



A qualitative study of a sample of women participating in an Australian randomised controlled trial of intrapartum fetal surveillance

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ABSTRACT

Background: The STan Australian Randomised controlled Trial (START), the first of its kind in Australia, compares two techniques of intrapartum fetal surveillance (cardiotocographic electronic fetal monitoring (CTG) plus analysis of the ST segment of the fetal electrocardiogram (STan+CTG) with CTG alone) with the aim of reducing unnecessary obstetric intervention. It is also the first comprehensive intrapartum fetal surveillance (IFS) trial worldwide, including qualitative examination of psychosocial outcomes and cost-effectiveness. In evaluating and implementing healthcare interventions, the perspectives and experiences of individuals directly receiving them is an integral part of a comprehensive assessment. Furthermore, the added value of using qualitative research alongside randomised controlled trials (RCTs) is becoming widely acknowledged.

Objective: This study aimed to examine women's experiences with the type of IFS they received in the START trial.

Methods: Using a qualitative research design, a sample of thirty-two women were interviewed about their experiences with the fetal monitoring they received. Data were analysed using thematic analysis.

Findings: Six themes emerged from analysis: reassurance, mobility, discomfort, perception of the fetal Scalp Electrode (FSE), and overall positive experience.

Conclusion: Interestingly, it was found that women who had an FSE in the CTG alone arm of the trial reported very similar experiences to women in the STan+CTG arm of the trial. Despite STan and CTG differing clinically, from women's perspectives, the primary difference between the two techniques was the utilisation (or not) of the FSE. Women were very accepting of STan+CTG as it was perceived and experienced as a more accurate form of monitoring than CTG alone. Findings from this study have significant implications for health professionals including midwives and obstetricians and implications for standard practice and care. The study has demonstrated the importance and significance of incorporating qualitative enquiry within RCTs.

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Introduction

Intrapartum fetal surveillance (IFS) using continuous cardiotocography (CTG) has become almost ubiquitous in the intrapartum setting (Kuah and Matthews, 2017), with routine data collection and other reports from Australia (East et al., 2015;

Pregnancy Outcome Unit, 2018), the setting for START (STan Australian Randomised controlled Trial), demonstrating that it is used in 60–70% of all labours (East et al., 2015; Pregnancy Outcome Unit, 2018). Although there is some benefit from CTG during labour (Alfirevic et al., 2017) there is also evidence of it being associated with increased rates of caesarean section which are accompanied by risks to the mother and child (Alfirevic et al., 2017; Paterno et al., 2016; Sandall et al., 2018). Furthermore, there are psychosocial sequelae of emergency caesarean section that are often not considered (Benton et al., 2019).

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Alfirevic et al. (2017) describe CTG as the electronic recording of the baby's heart rate and the mother's uterine contractions. The fetal heart rate can be monitored by one of two methods: external CTG utilises a Doppler ultrasound transducer which is held to the mother's abdomen by an elastic strap; internal CTG utilises a fetal scalp electrode (FSE) attached to the back of the baby's scalp to calculate the fetal heart rate from the R-R' interval of the fetal electrocardiogram (Symonds et al., 1999). Resultant restriction to mothers' mobility using either method has been noted by Alfirevic et al. (2017). A pressure transducer is also utilised regardless of external or internal means of detecting the fetal heart rate. This transducer is also held by an elastic strap to the mother's abdomen, typically in proximity to the top of the uterus in order to monitor the timing of their contractions.

An alternative to CTG alone, is monitoring which undertakes ST analysis (STan) of the fetal electrocardiogram (Neoventa Medical, Gothenburg, Sweden) (Rosén and Lindcrantz, 1989) in addition to CTG. This approach identifies changes to the ST segment which are related to metabolic acidosis in the unborn baby, and these changes are interpreted together with the CTG (Rosen et al., 1984; Rosén and Lindcrantz, 1989; Westgate et al., 2001). Similar to the internal CTG monitoring, STan monitoring requires the placement of an FSE to detect the fetal ECG (Belfort et al., 2015; Sacco et al., 2015). With up to a 60% false positive diagnosis of fetal distress using CTG alone (Chandraharan and Arulkumaran, 2007), the additional information afforded by STan may have considerable impact on the reduction of a false positive diagnosis of fetal distress and thus a reduction in unnecessary operative births (Sacco et al., 2015).

To date, there have been six international randomised controlled trials (RCTs) comparing STan in addition to CTG with CTG alone (Amer-Wahlin et al., 2001; Belfort et al., 2015; Ojala et al., 2006; Vayssièrre et al., 2007; Westerhuis et al., 2010; Westgate et al., 1992). Meta-analyses have also been conducted which include some or all RCTs (Becker et al., 2012; Blix et al., 2016; Neilson, 2015; Potti and Berghella, 2012; Salmelin et al., 2013; Schuit et al., 2013). To our knowledge, STan has not been previously utilised in the Australian maternity care system beyond its introduction and piloting at the study institution (Women's and Children's Hospital) in 2015. STan+CTG is being compared to CTG alone in our institution and the primary aim of the randomised controlled trial (START) is to determine if STan in addition to CTG can reduce emergency caesarean section rates and other interventions, whilst maintaining or improving neonatal outcomes (Turnbull et al., 2019).

In evaluating and implementing healthcare interventions, the perspectives and experiences of individuals directly experiencing those interventions are critical (Brewster et al., 2015; Sekhon et al., 2017; Smith et al., 2017). Examination of women's views and experiences of maternity care has become an important indicator of the quality of health-care provision, with growing acceptance of the need to adapt services to improve women's experiences (Karlström et al., 2015). Overall, women's views, including their thoughts, opinions, preferences and experiences toward aspects of maternity care, carry important implications for postnatal psychological functioning (Michels et al., 2013). Furthermore, the added value of using qualitative research alongside RCTs is becoming widely acknowledged (Cooper et al., 2014; Snowdon, 2015) and increasing numbers of RCTs are including qualitative components (Cathain et al., 2013). A number of benefits of this qualitative research in RCTs have been identified including; a more comprehensive interpretation of trial findings, exploration of users perceptions of the feasibility and acceptability of an intervention, and understanding of the effect of social context in which an intervention is delivered (Russell et al., 2016).

Surprisingly, little recent research has examined women's experiences and views in the broad area of IFS. Thus, this RCT offered the ideal opportunity to examine women's experiences of two different fetal monitoring techniques. A recent systematic review has explored women's views and experiences of electronic fetal monitoring during labour (Smith et al., 2017). The review reported on 10 studies from which four themes were identified including: discomfort; anxiety; reassurance; and communication (Smith et al., 2017). However, the systematic literature reviewed did not identify any studies that examined views and experiences of STan monitoring. To the author's knowledge, only one quantitative study conducted in the UK has examined women's retrospective self-reported satisfaction with STan (Parisaei et al., 2010), with the majority of women viewing STan as acceptable. However, beyond this binary measure of acceptability, no views or opinions were sought. Subsequently, a pilot exploratory investigation on pregnant women's hypothetical views about STan monitoring was conducted by our group prior to the current trial (Bryson et al., 2017). Pregnant women were interviewed about their perceptions of both STan and CTG after reading hypothetical vignettes describing the two forms of monitoring. While women tended to prefer CTG, their views were multifaceted and complex.

The current study builds on the earlier small study with the aim of generating insights in terms of IFS by investigating women's retrospective experiences of the type of fetal monitoring they received during their participation in START.

Methods

This qualitative study utilised individual, face-to-face, semi-structured interviews to explore women's experiences with the type(s) of IFS they received.

Procedure

Women were recruited for the qualitative study from the participants of START, conducted at the Women's and Children's Hospital, a public tertiary hospital that manages the largest number of births in South Australia. As part of the trial women were randomised to one of two arms: CTG alone or STan+CTG. In the study institution, continuous fetal monitoring by CTG is the most common method of IFS and its use over intermittent auscultation of the fetal heart during labour is guided by recommendations listed in the Royal Australasian College of Obstetricians and Gynaecologists (RANZCOG) guidelines for IFS (RANZCOG, 2019). In our study setting, women may have experienced several monitoring methods during their birthing experience. All women were deemed to require continuous CTG monitoring, per the RANZCOG guidelines (RANZCOG, 2019) prior to randomisation. If randomised to the CTG alone arm, the fetal heart rate may have been obtained via external (CTG no FSE) or internal (CTG with FSE) methods depending on the clinical situation. CTG was conducted with transducers connected to the monitor or via telemetry dependant on the type of machine already in the birthing room the woman was allocated to. Women who were randomised to the STan+CTG arm initially received CTG monitoring as described for CTG alone until it was clinically appropriate to commence STan monitoring. This was immediate if an FSE was already in situ and connected to a monitor capable of ST analysis (Neoventa) or may have been delayed until it was clinically possible to apply an FSE and/or connect to a Neoventa monitor brought into the birthing room.

Approximately seven weeks after birth, expressions of interest for interviews from women recruited to START were sought. A precursor letter and information sheet were sent to women who had expressed an interest in an interview. The researcher made telephone calls to these women to discuss the study, and interview

times and locations were arranged with those who wished to participate, with written informed consent obtained directly before conducting the interview.

It was initially planned to adopt 'maximum variation sampling' (Palinkas et al., 2015) in which participants are sampled based on predetermined criteria (i.e. type of IFS received in the trial, parity and previous experiences of fetal monitoring) in order to cover a range of constituencies to ensure representativeness and diversity. However, this approach proved to be impractical and so we moved to a more pragmatic approach where we interviewed consenting women based on the type of monitoring they received, irrespective of their broader clinical and demographic profile.

A pilot interview, aimed at gauging the comprehensibility and flow of the interview questions was conducted prior to the commencement of formal interviews with one woman who had recently given birth and received fetal monitoring (but was not enrolled in START) and clinical staff including a midwife. The pilot interviews provided feedback to the researcher regarding the effectiveness of the interview questions and amendments were made to the interview schedule accordingly.

Women interviewed were asked open-ended questions designed to elicit discussion which was guided by an interview schedule. The interview schedule allowed the researcher to pursue the same basic lines of enquiry with each participant and assisted in managing the interviews in a systematic and comprehensive way (Al-Busaïdi, 2008). The interview schedule was informed by relevant literature on women's experiences of fetal monitoring in labour (Smith et al., 2017), as well as literature on STan monitoring in general (Bryson et al., 2017).

To enhance methodological rigour throughout the research process, criteria for rigorous qualitative research were followed, specifically Tracy (2010) "Big-Tent" criteria for excellence in qualitative research. As recommended, an audit trail was kept by the researcher to ensure transparency and rigour in the research process, which included records of all interactions with participants, reflections on the quality of the interview process, notes surrounding emerging themes and methodological decisions.

A further important element of qualitative research is self-reflexivity, considered to be honesty and authenticity with one's self, one's research, and one's audience (Tracy, 2010). It is important to acknowledge the potential impact of the researcher's subjective values, biases and preconceptions on the research. The primary researcher, who conducted the interviews, is a young female who has no children of her own, and thus this may have influenced the way in which women responded to the interview. A number of women expressed their appreciation in being able to talk about their experiences. The third author is a male obstetrician with a child of his own and the remaining authors were women with children of their own. As such, the authors approached the data analysis from their respective positions.

Data analysis

Transcripts were analysed using Thematic Analysis (TA) to identify, analyse and report patterns (themes) within the data. A semantic approach was taken allowing the analysis to be driven by the research question without searching for meaning beyond what the participants reported (Braun and Clarke, 2006). We used a combined deductive/inductive approach in order to examine the data according to previous research, specifically the previous pilot study (Bryson et al., 2017), while also identifying additional themes suggested from the data itself (Nowell et al., 2017).

Braun and Clarke (2013) describe six steps involved in undertaking TA. The first step involved familiarisation and immersion with the data. The researcher achieved this through familiarisation with transcription, multiple readings and beginning to note pre-

liminary ideas. The second step involved generating initial codes by grouping interesting features across the dataset. Third, the initial codes were collated into potential emergent themes and sub-themes. Fourth, these themes were reviewed in relation to the raw data, initial codes, and relevance to the research aims. Fifth, themes that best represented the data were refined, defined and named. Finally, transcript extracts were selected to illustrate each theme. To improve the consistency and trustworthiness of the chosen themes, Braun and Clarke (2013) also recommend that the codes and themes are cross-checked by multiple researchers. Three authors discussed initial emerging themes (MB, DT, AS) at which point the observation was made that women were commenting in very similar ways, irrespective of the type of monitoring received; so the decision was made that study arms would not be routinely compared and the data set would be analysed as a whole, and not by treatment arm. Subsequently, two authors (DT and AS) cross-checked initial codes and emerging themes identified by the primary researcher (MB). Themes emerging from the data were discussed throughout analysis by three authors (MB, DT, AS).

Ethical considerations

Human Research ethics approval was gained from both Women's and Children's Hospital Network Human Research Ethics Committee and the University of Adelaide Human Research Ethics Committee (HREC/17/WCHN/14).

Results

Participants

Interviews were conducted with 32 women who were between 7 and 24 weeks postpartum from May, 2018 to August, 2019. All interviews were conducted by the primary researcher (MB) with four interviews being conducted in public locations, including cafes, and the remaining 28 completed in women's homes for their convenience. All interviews were audiotaped and the mean interview time was 23 min (between 11 and 60 min). Data saturation was determined by the 30th interview as the most recently conducted interview appeared to yield no new themes. To ensure this was the case, two additional interviews were completed (Guest et al., 2006). Audio-taped interviews were transcribed verbatim by the primary researcher using study numbers and pseudonyms to maintain anonymity of participants.

Participants were aged between 20 and 42. Sixteen participants were randomised to STan+CTG and 16 participants to CTG alone, of which 12 had a FSE applied for clinical reasons and 4 did not. Key characteristics of the participants are described in Table 1.

It is important to preface that meaningful differences in women's experiences between each treatment arm of the trial were expected to be found but this wasn't the case. Interestingly, it was found that the main point of difference for women was whether the FSE was present or not. Women's intrapartum monitoring experiences typically began with standard external CTG monitoring before they were randomised to either arm of the trial (CTG alone or STan+CTG). More often than not, women in the qualitative study population had received an FSE in the CTG alone arm due to clinical necessity and women in the STan+CTG arm always received a FSE (as described previously). Participants will have experienced one of four combinations of IFS: external CTG only; external CTG converted to internal CTG when a FSE was applied for clinical reasons; external CTG then CTG+STan after FSE was applied to enable STan as randomised to STan arm; and external CTG converted to internal CTG for clinical reasons and then STan enabled as randomised to STan arm. It should be noted that

Table 1
Participant characteristics.

Participant name*	Monitoring	Age	Parity	Weeks postpartum	Epidural
Ida	CTG wt FSE	26	1	15	Yes
Alice	STan	22	1	14	Yes
Olivia	STan	33	2	20	Yes
Sophia	STan	31	1	13	Yes
Samantha	CTG wt FSE	30	2	11	No
Mia	CTG no FSE	20	3	17	No
Christianna	CTG wt FSE	25	1	13	No
Michelle	CTG wt FSE	30	1	23	Yes
Caroline	STan	31	2	18	Yes
Julia	STan	27	1	17	Yes
Victoria	CTG wt FSE	27	2	13	Yes
Emily	CTG wt FSE	42	1	12	Yes
Naomi	STan	33	1	19	Yes
Isabelle	STan	31	1	14	Yes
Rose	STan	35	1	13	Yes
Mary	CTG no FSE	31	1	15	Yes
Irina	CTG no FSE	36	1	14	Yes
Florence	STan	36	1	16	Yes
Elena	CTG wt FSE	32	1	12	Yes
Grace	CTG wt FSE	31	1	16	Yes
Josephine	CTG no FSE	38	1	18	Yes
Charlotte	STan	36	2	9	Yes
Fiona	STan	31	1	17	No
Sarah	STan	31	2	11	Yes
Leila	CTG wt FSE	30	1	25	Yes
Jane	STan	31	1	14	Yes
Clara	STan	42	1	13	Yes
Ava	STan	41	2	12	Yes
Mila	STan	21	1	19	Yes
Penelope	CTG wt FSE	29	1	11	Yes
Zoe	CTG wt FSE	35	2	8	Yes
Caroline	CTG wt FSE	29	1	12	Yes

* Note: Participant names are pseudonyms.

women's descriptions of their monitoring experience may be influenced by, and in reference to any part of their IFS experience and therefore quotes may appear out of context with the type of IFS stated that they received.

Five key themes that describe women's experiences with the fetal monitoring they received were identified: reassurance, mobility, discomfort, perception of the FSE, and overall positive experience.

Reassurance

In general, reassurance emerged as a dominant theme across interviews and was strongly related to opportunities women had to hear their baby's heartbeat.

"It just gave me that sound of mind of everything being okay" (Mia - CTG no FSE).

Women explained that hearing their baby's heartbeat allowed them to feel more relaxed knowing the baby was safe so they could in turn increase focus on labour.

"It was lovely knowing that they knew exactly what was happening with him and they were confident, which made me a lot more relaxed and everything throughout the process" (Caroline - STan+CTG).

Belt-mounted ultrasound transducers: inaccuracy and stress

Several women described the belt-mounted ultrasound transducers as causing additional stress and anxiety in labour due to their experienced inaccuracy. This experienced inaccuracy was typically due to the ultrasound transducer moving and losing contact with baby's heartbeat.

"The whole time, I was super anxious because it was just all over the place... I found the bands just way to inaccurate" (Jane - STan+CTG).

FSE: reliable monitoring

Women described the FSE (whether it be with STan+CTG or CTG alone) as a more reliable form of monitoring and therefore more reassuring in comparison to their experiences with external CTG alone. Women reported that internal monitoring utilising a FSE was able to provide constant monitoring of their baby's heartbeat whereas belt-mounted ultrasound transducers often moved on women's abdomens and contact would be lost with the baby's heartbeat.

"I didn't have to ever worry about losing track of the baby's heart rate, it was actual proper continuous monitoring. Whereas I feel with the bands it wasn't, it was just up and down, up and down" (Isabelle - STan+CTG)

Several women also expressed increased feelings of safety with the FSE.

"I felt safer with it on her head because the fact that they kept losing the heart rate with the one on the tummy...it made me feel more comfortable so that I knew she was safe"(Christianna - CTG with FSE).

"It was good having that constant ... accurate monitoring as opposed to the CTG ... it just kept falling off" (Fiona - STan+CTG).

In addition to increased feelings of safety, women also described feeling more relaxed and in control when they had the FSE, either with STan+CTG or CTG alone in comparison to when belt-mounted ultrasound transducers were used (external CTG) as they didn't have to worry about a loss of contact with their baby's heartbeat.

"I felt like there was a lot more control and it was much more accurate because I know when I had the thing on my belly...it'd drop in and out and you're freaking out" (Olivia - STan+CTG).

"The clip [FSE] just gave us piece of mind and one less thing we had to worry about in labour" (Samantha - CTG with FSE).

Monitoring impact on partner

Women reported the continuous monitoring generally appeared to reassure their partners and generate a sense of their involvement in labour.

"He liked being able to see what was happening with contractions and things like that as well, because obviously I could feel them and I knew what was going on but he was able to be a bit more involved by actually being able to see what was happening" (Penelope - CTG with FSE).

In contrast, a small sub-set of women described anxiety the monitoring caused their partner either in terms the belt-mounted ultrasound transducer losing contact with their baby's heartbeat or in terms of the application of the FSE. One women described her husband's reaction to when the belt-mounted ultrasound transducer was not picking up their baby's heartbeat.

"He actually got quite stressed out and thought that the baby had died because everything had dropped of the monitor" (Grace - CTG with FSE).

Technology informing staff

Many women described further reassurance by the FSE (either with STan+CTG or CTG alone) as they considered it a valuable source of added information for staff to base clinical decisions on.

"They were able to explain more with the one on his head" (Caroline - CTG with FSE).

Furthermore, STan was seen as a new technology that could potentially reduce women's chances of experiencing additional intervention. Women also said if they were required to have an emergency caesarean section, they knew it was because it was necessary.

"It definitely made me confident that I could keep going the way I was going and made my obstetrician confident that everything was fine so there was no rushing to do anything" (Caroline - STan+CTG).

Mobility

Maintaining mobility was discussed as a significant preference and was consistently reported as an important pain management technique during women's labour. Women discussed the significance of mobility in terms of moving around the bed and changing positions. Women described the belt-mounted ultrasound transducer as inhibiting their desire to remain mobile as they reported the belts repeatedly moved on their abdomen and were having to be constantly readjusted.

"It didn't allow me to do any movement what so ever, every time I moved during a contraction ... the bands would slip off" (Isabelle - STan+CTG).

"In-between every contractions I had to lie back on my back for them to strap the thing back on and find the heartbeat. In between contractions, it's ridiculous" (Samantha - CTG with FSE)

To overcome the problem of the belts moving, women reported having to stay in one position or holding the belts so they would not slip off in order to allow for a consistent reading of their baby's heartrate.

"because it doesn't stay there properly, I didn't move after that. I just kept one position. Or when I wanted to move I just held it and pressed it. So I didn't move too much" (Florence - STan+CTG).

"I was literally stuck in the same position on the bed" (Josephine - CTG no FSE).

Several women discussed how this focus on the belt-mounted ultrasound interrupted their overall mindset and focus on labour, increasing their anxiety and frustration.

"every time ... I had a break in contractions I had to lie completely still in a position to get it reapplied ... so it just sort of disturbed my train of thought of not trying to get to caught up in the pain" (Isabelle - STan+CTG).

"it was frustrating, it was like I didn't want to be paying attention to those [belt-mounted ultrasound transducer], I wanted to be kind of in the moment I guess, talking to my husband rather than going "uh this freakin bands" it was definitely a distraction" (Leila - CTG with FSE).

In comparing their experiences, women who had an FSE either with STan+CTG or CTG alone reported considerably increased mobility during labour as it would provide constant readings of the baby's heart rate.

"You can kind of do whatever you wanted to, like you weren't restricted as much so it was a lot easier than the CTG for sure" (Fiona - STan+CTG).

"I felt a lot better when the clip [FSE] was on cause I felt like I could do whatever I wanted without disrupting it, I felt a bit more free to move compared the other scan thing [CTG alone]" (Jane - STan+CTG).

Discomfort

Discomfort was discussed and associated with the monitoring equipment for women in both treatment arms of the trial in terms of either the application of the internal FSE or the belt-mounted ultrasound transducer. Some women who had the FSE described the application as unexpectedly uncomfortable.

"I think because it did quite hurt when they attached it the first time. I didn't realise there would be any sort of discomfort to be honest so I wasn't prepared...so when it happened I was sort of a bit taken back by it (Caroline - STan+CTG).

Women expressed that more information surrounding the application may be useful to prepare them for any discomfort with application.

"would hate for it to discourage women to use it but I suppose if you are mentally prepared for it to be a little bit uncomfortable you are sort of more [physically] prepared for it (Caroline - STan+CTG).

Several women expressed the difficulty some staff had in inserting the FSE, with some women describing several application attempts having to be undertaken by staff causing women stress, anxiety and feelings of panic. One women described the application as traumatic and later resulting in a panic attack.

"The actual application of the clip [FSE] I found quite traumatic" (Grace - CTG with FSE).

One woman described the application of the FSE with staff attempting to attach it three times before it was successfully applied. She described the impact on her partner.

"It [the application] made my husband really anxious...he was concerned for her [baby] wellbeing and knowing there were three attempts at jabbing into her head and he was super just concerned" (Leila - CTG with FSE).

However, epidural anaesthesia reduced discomfort associated with the application of the FSE.

"Couldn't even feel it ... I don't even know they were putting it in there but I can imagine if I hadn't [had an epidural], maybe putting something in there might be uncomfortable" (Naomi - STan+CTG).

Women also described the application of the FSE as less invasive, relative to other procedures they had experienced during labour.

"Compared to all the other things going on it was insignificant" (Jane - STan+CTG).

Discomfort was consistently reported by women in terms of the belt-mounted ultrasound transducer.

"The belts were really uncomfortable after a while because they are pushing in to really get the heart beat and the contractions so they actually leave little dents (Rose - STan+CTG).

Women also described discomfort arising from the enforced immobility with the belt-mounted ultrasound transducer.

"It's uncomfortable because I need to stay there in one position for hours" (Florence - STan+CTG).

Perception of the FSE

In terms of the FSE, women who either received STan+CTG or CTG alone with the FSE described their initial concerns when staff described it to them.

"It sounds painful. Even just the name doesn't sounds appealing" (Sarah - STan+CTG).

"They called it the "scalp clip" and I was like that sounds terrifying "what", they're like we put it on your baby's head when they are still in there and I was like "how" ... This sounds silly, I didn't like the name scalp clip. I was like that sounds really invasive for the baby (Jane - STan+CTG).

Some women didn't understand how the FSE either with STan+CTG or CTG alone functioned.

"I actually thought it was going to be a little suction cap" (Caroline - STan+CTG).

"I was thinking...like a full metal clip that somehow attached" (Ava - CTG with FSE).

Other women were misinformed about the impact of the FSE, particularly on mobility, with some women opting not to have as FSE until they had an epidural.

"They told me that I couldn't move, that I had to be lying down for it [FSE], had to be still, not still but I had to labour on the bed with it and I was kind of like ohh no I don't want to do that " (Leila - CTG with FSE).

Many women further expressed concerns in relation to how the FSE would impact their baby.

"The idea of it being inserted and that it was a metal clip being attached to the scalp made me feel uncomfortable just cause you know its metal, and attaching to your new born baby's scalp like so I found it a little unsettling" (Ava - CTG with FSE).

However, these concerns in relation to the FSE were then typically described as an acceptable trade-off for potentially better outcomes for their baby.

"You worry that it's going to hurt the baby but I guess from our experience of knowing what could go wrong...[resuscitation in previous birth] that was a really minor impairment...I guess for us we rationalised that putting a probe in, in a really quick procedure...would be much better if it could avoid some of those more drastic medical procedures" (Sarah - STan+CTG).

Several women also described feelings of guilt they had in terms of the marks left by the FSE on the baby's head.

"There was like a little bit of mark on the head for a while and I was like "ohh" you know, of course you're a mother and you're like "ohhh I'm sorry" (Fiona - STan+CTG).

"When baby was born I found it a little distressing to see the clip [FSE] and to see clearly that she had been bleeding...not that it was gushing but it's still again your brand new little baby to see a little sore on their head already...you kind of have to reconcile that" (Ava - CTG with FSE).

Women suggested additional information about the potential impact on their baby would be beneficial.

"Setting that expectation of what you can visibly see when the baby comes out" (Ava - CTG with FSE).

Positive experience

Overall, women described having the FSE whether it be with STan or with CTG to be a more positive experience overall in comparison to experiences with the belt-mounted ultrasound transducer. The FSE allowed women to focus on labour and reduce worry in relation to fetal monitoring.

"they switched to the scalp monitoring [STan] which obviously once that was connected it never lost connection again I found it a lot more relaxing, I could just focus on labour and delivery...the whole experience was a lot more positive and less bothersome than the bands" (Isabelle - STan+CTG).

The FSE was discussed as a method to possibility mitigate unnecessary interventions such as emergency caesarean section and therefore was frequently embraced by women.

"I definitely had more faith...if there was distress then it was genuine distress...if there was intervention to come from it then that was necessary" (Ava - CTG with FSE).

Women conveyed they would have liked to have been offered and received the FSE earlier in their labour.

"If anything I probably would have asked for the scalp monitoring sooner even right from the beginning instead of struggling with the bands for so long" (Isabelle - STan+CTG).

Discussion

The current study examined women's experiences with two different techniques of IFS. Overall, the FSE was found to be used more frequently than anticipated, due to clinical indication of need rather than solely to facilitate STan, which led to findings that were not originally anticipated. Interestingly, it was found that women who had an FSE in the CTG alone arm of the trial reported very similar experiences to women in the STan+CTG arm of the trial. Despite STan+CTG and CTG alone differing clinically, from women's perspectives the primary difference between the two IFS techniques was the utilisation (or not) of the FSE. Overall, five key

themes were identified that describe women's experiences with the fetal monitoring they received including: reassurance, mobility, discomfort, perception of the FSE, and overall positive experience.

Reassurance

Supporting previous research (Barber et al., 2013; Smith et al., 2017) women found IFS generally reassuring. However, women reported the FSE added an additional layer of reassurance to their labour experience, especially when compared to the belt-mounted ultrasound transducers alone. This was typically a result of the inaccuracy of the belts related to loss of contact with the baby's heartbeat with women's movements. The FSE was perceived as a more reliable and accurate addition to monitoring as it provided women with a constant record of their baby's heart rate resulting in increased feelings of safety and allowing women to relax and focus during labour. Women who experienced STan+CTG expressed that knowing they were using newer technology that had the potential to reduce their chance of intervention provided them additional feelings of safety. These findings are contrary to the previous pilot study of women's prospective views (which examined women's preferences guided by hypothetical scenarios) rather than lived experiences towards different IFS techniques whereby STan+CTG was perceived as somewhat risky as it was a newer technology to the study institution (Bryson et al., 2017). Monitoring of either type was also discussed as helpful in providing reassurance to partners and an increased sense of involvement. This finding has also been described in other studies (Barber et al., 2013; Starkman, 1976).

Mobility

It is recognised that mobility is an important preference in labour for women due to its perceived physiological benefit such as pain management (Priddis et al., 2012). Interestingly, the limited research examining women's experiences of FSEs suggests that they do not increase women's mobility. A qualitative study of staff perspectives describe contrasting views of staff in relation to mobility and the FSE (Kerrigan et al., 2015). The study described a common assumption of staff that the application of an FSE would lead to a higher incidence of immobility during labour whereas other staff members saw the use of the FSE as a way to increase mobility (Kerrigan et al., 2015). Women in the current study described meaningful increases in mobility with the FSE in contrast with CTG alone which utilised the belt-mounted ultrasound transducer. Women reported the belt-mounted ultrasound transducers would often lose contact with their baby's heart rate, due to the belts moving on their abdomen leading to a reduction in mobility as women felt the need to stay in one position so a consistent fetal heart could be detected. Thus, with regard to mobility, the authors suggest that women perceived the advantage of the FSE as contributing to the ability to move and change position without losing contact with the fetal heart rate, rather than permitting movement around the birthing room during labour per se. In our study setting, the ability for unrestricted ambulation is facilitated by the monitors that have telemetry (not all monitors) and additionally these monitors can only be used for CTG only (with or without an FSE). Our version of Neoventa monitors (S31) do not have telemetry and additionally, current STan technology does not allow for telemetry with STan enabled.

Overall these findings highlight the need for updated consumer information from women's perspectives to clearly explain the impact of the FSE on mobility, and the potential for it to actually increase women's mobility rather than decrease it as previously suggested.

Discomfort

Discomfort was associated with the monitoring equipment for some women in both treatment arms of the trial in terms of ei-

ther the application of the internal FSE or the enforced immobility and continual readjustment of the transducer belts. We acknowledge that the belt holding the pressure transducer to measure contraction timing remained after the application of a FSE, however, women did not specifically state that this belt presented a problem. Similarly, to the current findings, discomfort in the systematic literature review was reported in relation to the FSE and transducer belts particularly around enforced immobility associated with continuous monitoring and considerable restriction in movement (Smith et al., 2017).

Perception of FSE

Women expressed initial concerns when the FSE was introduced to them by midwifery and medical staff. Concerns were typically centred around the impact the FSE may have on their baby and women described a lack of adequate information in relation to this. Interestingly, the previous pilot study also described women's feelings of uncertainty and concern in relation to the FSE (Bryson et al., 2017). Furthermore, women in the current study outlined that staff primarily referred to the FSE as a "scalp clip" which frightened women and they also felt it was not an accurate representation of the technology. Several women suggested that staff referring to it as a "scalp electrode" may increase acceptability of the technology. Women's initial concerns towards the FSE underlines the need for clear information to explain the procedure and potential risks, to enable decision making and that is aligned with women's views and preferences. The provision of clearer information will assist in mitigating potential issues around the application of the FSE and perceived mobility. However, it should be noted that this is not always possible, women described several instances where there was often no time for full explanation and consideration of the intervention if there were serious clinical concerns about the unborn baby's heart rate and the FSE needed to be placed immediately.

Positive experiences

Women described several positive impacts that the FSE had on their labour experiences, particularly when compared to their experiences with the belt-mounted ultrasound transducer. Benefits of the FSE reported by women included: increased mobility during labour; providing further reassurance; providing increased information for staff, which lead to increased feelings of safety, allowing women to relax and concentrate on labour. Contrary to our findings, the pilot study of women's prospective views towards monitoring described the FSE as adding an additional level of uncertainty to labour (Bryson et al., 2017). This speaks to the need for care providers to examine and consider women's experiences towards their care, and incorporate them into practice.

Strengths and limitations

To our knowledge, this is the first qualitative study to explore women's retrospective experiences with STan, which, for the first time, is being trialled in Australia. Previous research incorporating women's perceptions and experiences with STan has been limited with only one other qualitative study exploring women's prospective views of the monitoring using hypothetical vignettes. Furthermore, this is one of the few studies to examine women's experiences with different techniques of IFS. In terms of the research methodology, following Tracy's (2010) model for quality and excellence in qualitative research lends additional credibility to the study's findings. Moreover, analysis was conducted with rigour, with emerging themes being corroborated between authors (MB, DT & AS) and all authors reaching consensus on the final interpretations. While this study provides significant insight into women's experiences of monitoring of the fetal heart rate during labour, the

findings need to be considered within the context of the following limitations.

Despite the sample having diverse demographic characteristics, women were only sampled from one hospital (the RCT site), thus potentially limiting the generalisability of the findings beyond this setting. Women had to express interest in the interview to take part, and they may have been more inclined to participate when having criticism they wanted to share and it is also possible that women experiencing too much stress may have been less inclined to participate. Many of the birthing women at Women's and Children's Hospital have risk factors that may have necessitated periods of continuous CTG during the antenatal period and thus may be exposed to more than one monitoring experience during that pregnancy episode which could shape their experience and perception beyond what was directly experienced within the RCT setting. Furthermore, as previously described, there was a range of potential experiences women may have had with fetal surveillance during participation in START. This study did not aim to tease out the nuanced differences but rather to examine experiences with monitoring at a more general level – STan+CTG compared with CTG alone, with the main finding being that differences related more to whether or not a woman received an FSE. Additionally, although all of the women openly shared their experiences, there is always the potential for recall bias in interviews that are retrospective in nature.

Implications

Incorporating this qualitative component in relation to women's experiences of monitoring alongside the RCT with a primary focus on clinical outcomes has allowed for an exciting opportunity to demonstrate the importance of the additional examination of women's views and experiences. Findings from this study will have significant implications for health professionals including midwives and obstetricians, as well as implications for standard practice and care. Overall, women were very accepting of STan in addition to CTG as it was perceived and experienced as a more accurate form of monitoring than CTG alone. STan was reported to provide several benefits to women including a reduction in the chance of medical intervention including emergency caesarean section. In terms of the FSE which is always used with STan and more often than not used with CTG, women described it as reassuring, proving more accurate monitoring, and enabling increased mobility when compared to the belt-mounted ultrasound transducer belts alone. In contrast the belt-mounted ultrasound transducers were described as reducing mobility, providing less accurate monitoring and distracting women. These findings may therefore be used to inform staff perspectives and the development of consumer information to best support women to make informed and value-based choices about monitoring methods in labour. Further, findings provide support for the acceptability of STan in addition to CTG to women in Australia.

Conclusion

The current study has demonstrated the diverse impact that variances in monitoring technique can have on women's experiences of labour. Consideration of women's experiences and perceptions towards IFS is crucial to an understanding of this important aspect of care. Health care professionals must remain knowledgeable of the current evidence on IFS to engage in evidence-based care. Regular education for all staff that incorporates experiences of women, as identified in this study, will provide a useful opportunity to engage in effective evidence base practice informed not only by clinical outcomes, but also by views of women receiving this care. Findings may be used to inform the development of staff and consumer information to best support both women and staff

make informed and value-based individualised choices about utilisation of fetal monitoring technology during labour. Whilst START is comparing two forms of IFS (CTG alone compared to STan+CTG) from a clinical perspective, the current study has outlined that women's lived experiences were not determined by trial arm, but by whether the FSE was used or not. As a result, this study has importance and relevance in advancing the value of RCTs, as it provides an example of the valuable contribution that a qualitative enquiry can bring.

Ethical approval

This study was approved by both the Women's and Children's Hospital Network Human Research Ethics Committee and the University of Adelaide Human Research Ethics Committee (HREC/17/WCHN/14).

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Declaration of Competing Interest

None declared.

CRediT authorship contribution statement

Madeleine Benton: Conceptualization, Methodology, Investigation, Formal analysis, Writing - original draft, Writing - review & editing. **Amy Salter:** Conceptualization, Methodology, Formal analysis, Writing - review & editing. **Bronni Simpson:** Conceptualization, Methodology, Writing - review & editing. **Chris Wilkinson:** Conceptualization, Writing - review & editing. **Deborah Turnbull:** Conceptualization, Methodology, Formal analysis, Writing - review & editing.

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Supplementary materials

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