models could be extrapolated to the experience of the NQMs to explain their feelings, and help us understand why their transition can be so challenging.

However, Bridges (2002, p4), has a different take on the process of transition: "The starting point for transition is

not the outcome but the ending you will have to make to leave the old situation behind. Situational change hinges on the new thing, but psychological transition depends on letting go of the old reality and the old identity you had before the change took place."

Bridges Transition Model (2011) suggests three stages:

- Ending, losing and letting go.
- The neutral (transition) zone.
- The new beginning.

This model of transition can be used as a framework which helps enhance our understanding of the findings of this study.

Ending, losing and letting go

For NQMs their loss has been significant, their cohort, their mentor, their protected status, their institution. A network of friendship and familiar support mechanisms has been lost to be replaced by the unknown as an employee of the NHS at a time of uncertainty and considerable challenge. Although it could be argued that they should have felt prepared and they should have foreseen what it would be like, the evidence from this study suggests otherwise.

The discussion differentiated between those who had worked in the unit before and those who had not:

"These girls have never set foot on that ward until their first shift. They would come to me and say: 'I've been crying in the toilet today.' If some of them were here now, they'd be saying to you: 'I cried for probably most shifts for the first two or three months.' They coped so much worse and they didn't know the people, they hadn't met the Band Sevens upstairs, they didn't know their names, such a small thing. They didn't know who they could ask. They didn't know the midwives who would be helpful to them. They just saw them all as navy. It was scary, a lot of them struggled." (FG1.1)

The group shared the view that if they had trained in the unit then they knew about the geography and the culture. They knew which staff to ask for help and those who were less approachable, and so felt they had an advantage.

However, a midwife who had been a new starter didn't agree and felt it was more about the clinical area where they started:

"Obviously, I had no expectations. I started on the (triage) unit and they were brill. I settled in quite quickly. I think I was lucky that my PIN hadn't come through, so I had a week as a health care assistant before I was a midwife. So that gave me a little bit of time to get used to where everything is, who everyone is before having to do the midwifery on top of that." (F2.5)

Supernumerary status gave this midwife the time to familiarise herself with the environment and what was expected of her within a small team. This enabled some continuity because she was working with the same individuals most of the time. The significance of the supernumerary status was important in giving her space and time to adjust.

Although there were several references to feeling unsupported, there was also recognition that many of the staff were very supportive; this raises a question as to whether the extent of support was related to the midwife's confidence to ask for help or perceptions of their preceptor's willingness to help. There was a shared feeling that being seen to cope was admired by colleagues and asking for help was a weakness.

Therefore, even if they wanted to ask for help some felt unable because they wanted to be seen to be coping:

"You don't want to be seen as the one who's not coping, you don't want to be the one that, after you've had handover and they're like, 'Oh fine, don't worry.' Then they go to the desk and they're like: 'I don't want to come on to work after her, she leaves everything for the night staff.'" (FG1.3)

"It's just having the guts to just keep asking and asking the right person, and asking somebody and not feeling a fool for asking, because sometimes they make you feel a fool in front of the women you're looking after." (FG1.1)

The measure of their coping, and their source of anxiety was related to completing the tasks, for example postnatal discharges and getting their preceptorship document signed off in a busy environment by hard-pressed colleagues. Several participants were dismissive of the value of the preceptorship document in supporting their early practice, although they recognised its importance to the organisation.

Bridges (2011) asserted that the consequences can be significant if the new organisation is not prepared to recognise and be ready for the endings and losses involved in change. Letting go of the old way is essential for moving forward. In Bridges' (2011, p5.) model the next phase is the 'neutral zone' which is described as the 'no man's land' between the old reality/identity and the new. The neutral zone involves a psychological transition that can take some time. Trying to rush this process can result in discouragement, confusion and fear, resulting in the need to escape. Handled well, the neutral zone can be a great opportunity for rebirth, creativity and development (Bridges, 2011).

The findings of this study and evidence from the literature find a strong correlation with this theory of transition (Hobbs, 2012; Kitson-Reynolds et al, 2014).

The neutral zone

Relationships with colleagues

The participants' experience of practice and their feelings were heavily influenced by their perceptions of their relationships with their colleagues. Fitting in and being recognised as a valued member of the team was an aspirational goal. There was an awareness that the quality of support related to the workload and the staffing levels, so there were a number of competing demands, particularly in the ward situation:

"Most of the time the midwives were as supportive as they could be. Most of them were really nice… they were under the same pressure so they did as much as they could." (FG1.3)

Due to the nature of the work in the ward environment it is more difficult to ask questions or reflect with a more experienced colleague on decision making. There seemed to be a notion that it was a baptism of fire to be endured in order to get the badge of honour or acceptance, a rite of passage, judging by things that were said to these midwives by more experienced colleagues:

"We did it, so you're just going to have to go through

it too." (FG1)

"You know, you new girls, you're going to have to suck it up. It's sink or swim here" (FG1).

"She just can't hack it in here; she really needs to move to a quieter unit." (FG1)

The midwives' focus throughout the discussions was mainly on the tasks that must be completed in an environment with multiple competing workload demands. There was little reference to reflection and no mention of clinical supervision. Recognising a 'neutral zone' as a time of stress and anxiety, and offering support to lessen the effect could have a positive impact on the experience and be an influencing factor in enabling the midwives to move forward.

Bridges (2011 p6) stated that: "Anxiety rises and motivation falls. People feel disorientated and self-doubting. They are resentful and self-protective. Energy is drained away from work into coping tactics."

On the labour ward it was felt that, although still a very busy environment, there were more opportunities for one-to-one support:

"The Band Seven that was on was fab. We actually went to theatre for it all and needed the crash team and, once everything had settled, she called me out and put another midwife in and said: 'Go and have a biscuit and a cup of tea, sort yourself out and then you go back and do your notes.' I think sometimes that's what you need – someone to look after you." (FG2.2)

The first focus group felt that whether or not they had mastered it was down to previous experiences of mentorship, and how much opportunity for independent learning they had been given. There was a strong view that student midwives should have more opportunity to practise more independently in the final year in order to ease the transition to qualified practice.

Relationships with women

The midwives referred to their relationships with women, but mostly when things weren't going so well. In the early days they were battling to keep up with the workload and the tasks and didn't talk about the care of women. When they did talk about them, it was in relation to discharges, and then in situations where they felt inadequate and unsupported. It was in a focus group three months later that they talked about more positive experiences. An early data extract highlights the midwives' stress:

"I had a shift and one of the women was really upset about not going home; she was crying. I just hadn't been able to get to her because I had a social worker case as well. I'd spent three hours on the phone to the social worker. Seven discharges." (F1.3)

"In my break I was feeling ill and she was saying: 'I'm going to make a complaint about you, you didn't tell me I was going to be here until seven in the evening.' It's a communication thing." (F1.4)

There were other references throughout the focus groups and in the validation group about the cumbersome discharge paperwork, the time it took and the irritation of the women and their partners waiting to go home.

The midwives also worried that the women would think less of them because they were newly qualified:

"I found that I didn't want to say I was an NQM because then.. I think there's an air of do they really want you looking after them? I would say I was new with the Trust." (FG1.2)

The evidence in the study would suggest that the critical time of this period in the 'neutral zone' lasts around three months although this will depend on the individual. During this time a significant change takes place within, a new definition of self which, hopefully, discards old dependencies and moves ahead into a new place of recognition that a different way of being is required.

A new beginning

The new beginning can be a fearful time. Although individuals have been wandering around in the neutral zone and are pleased to feel that they are reaching their 'promised land' (Bridges, 2002, p51), this time may still feel a bit risky. It is the final closure on letting go.

Coming out of the neutral zone means that individuals have a clearer vision of the way ahead, they understand the part they are expected to play. As well as feeling part of the team, they also felt more able to stand up for themselves, as can be seen in this excerpt:

"The other day I has a delivery and it had been an hour and the Sister was like: 'Oh.' I'd literally just sat down to write notes and been with the woman and the Sister was saying: 'Are you nearly finished to take her down?' I said: 'No, I haven't written anything yet.' She replied: 'Oh come on.' I was like: 'It's only an hour.'" (FG4.4)

Relationships with other members of the multi-disciplinary team were also discussed. The group agreed that the medical staff were usually very helpful and, although they felt in awe of them in the early days, they grew in confidence as time progressed. In the validation focus group one of the participants described how the doctors calling her by name had really made her feel part of the team.

One of the midwives also talked about how she had to insist that a reluctant attending doctor came to review one of the women on the ward:

"If you don't do this now I'm going to escalate to your senior because I need this woman seen now, and as a midwife I can't sit on her. Then they're a bit 'I will come and see her. I'm not saying I won't come and see her.'" (FG3.5.)

This midwife exercised her professional duty of care to ensure that the woman was cared for appropriately, demonstrating her growing confidence.

An excerpt from a diary referred to confidence:

"I find you have to be quite bold. I'm naturally quite a quiet person, not shy, but just quiet. I have to learn to portray a boldness of character and also that it is a process of learning to have confidence in my own practice. Confidence in what I know and confidence in what I don't know." (P010)

The data from the primary focus groups revealed that the NQMs' main sources of anxiety relate to their relationships with their colleagues and with the women in their care. They measured themselves in relation to coping and striving to contribute effectively to the team. They found barriers to their

progress in the delays in receiving mandatory training and the task orientated processes of the organisation.

A theoretical framework related to theory of transition has given a structure to this process and highlighted this period as a dynamic and evolving process which passes through distinct stages. Recognition of the inevitable psychological processes through which the NQMs will pass, and an increased emphasis on a caring and supportive dimension to the preceptorship programme, is a logical step towards developing programmes of support that will be more effective than a simple preceptorship document.

Development work on flipcharts to compile recommendations

The findings of the focus groups were confirmed and given authenticity by the group work to develop recommendations for improving the approach to programmes of support. Flipchart paper was used with headings on each. Each heading was composed of a key question based on action points that had emerged from the focus group data.

The chart exercise took place four months following the commencement of the focus groups, and so the participants were able to look back and reflect from a more reflexive perspective. This is an important learning process that enables the acquisition of cognitive and metacognitive skills essential for independent thinking and clinical decision making (Kuiper and Persut, 2004). From this group exercise, recommendations were developed and are included below, as the participants originally wrote them.

Recommendations made by participants

1. More independent practice as a third-year student with an experienced mentor;
2. Pre-qualifying placement in health board and clinical area where due to commence employment;
3. Review of preceptorship documentation to include a transition document;
4. Formal introduction to the team recognising the needs of the new band-five midwife;
5. Induction and orientation to every new area; and
6. Buddy system with band-six midwife.

Despite earlier literature that highlights similar issues for NQMs, in relation to challenging and stressful experiences, little has changed over time. There is no doubt that more can be done, in a cost-effective way, to improve support mechanisms.

These recommendations are a starting point for a discussion about measures that could support the NQM through the challenging time of transition as described in the earlier discussion. Whatever measures are put in place, the newly qualified practitioner will go through a psychological process of loss and letting go, adjusting and adapting in the neutral zone, before being able to move on as a competent and confident practitioner.

It is important to recognise that a preceptorship programme is experienced as a paper exercise by the NQMs unless personal peer/colleague support is ensured as a recognised and essential component of this time period.

Limitations

It could be suggested that the sample size might not have produced sufficient data to fully meet the aims of the study. However, in qualitative research the sample size is likely to be small (Silverman 2006) to achieve the depth of analysis required. In this study, when only a small number of participants came forward, additional recruitment took place to increase the sample. Reflexivity and flexibility in qualitative research can enhance the trustworthiness and authenticity of the conduct of a study (Etherington, 2005).

Another limitation could be that the participants who came forward had 'an axe to grind' and so their views could have been biased; however lively discussion during the focus groups revealed a balance of views, which led to reasonable and valuable recommendations for improving the support offered to NQMs.

A new initiative

Keen to respond to these recommendations quickly, an initiative was implemented to introduce a pre-qualifying placement in Wales. An agreement between Lead Midwives for Education (LME) in the Higher Education Institutions (HEI) and the Heads of Midwifery (HOM) in Health Boards made significant changes to assessment timetables and the time period of recruitment. This has enabled the introduction of the placement to take place, firstly as a pilot with a plan for it to be rolled out more widely. This has involved extensive partnership working between Universities and Health Boards to introduce this placement across Wales.

Early evaluation shows that this initiative has reduced the feelings of stress and anxiety that were highlighted in this study, and has engendered feelings of motivation and positivity as the student midwives approach their new career. A further evaluation will be undertaken six months after registration.

Furthermore, the Royal College of Midwives in Wales is leading an All Wales project to develop a new programme of support for NQMs alongside a new preceptorship passport, which will ensure equity of support and experience across the maternity service in Wales. A wider evaluation of the pre-qualifying placement and the new preceptorship programme will take place. Dissemination of this in-depth evaluation will be important to demonstrate the effectiveness and sustainability of this model of support.

Conclusion

This paper has discussed an action research study that explored the experience of NQMs. Although the sample was small, the data was rich and was verified by other participants. The findings highlighted the emotion and distress encountered by

the participants in the early months of their new employment and resonate with theories of transition, which recognise that in the process of any change from one status to another.

Individuals are likely to experience feeling of loss and bereavement, fear, uncertainty, bewilderment and loss of performance. They need to let go of their former identity as students, accept that they will feel 'in the wilderness' for a while before they can move forward as qualified midwives.

The findings of the study supported this theory and the recommendations that resulted suggest ways in which the support around this challenging time should be improved. An immediate response from LMEs and HOMs has resulted in a pre-qualifying placement across the area and further work on the development of a preceptorship programme.

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Epidural analgesia and its effects on maternal and neonatal outcomes: a retrospective comparable study in Northern Jordan

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Date submitted: 18/07/2019 Date accepted: 21/11/2019 Date published: 20/12/2019 Date open access: 20/03/2020

The study is limited as it was retrospective and limited in terms of data accuracy and verification. Therefore, analyses must be viewed with caution.

Abstract

Background. Epidural analgesia (EA) is well-known method for reducing pain during labour. However, negative outcomes may be associated with its use.

Aim. To assess the rate of EA as a pain-control method during labour in a major university hospital in the north of Jordan, and to compare the outcomes for women who had EA with women who had no EA during their labour and their babies.

Method. A comparative retrospective study used birth medical records from 2013 to 2014 at the largest hospital in northern Jordan to obtain the birth data for the study. A specifically designed data-abstraction form was used to collect demographics, social data and maternal and neonatal outcomes. A convenience sample of 414 birth medical records was available for the study. The obtained sample was divided into two groups: parturient women who had epidural analgesia (EA) and women who had no epidural analgesia or used other method for labour analgesia, to compare maternal and neonatal outcomes. Ethical approval was granted from the human subject committee at Jordan University of Science and Technology.

Results. The total sample consisted of 414 birth medical records; more than half of the sample 52.2% (n=216) nulliparous women used epidural analgesia during the study period. The group of women who had EA had a significantly higher rate of instrumental birth, prolonged second stage of labour, and higher rates of maternal complications (fever, hypotension) compared with the group of women who had no EA.

Conclusion and implications. EA should be used with caution and when required as it appears to hold risks for the health of the mothers and their babies. Therefore, women need to be informed about the possible risks of EA and should have appropriate counselling. Further research to assess the long-term effects of EA on both mothers and their babies needs to be undertaken in both high- and low-income countries.

Keywords. Epidural analgesia, birth outcome, labour, birth, Jordan, evidence-based midwifery

Introduction

Epidural analgesia (EA) is considered to be one of the best pain-relief methods during labour, but it can still cause both short and long-term side effects, to both mothers and their babies (Anim-Somuah et al, 2011; Jones, 2012; Jones et al, 2013). Currently, epidurals are widely used for pain relief in labour in both high- and low-income countries (Anim-Somuah et al, 2018).

EA was proven to have benefits when used appropriately during childbirth. Some of these benefits include continuing pain relief and allowing the mother to remain alert during labour, which results in higher maternal engagement and satisfaction. Furthermore, an EA would facilitate the option for urgent interventions such as a CS (Jones, 2012). Conversely, the use of EA has been identified as carrying a number of adverse risks on mothers, such as: in inadequate analgesia, motor blockade, moderate to severe maternal hypotension and decreased bladder sensation (Anim-Somuah et al, 2011; Sindik et al, 2012; Jones et al, 2013; Van Zyl and Burke, 2017).

In addition to prolonged second stage of labour and dystocia during labour (Gerli et al, 2011; Tamagawa and Weaver, 2012; Hasegawa et al, 2013; Srebnik et al, 2019), nausea and vomiting, drowsiness, shivering and fever are also reported (Anim-Somuah et al, 2011; Tamagawa and Weaver, 2012). Furthermore, EA increased the use of oxytocin for augmentation and led to an increase in instrumental vaginal births (Jacobs-Martin et al, 2014; Srebnik et al, 2019).

Finally, EA increases the need for human and physical resources, which add an extra demand on the limited resources of the health care system. It was estimated that the cost of using EA in one university hospital in Jordan was around 225000 JD (USD$317,348.38) with an average of an extra 200 JD (282.087USD) for each birth.

To the best of our knowledge, there have been no studies conducted in Jordan to either assess the rate of use of EA or investigate its effect on maternal and neonatal outcomes. The purpose of this current study was to provide baseline knowledge about the rate of EA use and its effect on mothers and their babies' health with the aim of improving the childbirth experience among Jordanian nulliparous women. The study was designed to answer the following research questions:

- What is the rate of using EA as a pain control method during labour in a major university hospital in northern Jordan?

- What are the maternal outcomes that arise from EA use during labour?
- What are the neonatal outcomes that arise from EA use during labour?
- Are there any differences in the incidence of maternal and neonatal outcomes between women who had EA and those who did not have EA?

Methods

Design

A descriptive-comparative study was conducted to collect data on maternal and neonatal outcomes from the paper-based medical files of nulliparous women who had an EA during labour from October 2013 until September 2014.

Setting

The study was conducted in the largest major teaching hospital in northern Jordan. EA is available 24-hours per day for pain relief during labour. No official statistics related to the percentages of EA were available either in the hospital where the study took place or at the national level.

Sample

A convenience sample was obtained during the study period. The sample size was calculated based on power analysis for difference between two independent means using a power of 0.80, significant level 0.05 and medium effect size 0.50. Based on this, the minimum required sample size was 128 women. To minimise any confounding variables related to pre-existing maternal medical conditions or previous obstetric history, the inclusion criteria included were: nulliparous women with a full-term low-risk pregnancy and a singleton fetus.

Instrument

A data abstraction form was used that focused on demographic variables and maternal and neonatal outcomes (See table 1). This abstraction form was subjected to several reviews by the investigators (one senior neonatologist and two senior midwives) and a pilot study to ensure specificity and clarity. Maternal outcomes include: length of second stage of labour in minutes, type of labour, maternal complications and type of birth (See table 2).

Maternal length of hospitalisation was measured in minutes because it is a normal routine in the selected setting to discharge mothers and their newborn infants as soon as they show no need for medical attention, which may be within a couple of hours after birth. Neonatal data was collected on: gestational age, birth weight, resuscitation after Apgar scores, naloxone administration, meconium stained liquor and admission to neonatal intensive unit.

Data collection procedures and ethical consideration

Approval to conduct the study was obtained from the Institutional Review Board at Jordan University of Science and Technology. The researcher reviewed women's medical paper-based records and extracted the required data on an anonymous, coded data-abstraction form. All coded data was analysed using Statistical Package for the Social Sciences (SPSS) software version 17.

Data analysis

Descriptive statistics, including frequency, mean and SD, were presented for the total sample. Inferential statistics, chi-square and Independent t- tests were used to compare between groups as appropriate. P value was set at < 0.05 for statistically significant correlations.

Results

The total number of deliveries that occurred in the selected hospital was 3,228 in the study year. More than half of the births (51.3%, n = 1,655) were by caesarean section (CS), 46.7% (n = 1,508) were normal vaginal births and 2% (n=65) were instrumental (vacuum and forceps birth). A total of 1,158 (35.9%) women chose to use EA during their labour and birth onset. Of these, 414 (12.83%) women met the study's inclusion criteria and had completed data sets.

The obtained sample was divided into two groups: parturient women who had EA (n=216, 52.2%), and those who did not have EA or used other methods for labour analgesia (n=198, 47.8%). The EA formulas for the study were categorised into two groups according to the drug infused: Marcaine (bupivacaine) alone or Marcaine with fentanyl. The demographic characteristics for women and health characteristics of the newborn infants are displayed in Table 1.

Maternal outcomes for the total sample

The study sample consisted of 414 parturient women; 52.2% (n=216) received EA. As displayed in Table 2, more than half (51.9%) of the sample (n=215) had vaginal birth, 40.6% (n=168) had a CS and 7.5% (n=31) had an instrumental birth. Results, regarding the type of labour were gained from available data for 412 women, which showed that 54.9% of the sample (n=226) had augmented labour, 35.2% of the sample (n=145) had induced labour and 10% (n=41) of women had spontaneous labour. The majority (90.3%) had no complications after birth. The remainder of the sample had birth complications, which included hypotension and hyperthermia, but also post-partum haemorrhage, pruritus, general weakness and chest tightness.

The length of the second stage of labour data was available for women who had vaginal or instrumental birth in the study sample. For these women, the mean duration of the length of the second stage of labour was 65 minutes (SD=33.65). Also, analysis showed that 92.7% (n=228) had an episiotomy and 15.5% (n=38) of them had a perineal laceration and tear.

Neonatal outcomes for the total sample

In this sample, the gestational age of infants (n=414) at birth ranged from 37 to 42 weeks with a mean birth weight of 3.215 kg (SD=.4254); 2.9% (n=12) of them had a birth weight equal or below 2.5 kg (See table 1). Data showed that the majority of the babies (n=346, 83.6%) did not need help to breathe at the first minute after birth. Of 413 newborn infants 98.3% (n=405) did not need help at the fifth minute after birth. The number of babies who were admitted to the

Table 1 Demographic characteristics of mothers and health characteristics of the newborn infants in the study.

Characteristics	Percentage	N
Maternal characteristics		
Age mean (SD): 25.14 (3.59)		414
Education[1]		
Elementary school/High school	23.1	58
Diploma	9.2	23
University degree/post graduate degree	67.7	170
Medical insurance	97.8	405
Employed[2]	31.1	117
Smoking[3]	5.1	20
Infant characteristics		
Birth-weight mean (SD): 3.21kg (.42)		414
Gestational age (range) 37-42 weeks; mean=39+5day		
Female gender (%)	55.3	229
Apgar score at one minute (%)		
0-4 Need resuscitation	7.5	31
5-6 Need little help	8.9	37
7-10 No need for help	83.6	346
Apgar score at five minutes[4] (%)		
0-4 Need resuscitation	.5	2
5-6 Need little help	1.2	5
7-10 No need for help	98.3	405
NICU admission after birth (%)		
Yes	17.1	71
No	82.9	343
Meconium-stained liquor (%)		
Yes	14.7	61
No	85.3	353

[1] missing data =163,
[2] missing data=38,
[3] missing data=21,
[4] missing data=2.

Table 2. Comparisons between the EA (n=216) and the non-EA groups (n=198) maternal birth outcomes

Group	Non-EA	EA	Comparisons between groups
Variable	**n (%)**	**n (%)**	
Number of women	**198(47.8%)**	**216 (52.2%)**	
Mode of birth			
Normal	111 (56.1)	104(48.2)	Chi-square test Normal VS Instrumental: $x^2 = 4.06$, $p = 0.04$
Instrumental	10 (5.1)	21(9.7)	
CS	77(38.9)	91(42.1)	
Type of labour[1]			
Spontaneous	34(17.3)	7 (3.3)	Chi-square test[2] Spontaneous VS Augmented: $x^2 = 17.9$, $p <. 001$
Augmented	103(52.3)	123 (57.2)	
Induction	60 (30.5)	85 (39.5)	Chi-square test[2] Augmented VS Induction: $x^2 = 20.44$, $p <. 001$
Episiotomy[2] (Yes/No)			Chi-square test $x^2 = 5.18$, $p = .02$
Yes	107 (43.50)	121(49.19)	
No	14 (5.69)	4 (1.62)	
Length of second-stage of labour in minutes (mean, SD) [3]	58.85 (SD = 28.92)	70.95 (SD = 36.8)	t-test t= 2.77, p =.006
Presence of perineum tear/laceration	20 (10.1)	18 (8.3)	Chi-square test $x^2 = 2.03$, $p = .338$
Maternal complications (Yes/No)			Chi-square test $x^2 = 11.80$, $p = .001$
Hypotension	3(1.5)	18(8.3)	
Hyperthermia	0(0)	4(1.9)	
Hypotension and hyperthermia	0(0)	1(.5)	
Other	5(2.5)	9(4.2)	
No complications	190(96)	184(85.2)	
Length of hospitalisation in minutes (mean)	121 (Md=27.37)	124 (Md=35.73)	Mann Whitney U test U = 5572.5, Z = -3.480, P = .001
EA Formula[4]			
Marcaine alone		90 (42.1)	
Marcaine + fentanyl		124 (57.9)	

[1] two missing data, 1 from each set
[2] Bonferonni correction to control for type 1 errors thus the alpha level is strict to .017
[3] only for women who had vaginal birth
[4] two missing data

Table 3. Summary of the descriptive analyses of the neonatal outcomes for EA group(n=216) and non-EA group (n=198).

Characteristics		EA group		Non-EA group	
		n	%	n	%
Apgar score at first minute	Needed resuscitation	16	7.4	15	7.6
	Needed some help to breathe	19	8.8	18	9.1
	No need for help to breathe	181	83.8	165	83.3
Apgar score at fifth minute*	Needed resuscitation	1	.5	1	.5
	Needed some help to breathe	4	1.9	1	.5
	No need for help to breathe	209	97.7	196	99.0
Meconium stained liquor	Clear liquor	185	85.6	168	84.8
	Meconium-stained	31	14.4	30	15.2
NICU admission	Yes	36	16.7	35	17.7
	No	180	83.3	163	82.3

*2 missing data in the EA group

neonatal intensive care unit (NICU) were 71 (17.1%). The main reason for admission was due to respiratory distress syndrome (n=57, 80.3%).

Comparisons of maternal outcomes between epidural and non-epidural administration

Table 2 displays the maternal outcomes for EA and non-EA groups. Findings showed that the proportion of women who had augmented labour was significantly higher than the proportion of women who had spontaneous labour in the EA group; x2 = 17.9 (p<. 001). Also, the proportion of induced labour was higher than spontaneous labour in the EA group; x2 = 20.44 (p<. 001). Epidural comes first in Jordan, as women who are frightened of pain during labour and birth are offered EA, which is covered by health insurance.

When investigating a relationship between the use of EA and type of birth, a Chi-square test for independence indicated no significant association between these two variables (x2 (2, n = 414) = 4.5, p = .104, Cramer's V = .105).

When excluding women who had CS from the analysis, the sample size was 246 women who had either normal vaginal birth or instrumental birth. The analysis revealed that there was an association between type of birth and EA use. The EA use significantly increased the number of instrumental vaginal births from 10 women in the non-EA group to 21 women in the EA group. Women who had EA usually had a prolonged second stage of labour, which can lead to an instrumental birth.

The association between type of birth and EA use was significant; of the women who did not have CS, 104 who had EA had a normal delivery, while 111 women who did not have EA delivered normally. The Chi-square findings show that the proportion of women who had EA were significantly more likely to have an episiotomy (96.8%, n =121) than women who had no epidural (88.4%, n =107). For more details, see Table 2.

The independent sample t-test was conducted to compare the length of the second stage of labour for EA with the non-EA group. The analysis revealed that the length of the second stage was significantly higher in EA group. For all mothers who had EA, 31 (14.4%) developed maternal complications compared with only eight women (4%) in the non-EA group. The difference was statistically significant. Further details about maternal complications are presented in Table 2.

A Mann Whitney U test was employed to investigate the relationship between the use of epidural during birth and the length of hospitalisation as measured by minutes.

Based on Chi-square test there was a significant association between the use of fentanyl in the EA infusion and the maternal health complications (e.g. maternal hypotension, fever and post-partum haemorrhage) during labour and

delivery. Based on Chi-square test the use of fentanyl in the EA formula significantly increases the incidence of maternal health problems during labour and delivery (x2 (1, n = 214)=3.928, p=.047)

Comparisons of neonatal outcomes between epidural and non-epidural administration

Comparison of neonatal outcomes between the two groups (EA vs non-EA) were conducted (See table 3). Chi-square tests showed no statistical significance between the EA and non-EA groups based on the infants' Apgar scores either at the first minute or at five minutes. Also, no significantly different results were found between the two groups when comparisons were conducted based on meconium-stained liquor and newborn infant admission to the NICU variables.

Discussion

This was the first Jordanian study that assessed the rate and impact of EA on maternal and neonatal birth outcomes. It is hoped that the findings of this study will motivate health professionals and policy makers to implement appropriate cost-effective evidence-based practice for the use of EA in labour.

The findings of this study indicate that EA was widely used to manage labour pain in this hospital, as evidenced by the overall rate of EA, which was 35.9% (n=1,158) from the total number of women who had given birth during the study period in this hospital (n=3,228).

The percentage was even higher for the sample of primigravida women who had an EA during the study data collection period, reaching 52% (n=216) of the total study sample (n=414). When comparing the rate of our study with the rate in Israel (25%), which is the country closest to Jordan geographically – both countries are comparable in terms of area and population – we had more than double the rate (O'Hana et al, 2008). However, in comparison with the USA (60%), Jordan's rates of EA are considerably lower (Anim-Somuah al, 2011).

The high rates of using EA in our sample might be explained by the fact that almost all the mothers giving birth in this hospital had medical insurance and their insurance covered the cost of EA if requested. Another explanation could be the absence of the health care providers' role in implementing an effective childbirth preparation course for women during the antenatal period that might help them to cope with labour pain.

The findings showed that women who received EA had a prolonged second stage of labour, a higher rate of instrumental birth and episiotomy, an increased length of hospitalisation and an increased incidence of maternal health problems such as fever, hypotension and post-partum haemorrhage.

Our findings showed that the length of the second stage of labour in the EA group was significantly longer than the group with no EA. These results support the work done by many researchers (Hasegawa et al, 2013; Agrawal et al, 2014; Genc et al, 2015; Garcia-Lausin et al, 2018; Srebnik et al, 2019), all of whom found that EA is associated with a prolonged second stage of labour. This is due to the sensory nerves being blocked and the reduced muscle tone of the pelvic floor, which is induced by EA.

Moreover, the analysis revealed that the EA use increased the percentage of instrumental vaginal births from 8.3% in the non-EA group to 16.8% in the EA group, as a result of prolonged second stage of labour; this highlights a significant difference. These findings support previous studies such as (Tamagawa and Weaver, 2012; Agrawal et al, 2014; Van Zyl and Burke, 2017; Srebnik et al, 2019), who found that there was a significant difference between the two groups (EA and non-EA) in the incidence of instrumental birth. They conclude that prolonged second stage of labour resulted from the effect of EA on the sensory nerves blockage and absence of pelvic-floor muscle resistance.

These results could be due to the use of EA, which induces sensory and motor blockage. It makes mothers lose their Ferguson's reflex and the spontaneous urge to push during the second stage of labour, which increases the duration of the second stage of labour, thus increasing the incidence of instrumental birth (Anim-Somuah et al, 2011; Agrawal et al, 2014; Genc et al, 2015; Van Zyl and Burke, 2017; Srebnik et al, 2019).

Another explanation was that only nulliparous women were included in our sample and this is consistent with the previous work done by Gerli et al (2011) and Srebnik et al (2019), who found that nulliparity was one of the most influencing variable on prolonged second stage of labour for women who had EA.

These results indicated that the incidence of maternal health problems such as hypotension and hyperthermia were common in the EA group. The incidence of hypotension could be explained by the effect of EA on the sympathetic nervous system by causing vasodilation and a fall in blood pressure (Jones et al, 2013).

Moreover, the incidence of hyperthermia was common in the EA group. This might be due to longer duration of ruptured membranes, prolonged labour and more frequent cervical examinations. Another explanation was that only nulliparous women were included in this study. These findings were consistent with previous studies that reported an association between the use of EA and the occurrence of maternal health problems (Anim-Somuah et al, 2018; Jones et al, 2013; Sindik et al, 2012; Jacobs-Martin et al, 2014; Van Zyl and Burke, 2017; Srebnik et al, 2019).

Women need to be informed about the possible risks for mother and baby from EA use during labour. Therefore, it is very important that women should have explanations about benefits and risks of EA during pregnancy.

The analysis showed that Marcaine with fentanyl use was associated with an increased incidence of maternal complications compared with Marcaine alone. These findings were consistent with the work done by Genc et al (2015), who found that the addition of fentanyl to Marcaine had an impact on shortening the duration of the first stage of labour while it lengthened the duration of the second stage of labour. There is need for further research to assess the impact of Marcaine with fentanyl on maternal and neonatal

outcomes using a larger sample size.

Previous studies reported that the use of EA increased the incidence of episiotomy (Loewenberg-Weisband et al, 2014; Garcia-Lausin et al, 2018). This is because instrumental birth is one of the complications of EA and episiotomy is one of major complications of instrumental birth. However, this was not the case for women included in this study. It is worth mentioning that in Jordan, it is a routine practice to perform an episiotomy for almost all births, especially nulliparous women, which is not based on current evidence but accepted clinical practice and often without medical indication (Shaban et al, 2011). Therefore, the authors would argue that the high rates of episiotomy in this sample might be related to the current practice of liberal use of episiotomy in Jordan rather than episiotomy for indications. This reflects practitioner-led practice and not women-centred care.

A statistically significant difference was also found in the length of hospitalisation between the groups (EA and non-EA), as women with EA stayed longer in hospital than those who did not have EA. This might be reconciled by the increased probability of having labour induced, an increased length of second stage of labour, an increase incidence of instrumental birth and an increased need for an episiotomy, which results in increased complications and a longer time in hospital.

The findings, in terms of neonatal outcomes, were consistent with previous studies that reported that there was no association between the use of EA and the occurrence of neonatal health problems (Agrawal et al, 2014; Srebnik et al, 2019). However, the increased incidence of instrumental vaginal births and maternal complications could put babies in great risk. Thus, a full-scale Jordanian study with geographical clustering and multi-centre involvement is recommended to examine long term maternal and neonatal outcomes.

The authors recommend that policy makers encourage the implementation of evidence-based practice for EA, identifying the following: indications, methods of how to be used, monitoring and special precautions. For practice, we recommend that health professionals should practise their role as educator, consultant and advocator competently to empower women to have an informed choice regarding their use of EA. Furthermore, they should adopt a multidisciplinary approach and obtain informed consent as an important consideration in the management of women who wish to use EA.

Conclusion

One major limitation of this study is the time-frame for data collection, 2013-2014, which is now more than five years old. It would be more significant if data was collected from more recent years and over a longer period. However, this is the first study undertaken in Jordan to investigate EA rates and its effects on maternal and neonatal outcomes. Another limitation of this study related to the quality of medical records as some important data was not recorded and could not be retrieved. Finally, this research has been limited due to the lack of geographical clustering and the need for multi-centre involvement. These findings lead us to conclude that EA was common practice in this hospital, which poses potential risks to mothers and their babies. However, with appropriate use of EA and multi-professional teamwork, the EA rate and associated possible risks might be reduced through the use of the best available evidence. Women need to be well-informed about possible associated risks to themselves and their baby from EA. Therefore, weighing up the benefits and risks of using EA as a pain control method is recommended to ensure the safety of mothers and their babies.

Acknowledgements

We thank the health records department staff of King Abdullah University Hospital for their assistance in facilitating the conduct of this study. We also thank Louise Arthur for assistance with proof reading.

Conflict of interest

The authors declare that they have no conflict of interest.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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