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Labour augmentation and fetal outcomes in relation to birth positions: a secondary analysis of an RCT evaluating birth seat births

Li Thies-Lagergren, Linda J. Kvist, Ann-Kristin Sandin-Bojö, Kyllike Christensson and Ingegerd Hildingsson
Introduction

Today many women in high income countries, as well as in countries that have adopted the birth culture from high income countries; give birth in a semi-recumbent or recumbent position (Lavender & Mlay, 2006; Sandin-Bojö & Kvist, 2008; de Jonge et al., 2009). It has however, been suggested that upright positions during birth can benefit the birthing woman by allowing spontaneous pushing, more efficient contractions, a shorter second stage of labour, less interventions and women experience their labour pain as easier to handle (Gardosi et al., 1989; de Jong et al., 1997, Bodner-Adler et al., 2003, Gupta et al., 2004; de Jonge et al., 2008). A birthing seat may facilitate women’s maintenance of an upright position during the second stage of labour. Labour and birth will possibly progress more efficiently when the birthing woman acts in accordance with her body’s signals, assuming upright positions or changing position frequently to find the best fit for the fetus through the pelvis (Romano & Lothian, 2008).
Synthetic oxytocin is the most commonly used drug in modern obstetrics (Holmgren et al., 2011). According to O’Driscoll et al. (1973) synthetic oxytocin is the main component, together with support from a personal midwife, in the concept of Active Management of Labour. Although the World Health Organization (WHO) states that initiation of augmentation of labour should be based on valid clinical indications and not performed routinely, the opposite has been found in clinical practice (WHO, 1996). It has been shown that women with uncomplicated pregnancies are subjected to routine intravenous infusions and augmentation of labour (Johanson et al., 2002; Sandin-Bojö & Kvist, 2008). A descriptive study from Sweden (Svärdby et al., 2007) showed that 70% of primiparous women were given synthetic oxytocin for augmentation sometime during labour and birth. In a further Swedish study it was shown that augmentation was used in an unstructured manner, where some women were inadequately treated and others were treated unnecessarily (Selin et al., 2009).

The benefits of synthetic oxytocin can be questionable. It may be helpful in preventing prolonged labour (Dencker et al, 2009) although no consensus regarding definition of prolonged labour is reached (Kjärgård et al., 2008). In a Swedish randomized controlled trial
(RCT) studying the effects of early versus delayed augmentation, Dencker et al. (2009) report a statistically significant reduction in total labour duration; measured as the time from randomization to birth. Yet no significant difference in duration of the second stage of labour was reported. A Cochrane systematic review showed that early augmentation of labour was associated with an increase in spontaneous vaginal births (Wei et al., 2009). Due to an increase in error reports, the Institute for Safe Medication Practices in the USA (2007) added intravenous synthetic oxytocin to their list of high-alert medications. When synthetic oxytocin is used incorrectly there is an increased risk for significant patient injury (Institute for Safe Medication Practices, 2007). In a recent Cochrane review, Bugg et al., (2011) did not find any detectable adverse effects for mother or infant with oxytocin use. However several researchers have reported that women who were given synthetic oxytocin were less likely to achieve a spontaneous vaginal birth. These women had increased risk for adverse maternal and foetal events; such as higher levels of pain and discomfort in labour, increase of cesarean section due to non-reassuring foetal heart rate (FHR) patterns, increased numbers of instrumental vaginal births and postpartum hemorrhage more than 1000 ml (Bugg et al., 2006; Oscarsson et al., 2006; Wei et al., 2009). Infants born to women subjected to augmentation had a significantly higher risk of Apgar score less than 7 at 5 minutes and for transferral to a
neonatal intensive care unit (Bugg et al., 2006; Oscarsson et al., 2006). In a Cochrane Review by Hodnett et al., (2011) the authors conclude that augmentation with synthetic oxytocin may increase the risk for a cascade of interventions during labour and birth. Kjärgård et al. (2009) found in a multi-center cohort study with prospectively collected data that birthing women diagnosed with dystocia and augmentation had more instrumental and cesarean deliveries, more often non-clear amniotic fluid and more post-partum hemorrhage.

The aim of this study was to assess whether there is a relationship between the use of synthetic oxytocin for augmentation, duration of labour and birth and infant outcomes in nulliparous women randomized to birth on a birth seat or any other position.

**Methods**

**Design and trial size**

The study was initially carried out as a trial to compare levels of instrumental vaginal birth in women who gave birth on a birth seat or in any other position for vaginal birth (Thies-Lagergren et al., 2011). The present paper presents a secondary analysis of the material where the use of oxytocin augmentation has been used as the primary outcome. Recommendations
from the CONSORT group (Consolidated Standards of Reporting Trials) were followed in this study (Schultz et al., 2010). Data were collected between November 2006 and July 2009 and during this period the average annual birth rate at the partaking hospitals was 3000 births.

**Inclusion criteria**

The study included nulliparous women who understood the Swedish language sufficiently well to receive information and give informed consent or refusal for participation.

Requirements for inclusion were; a healthy, uncomplicated pregnancy exclusive of any medical diagnosis, with a singleton foetus in cephalic presentation and spontaneous onset of labour occurring between gestational weeks 37 + 0 and 41 + 6 and a Body Mass Index (BMI) less than 30. Women diagnosed with gestational diabetes not requiring medical treatment were included. Women who were planning a vaginal birth after a previous caesarean section (VBAC) and women induced because of spontaneous rupture of membranes without spontaneous contractions for longer than twenty-four hours were also included.

**Recruitment of study participants**
Study participants were women who gave birth at two hospitals in Sweden, which were chosen for convenience. Women were given oral and written information and an invitation to join the study by midwives working in antenatal clinics. All participants gave written consent for participation in the study and this was documented in the participants’ case notes. Women were free to withdraw their consent throughout the whole trial. On admission to the delivery ward, the woman’s eligibility for participation in the trial was confirmed by the assisting midwife, who checked that the inclusion criteria were met.

**Randomisation and information**

Opaque and sealed envelopes containing randomization assignment were randomly mixed, numbered and placed in the central office on the labour wards. Each envelope also contained a data collection sheet. When the woman was admitted in active labour, the midwife asked whether the woman was still willing to participate and if so, drew an envelope in strict numerical succession. Figure 1 shows a flow-chart of the randomization process.
Data collection

Data collection sheets contained the mother’s date of birth, identification number and randomization number. If birth did not occur according to randomization the midwives were asked to record the reason for this on the data collection sheet. All other outcome measurements were available from the electronic case notes.

Outcome measurements

The primary outcome measurement was the use of synthetic oxytocin for labour augmentation during the second stage of labour.

Secondary outcome measurements were duration of synthetic oxytocin administration, duration of the second stage of labour (calculated as the number of minutes from the first cervical examination that revealed full dilation and vertex had reached the pelvic floor until birth), duration of third stage of labour, neonatal Apgar scores at five minutes, pH in umbilical cord blood and transfers to the neonatal intensive care unit (NICU).
Statistical analyses

The present article is a secondary analysis of a study that was powered to detect differences in instrumental deliveries. Analysis was by intention to treat and the data were analyzed using PASW (Predictive Analytics Software) version 18.0. For continuous data, mean values were compared using independent samples t-tests. For categorical data we calculated the relative risk (RR) with a 95 % confidence interval using a method described by Mantel and Haenszel in Rothman (2002). The study was approved by the committee for research ethics at Lund University [Dnr 2009/739].

Findings

Background variables are shown in Table 1. A majority (71.8 %) of the women in the trial were between 25 and 35 years of age, mean 28 (± 4.5). A total of 11 (1 %) had previously given birth by cesarean section and were therefore considered to be obstetrically nulliparous. Mean body mass index (BMI) at the first antenatal visit was 23 (±5) (data not shown).
Table 2 shows that nearly half of the women in the experimental group gave birth as allocated. Midwives documented reasons for non-compliance with randomization were as follows; medical indications were documented for 57 %, midwife’s preference for 11 % and maternal preference for 32 % of the non-compliances. In the control group the most usual birth position was semi-recumbent with or without stirrups. This position was used in 74 % of births. Seven women in the control group gave birth on the birth seat because that was their preferred position for birth (maternal preference). Of the study population 662 (66.2 %) were given synthetic oxytocin infusion for augmentation at some stage during the labour process.

Table 3 shows a comparison between the groups for augmentation of labour initiated during the first and second stages. There were no statistically significant differences between the groups regarding oxytocin for labour augmentation during either the first or second stages of labour. The mean duration of augmentation for the experimental group was 210 (±183) minutes and for the control group 205 (±178) minutes. This difference was not statistically significant ($t = 0.350, p = 0.730$).

Table 3 shows a comparison between the study groups for duration of labour. The experimental group showed a statistically significant shorter second stage of labour than the
control group. There were no significant differences between the groups for duration of the first or third stages of labour.

A majority (97%) of the infants were healthy at birth. Table 4 shows birth outcomes among the infants in the study. There were no statistically significant differences between the groups for infants with Apgar score $< 7$ at five minutes, with cord pH $< 7.05$ or who were transferred to the NICU. Among the infants transferred to NICU, 24 (75%) were born by mothers subjected to oxytocin augmentation.

Discussion

There were no differences between the experimental and control groups for use of synthetic oxytocin for augmentation or for neonatal outcomes. The study showed that women randomized to the experimental group had a statistically significant shorter second stage of labour than women randomized to the control group. However, less than half of the women randomized to give birth on the birth seat actually gave birth as allocated. It is important to
bear in mind that the analyses in this study are not based on a power calculation for a reduction in the use of synthetic oxytocin and results should be considered with this in mind.

**Synthetic oxytocin for augmentation**

Although it was not one of the outcome measurements in this study we compared the two study groups for the occurrence of oxytocin augmentation during the first stage of labour in order to clarify whether there was any difference between the groups as the women approached the second stage of labour. The difference between the experimental group and the control group for augmentation with synthetic oxytocin during the second stage of labour was not statistically significant. A “per protocol” analysis of the outcome variables is currently in progress and is planned for publication at a later date. The most recent review of upright birth position (Gupta et al. 2004) did not include labour augmentation as an outcome variable. However, our results regarding augmentation are consistent with an analysis of specific sub-groups by Waldenström and Gottvall (1991) who found that less women in the experimental group required synthetic oxytocin for augmentation compared to the control group.
In Sweden, augmentation with synthetic oxytocin is a frequent intervention and in the present study large numbers of nulliparous women were subjected to augmentation. This may in part be explained by the large number (45% in each group) of women who used epidural analgesia for labour pain. It is well-known that epidural is associated with an increased use of oxytocin for augmentation (Selin et al., 2009; Eriksen et al., 2011; Kesmodel & Jølving, 2011). Another explanation could be the lack of compliance with the local guidelines at the hospitals where the study was carried out. Local guidelines recommend augmentation when diagnosis of dystocia has been made; that is, two hours of non-progress in a labour which has been clearly established earlier.

Despite its benefit in prolonged labour, the side-effects of synthetic oxytocin must be acknowledged. The association between use of synthetic oxytocin and hyper uterine action, foetal distress and adverse neonatal outcomes are well known (Jonsson, 2009). The culture of “getting through the work”, so that less work is left for the midwives on the next shift, results in an acceleration of labour as described by Blix-Lindström et al. (2008). This culture influences those midwives who need to feel in control over decisions and to feel that they have decisive power within their profession (Blix-Lindström et al. 2008).
The evidence described in the scientific literature regarding synthetic oxytocin for augmentation during childbirth is difficult to construe due to conflicting results (Jonsson et al., 2008). No studies on long-term consequences of intravenous oxytocin administration to birthing women have, to our knowledge, been reported which means that at the present time it is not possible to judge whether its frequent use during labour and birth is medically justifiable.

**Infant’s health**

The trial did not affect outcomes for the infants and this is in accordance with results in a meta-analytic review concerning maternal position during the second stage (de Jonge et al., 2004). Few infants had any adverse outcomes. However, two-thirds of the infants who were transferred to the NICU were born by mothers subjected to synthetic oxytocin for augmentation and of these infants, 70% of their mothers were either in a semi-recumbent position \( n=5 \) or in supine with stirrups \( n =17 \) during the birth. The inferior vena cava syndrome is known as a consequence of maternal supine position (Goodlin, 1971). The
International Federation of Gynecology and Obstetrics (FIGO) states that a fetus that is healthy and well oxygenated can handle quite powerful and frequent contractions, while a fetus with reduced metabolic reserves and supply of oxygen will suffer at the same labour intensity and frequency (FIGO, 1987). Lack of longitudinal studies of the effects oxytocin may have on infants, requires that exposure to oxytocin should be limited. At the present time it is not possible to identify which infants may be negatively affected by the use of oxytocin and therefore its indiscriminate use by midwives is not either justifiable.

**Shorter second stage**

Despite similar background characteristics, similar proportions of epidurals and augmentation, women allocated to the birth seat had a significantly shorter second stage of labour and it has been shown that this did not cause any increase in perineal lacerations (Thies-Lagergren et al., 2011). This finding could be explained by the upright positioning facilitated by the birth seat, which is in accordance with the results reported by Waldenström & Gottvall (1991). It is even possible that the position facilitates spontaneous pushing. Gupta et al., (2004) suggested that a shorter duration of the second stage was related to the upright position and not to the birth seat.
per se. It is imperative for midwives, in their care of birthing women during the second stage of labour, to recognize the value of women’s spontaneous bearing-down efforts and the effect this has on progress of the birth (Hanson, 2009).

Michel et al. (2004) performed a study at an institute of radiology in Switzerland which aimed to measure the impact of supine and upright birthing positions on pelvimetric dimensions measured by MR (magnetic resonance). Their findings suggested an obstetrical advantage to being upright during the second stage; the sagittal outlet and interspinous diameters were significantly greater in a squatting position compared to a supine position (Michel et al., 2002). The position when sitting on a birth seat is similar to the squatting position.

The reduction in the second stage of labour by six minutes may seem too short a time to have any clinical relevance. It is certainly one of statistics greatest problems that “mean values” which are based on more than 1000 observations have little meaning for the individual. However, the mean value of 6 minutes tells us that in some of the observations the second stage will be longer rather than shorter but also that some will be shortened considerably more
than 6 minutes and therefore of clinical relevance for those women whose second stage of labour is significantly reduced.

**Methodological considerations**

The strengths of this study are the RCT-design and the fairly large number \((n =1002)\) of women included. However, the high rate of non-compliance must be taken into account when interpreting the results. According to Hundley and Cheyne (2004) loss of study participants is a common problem in intrapartum trials and levels of non-compliance tend to be high. Only half of the women allocated to birth on the birth seat actually gave birth this way. Similar results regarding non-compliance were reported in a Swedish RCT which was carried out 20 years ago and included 294 women (Waldenström & Gottvall, 1991). They found that 49.3 % of the women allotted to a birth seat actually followed the model of allocation. Apart from non-compliance, major problems in RCT research are high dropout rates and selection bias due to reliance on midwives in identifying appropriate participants. These problems result in
difficulties in assessing the generalisability of trials (Hundley & Cheyne, 2004; Shepherd et al., 2010).

It can be questioned whether it is ethical to ask pregnant women to participate in intrapartal randomised controlled trials. Childbirth is a personal and individual experience as well as a very vulnerable state of being for the birthing woman. A feasibility study regarding randomisation to either water birth or land-birth indicated that women were willing to participate (Woodward & Kelly, 2004). However it must be acknowledged that women willing to participate in intrapartal trials may differ from the birthing population in general. The water birth study found that the women were happy to participate to help produce evidence for healthcare professionals and other parents (Woodward & Kelly, 2004).

Medical reasons for non-compliance

In the present study the major reasons for reported non-compliance registered in the protocols were medical indications. In many cases midwives determined either that foetal wellbeing was compromised or that more surveillance was needed due to signs of foetal distress and
therefore did not recommend the women to continue birthing on the birth seat. Birth on a birth seat does not restrict internal or external foetal surveillance. Of the 251 non-compliances with randomization, less than five percent were due to emergency caesarean section and 13.6 % were due to instrumental vaginal birth. Some cases were assessed as prolonged second stage of labour and midwives encouraged women to move from the birth seat to the bed and give birth in a semi-recumbent position.

**Midwives’ reasons for non-compliance**

Non-compliance was also related to midwives’ judgments of presumed participants.

Researchers have argued that midwives are moderately research oriented but lack sufficient research training and time for involvement in research activities including RCTs (Roxburgh, 2006; Watson & Torgerson, 2006). It has been suggested that midwives judge some patients as not up to trial involvement and don’t bother trying to recruit them; around 30 % of women eligible for perinatal trials are not recruited, probably because the midwife judged they were too far advanced in labour (Hundley & Cheyne, 2004). Personal attitudes and midwives’ own physical capacity may have had an impact in the present study. There could also be a discrepancy between women’s and midwives’ preferences about birth position. In an RCT by
Waldenström & Gottvall (1991) only 33% of the assisting midwives indicated that the experience of assisting women on a birth seat were positive. They found that midwives assisting women on a birth seat were less satisfied with their own working postures compared to midwives who cared for women in a supine position. Similar findings were also reported in a feasibility study of birth on a birth seat (Thies-Lagergren & Kvist, 2009) where midwives expressed problems in finding a comfortable position that would allow them an overview of the perineum when assisting women giving birth on a birth seat. Midwives’ preferences in assisting women in upright positions in the second stage of labour has been scantily investigated, but Coppen (2005) found in a survey that midwives who need to feel in control of birth preferred women to be in a position that they were familiar with. In most cases this meant a recumbent or semi-recumbent position. In contrast midwives who allow women control over birth gave highest priority to upright positions (Coppen, 2005).

**Maternal reasons for non-compliance**

Among the women who did not comply to allocation nearly one third of the reasons were, according to the midwives’ protocols, women’s preferences or circumstances around birth
that were not medical reasons. Participating women were free to withdraw their consent and change birth position without explanation. Midwives reported that 50 women regretted giving their consent for participation or were not able to get down on the birth seat because of exhaustion or physical limitations. We have, however, no information about the discourse in the labour room, about the midwife-woman relationship or to what extent midwives reminded women about their allocated birth position. Nevertheless, Waldenström & Gottvall (1991) described that women allocated to the birth seat group were more satisfied than women in the control group who gave birth in a conventional semirecumbent position.

Upright birth positioning can be a symbol the hierarchy of birth; when a woman chooses to give birth in a upright position she is on top, she has much more control over the environment and other actors in the birth room and the postural change to upright can impact on her psyche and be empowering (Jones, in Davis-Floyd et al., 2009). The authors of the present study agree that the woman’s autonomy in the birthing room is paramount and her wishes for birth position should always be respected. However, women may not always be aware of the possibilities available. In 1997 de Jong et al. suggested that pregnant women should be informed of the benefits of upright birthing positions and be encouraged to take an upright
position during labour. de Jonge et al. (2008) discuss the possibility of giving women informed choice during antenatal care regarding birthing position and of considering women’s preferences as a starting point. Midwives should, according to the Royal Colleges of Midwives (RCM), be proactive in demonstrating and encouraging different positions in labour (RCM, 2011).

**Conclusion**

Women allocated to the birth seat had a significantly shorter second stage of labour even though similar numbers of women in both groups were subjected to oxytocin augmentation. No adverse outcomes were found among infants born by mothers allocated to the birth seat. The birth seat can be suggested as a non-medical intervention that may facilitate reduced duration of the second stage of labour. Furthermore it is recommended that caregivers, both midwives and midwifery students, should learn skills to assist women in using a variety of birth positions.
<table>
<thead>
<tr>
<th></th>
<th>Previous Casey Sm.</th>
<th>Current Casey Sm.</th>
<th>Previous Casey R.</th>
<th>Current Casey R.</th>
<th>Age Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.01 (12)</td>
<td>0.01 (12)</td>
<td>0.01 (12)</td>
<td>0.01 (12)</td>
<td>35 years</td>
</tr>
<tr>
<td></td>
<td>0.01 (12)</td>
<td>0.01 (12)</td>
<td>0.01 (12)</td>
<td>0.01 (12)</td>
<td>35 years</td>
</tr>
<tr>
<td></td>
<td>(0.01) (12)</td>
<td>(0.01) (12)</td>
<td>(0.01) (12)</td>
<td>(0.01) (12)</td>
<td>35 years</td>
</tr>
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<td></td>
<td>(0.01) (12)</td>
<td>(0.01) (12)</td>
<td>(0.01) (12)</td>
<td>(0.01) (12)</td>
<td>35 years</td>
</tr>
</tbody>
</table>

Table 1: Background variables in relation to randomization
Table 2. Birth position variables described in relation to randomization

<table>
<thead>
<tr>
<th>Position</th>
<th>Control Group</th>
<th>Experimental Group</th>
<th>Total Study Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>21 (9.8)</td>
<td>21 (4.5)</td>
<td>21 (4.5)</td>
<td>21 (4.5)</td>
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<tr>
<td>49 (23.8)</td>
<td>49 (23.8)</td>
<td>49 (23.8)</td>
<td>49 (23.8)</td>
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<tr>
<td>61 (29.6)</td>
<td>61 (29.6)</td>
<td>61 (29.6)</td>
<td>61 (29.6)</td>
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<tr>
<td>82 (40.8)</td>
<td>82 (40.8)</td>
<td>82 (40.8)</td>
<td>82 (40.8)</td>
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<tr>
<td>113 (55.3)</td>
<td>113 (55.3)</td>
<td>113 (55.3)</td>
<td>113 (55.3)</td>
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<tr>
<td>135 (66.5)</td>
<td>135 (66.5)</td>
<td>135 (66.5)</td>
<td>135 (66.5)</td>
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<tr>
<td>157 (76.7)</td>
<td>157 (76.7)</td>
<td>157 (76.7)</td>
<td>157 (76.7)</td>
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<tr>
<td>179 (88.9)</td>
<td>179 (88.9)</td>
<td>179 (88.9)</td>
<td>179 (88.9)</td>
</tr>
<tr>
<td>201 (99.1)</td>
<td>201 (99.1)</td>
<td>201 (99.1)</td>
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<tr>
<td>223 (100)</td>
<td>223 (100)</td>
<td>223 (100)</td>
<td>223 (100)</td>
</tr>
<tr>
<td>Birth position</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kneeling/standing position</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supine position + supports</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supine position</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laternal position + one stripe</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laternal position</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Brim seal</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>HB (95% CI)</td>
<td>Duration of Labour and Birth</td>
<td>Experimental Group</td>
<td></td>
</tr>
<tr>
<td>-------------</td>
<td>-----------------------------</td>
<td>--------------------</td>
<td></td>
</tr>
<tr>
<td>0.00</td>
<td>0.00 (0.98-1.12)</td>
<td>2.26 (4.35)</td>
<td></td>
</tr>
<tr>
<td>1.00</td>
<td>1.00 (0.98-1.12)</td>
<td>2.25 (4.35)</td>
<td></td>
</tr>
</tbody>
</table>

**Obstetric intervention during Labour and Birth**

- No oxytocin during Labour and Birth
- Oxytocin administration initiated during second stage of labour after cervix of the birth
- Oxytocin administration initiated during first stage of labour

<table>
<thead>
<tr>
<th>Duration of Labour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time in minutes</td>
</tr>
<tr>
<td>First stage in minutes</td>
</tr>
<tr>
<td>Second stage in minutes</td>
</tr>
<tr>
<td>Third stage in minutes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(%)</th>
<th>(n=502)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td></td>
</tr>
<tr>
<td>n=502</td>
<td></td>
</tr>
</tbody>
</table>

Table 3. Duration of labour and oxytocin administration during labour and birth compared to all other positions except caesarean section.
<table>
<thead>
<tr>
<th>$P_H &gt; 7.05$</th>
<th>0.94 (0.69-1.26)</th>
<th>1.17 (1.09-1.25)</th>
<th>1.27 (1.14-1.42)</th>
<th>1.05 (0.88-1.25)</th>
<th>1.04 (0.87-1.26)</th>
</tr>
</thead>
<tbody>
<tr>
<td>After $\text{Hemoglobin} &lt; 1000$</td>
<td>12 (1.4)</td>
<td>69 (1.2)</td>
<td>69 (1.2)</td>
<td>69 (1.2)</td>
<td>69 (1.2)</td>
</tr>
<tr>
<td>Prescribed: occupational position (seated, light)</td>
<td>18 (1.6)</td>
<td>43 (4.5)</td>
<td>43 (4.5)</td>
<td>43 (4.5)</td>
<td>43 (4.5)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(%)</th>
<th>(%)</th>
<th>(%)</th>
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</thead>
<tbody>
<tr>
<td>$u$</td>
<td>$u$</td>
<td>$u$</td>
</tr>
<tr>
<td>$n=42$</td>
<td>$n=292$</td>
<td>$n=1002$</td>
</tr>
</tbody>
</table>

| Total study population | Experimental Group | Control Group |

| RR | |

*Table 4: Birth outcome in relation to randomization*
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