Studies on induced labor
Bakker, J.J.H.

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Internal versus external tocodynamometry during induced or augmented labour (Review)

Jannet J. H. Bakker
Petra F. Janssen
Karlijn van Halem
Birgit Y. van der Goes
Dimitri N. Papatsonis
Joris A. M. van der Post
Ben Willem J. Mol

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ABSTRACT

**Background** Uterine contractions can be registered by external tocodynamometry (ET) or, after rupture of the membranes, by internal tocodynamometry (IT). Monitoring of the frequency of contractions is important especially when intravenous oxytocin is used as excessive uterine activity (hyperstimulation or tachysystole) can cause fetal distress. During induction of labour as well as during augmentation with intravenous oxytocin, some clinicians choose to monitor frequency and strength of contractions with IT rather than with ET as an intrauterine pressure catheter measures intrauterine activity more accurately than an extra-abdominal tocodynamometry device. However, insertion of an intrauterine catheter has higher costs and also potential risks for mother and child.

**Objectives** To assess the effectiveness of IT compared with using ET when intravenous oxytocin is used for induction or augmentation of labour.

**Search methods** We searched the Cochrane Pregnancy and Childbirth Group’s Trials Register (11 April 2012) and PubMed (1966 to 7 March 2012).

**Selection criteria** We included all published randomised controlled trials with data from women in whom IT was compared with ET in induced or augmented labour with oxytocin. We excluded trials that employed quasi-randomised methods of treatment allocation. We found no unpublished or ongoing studies on this subject.

**Data collection and analysis** Two review authors independently assessed trial eligibility and risk of bias, and independently extracted data. Data were checked for accuracy. Where necessary, we contacted study authors for additional information.

**Main results** Three studies involving a total of 1945 women were included. Overall, risk of bias across the three trials was mixed. No serious complications were reported in the trials and no neonatal or maternal deaths occurred. The neonatal outcome was not statistically different between groups: Apgar score less than seven at five minutes (RR 1.78, 95% CI 0.83 to 3.83; three studies, n = 1945); umbilical artery pH less than 7.15 (RR 1.31, 95% CI 0.95 to 1.79; one study, n = 1456); umbilical artery pH less than 7.16 (RR 1.23, 95% CI 0.39 to 3.92; one study, n = 239); admission to the neonatal intensive care unit (RR 0.34, 95% CI 0.07 to 1.67; two studies, n = 489); and more than 48 hours hospitalisation (RR 0.92, 95% CI 0.71 to 1.20; one study, n = 1456). The pooled risk for instrumental delivery (including caesarean section, ventouse and forceps extraction) was not statistically significantly different (RR 1.05, 95% CI 0.91 to 1.21; three studies, n = 1945). Hyperstimulation was reported in two studies (n = 489), but there was no statistically significant difference between groups (RR 1.21, 95% CI 0.78 to 1.88).
Authors’ conclusions This review found no differences between the two types of monitoring (internal or external tocodynamometry) for any of the maternal or neonatal outcomes. Given that this review is based on three studies (N = 1945 women) of moderate quality, there is insufficient evidence to recommend the use of one form of tocodynamometry over another for women where intravenous oxytocin was administered for induction or augmentation of labour.

BACKGROUND

Oxytocin in labour
Since 1906 the contractile properties of oxytocin on uterine myometrial smooth muscle has been described.1 Initially, an extract of the posterior pituitary was used for treatment of postpartum bleeding. Since the cloning of the gene in 1983, synthetic oxytocin is now produced in different forms by pharmaceutical companies.2 Oxytocin is usually administered in a diluted intravenous infusion; it cannot be administered orally because it is quickly metabolized in the gastrointestinal tract. Uterine muscle cells respond rapidly to administration, within three to five minutes, and a steady state is achieved within 40 minutes.3 Oxytocin is quickly metabolized by several enzymes including peptidases in the kidneys and oxytocinase excreted by the placenta.3 Administration of intravenous oxytocin is the most common intervention in obstetrical care and is used for induction of labour as well as for augmentation in cases of arrest of labour. Oxytocin has a positive impact on the strength and frequency of contractions. Some obstetricians combine low amniotomy with intravenous oxytocin titrations immediately following or within an hour, while others advocate a delay of four to six hours.4 A Cochrane review demonstrated that the combination of oxytocin administration for induction with amniotomy compares well with other forms of induction.5 Another Cochrane review demonstrated that use of prostaglandins is more effective than oxytocin alone for ripening of the cervix in the case of an unfavourable cervix, but that oxytocin is as effective when used alone in women with ruptured membranes.6

Oxytocin complications
Potential complications caused by the use of intravenous oxytocin for induction or augmentation of labour are hyponatraemia, hypotension and hyperstimulation.3 Hyponatraemia is an electrolyte disturbance in which the sodium concentration in the serum is below 135 mEq/L. Excessive uterine activity (hyperstimulation or tachysystole) is defined by the American College of Obstetricians and Gynecologists (ACOG) as more than five
contractions in 10 minutes, lasting at least two minutes, or contractions of normal duration within one minute of each other. When contractions are too frequent, the recovery period between contractions shortens and this may affect fetal oxygenation, cause fetal hypoxia and even lead to brain damage. On the other hand, signs of fetal hypoxia increase the risk for instrumental delivery and consequently iatrogenic damage to mother and child. Reducing the risk of hyperstimulation and thus fetal hypoxia by accurate measurement of contractions could therefore lead to a reduction in fetal and maternal morbidity.

Internal tocodynamometry complications
Intrauterine pressure catheter placement, a routine procedure in labour and delivery, has the possibility of infrequent but potentially hazardous risks for mother and child. Insertion of an intrauterine catheter during labour is usually an easy procedure to accomplish. In the literature, however, there have been reports of an increased risk of intrauterine infections and repeated case reports of placental or fetal vessel damage despite management lege artis. Extramembranous placement occurs 14% to 38% of the time, with adverse events occurring in one in 1400 placements. More recently two cases were reported with an anaphylactoid syndrome of pregnancy, previously known as amniotic fluid embolism, after intrauterine pressure catheter placement. This was expressed as a life threatening anaphylactic reaction with acute onset of severe hypoxia, neurologic sequelae, and haemodynamic collapse with subsequent cardiopulmonary failure followed by disseminated intravascular coagulation.

Internal tocodynamometry versus external tocodynamometry
Uterine contractions can be assessed by palpation of the fundus of the uterus and observation of the mother. With this method the obstetrician gets a snapshot and no long term hard copy registration of the contraction in relation to the fetal heart rate. Therefore, this method will not be included.

External tocodynamometry (ET) is a method that continuously records contractions by using a belt to place a transducer on the fundus; these recordings are affected by maternal movements. ET measures the change of the shape of the uterus in relation to the abdominal wall during a contraction. This method is used to measure the frequency of the contractions, but not the intrauterine change of pressure.

Internal tocodynamometry (IT) monitors uterine activity with a strain gauge (an intrauterine pressure catheter) inserted into the cavity of the uterus next to the fetus, which provides data on the frequency and duration of uterine contractions. Insertion of an intrauterine pressure catheter is done during a vaginal examination and is a simple procedure that is carried out by both midwives and doctors. The device measures the intrauterine pressure, expressed in Montevideo units, at rest and during contractions. All methods provide good information on the frequency of contractions and an indication of their duration.
Both during induction of labour as well as augmentation, some clinicians choose to monitor the frequency and strength of contractions with IT rather than ET, as IT measures intrauterine activity more accurately. 18

There are several arguments in favour of IT.

1. When using oxytocin, exact monitoring of contractions is demanded in order to prevent hyperstimulation. ET does not accurately register contractions in all women and in all positions of the labouring woman so it can underestimate the uterine contractions, which may lead to excessive use of oxytocin and thus hyperstimulation. Some state that the use of IT, by accurately measuring uterine contractions, leads to a more moderate amount of oxytocin and reduces the risk of hyperstimulation.

2. Among women in their child bearing years, 8% have severe obesity with a body mass index above 40 kg/m². 19 This group have more obstetric complications such as pre-eclampsia and gestational diabetes. Induction of labour is common in this group of women and uterine activity can be difficult to assess with ET. The distance from the external tocodynamometer on the skin to the uterine wall could be such that reliable measurement of uterine contractions is not possible. IT could therefore be more useful in this group of women.

3. Some argue that the use of IT might facilitate the clinical diagnosis of uterine rupture, especially in women with a previous caesarean section, because the expectation is that the pressure inside the uterine cavity flattens and lowers when the uterine wall is ruptured. This, however, is not supported by the literature. 20 In this review of 76 cases of uterine rupture, 39 were monitored with an intrauterine pressure catheter. The classic description of a loss of intrauterine pressure or cessation of labour was not observed in any of the patients.

Furthermore, routine use of IT in every induced or augmented woman is costly as the rates of induction and augmentation are increasing. Labour induction rates in the United States has risen from less than 10% of deliveries to more than 22% between 1990 and 2008; and augmentation took place in more than 20% of all deliveries in 2008 according to data from the Centers for Disease Control and Prevention. 21 Routine use of IT in 40% of all deliveries would add significant public health costs, of roughly USD 200 million/year.

OBJECTIVES

The primary aim of this review was to evaluate the effectiveness of internal tocodynamometry (IT) compared with external tocodynamometry (ET) when intravenous oxytocin is used for induction or augmentation of labour.
Criteria for considering studies for this review

Types of studies
We included all published, unpublished and ongoing randomised controlled trials in which IT was compared with external monitoring or no monitoring in women undergoing induction or augmentation of labour with oxytocin. Cluster-randomised trials and trials using a crossover design were excluded. We excluded trials that employed quasi-randomised methods of treatment allocation.

Types of participants
Pregnant women undergoing induction of labour or augmentation of labour with intravenous oxytocin.

Types of interventions
Insertion of all types of intrauterine pressure catheters during labour compared with ET or no monitoring

Types of outcome measures
Primary outcomes
- Uterine rupture
- Hyperstimulation
- Apgar score less than seven at five minutes
- Umbilical artery pH
- Admission of newborn to neonatal intensive care unit

Secondary outcomes
These included other measures of effectiveness, complications and health service use.

Maternal
- Mode of delivery
- Number of instrumental deliveries
- Antepartum haemorrhage
- Postpartum haemorrhage
- Placental or fetal vessel damage
- Duration of hospital stay
- Serious maternal outcomes (defined as death, coma, cardiac arrest, respiratory arrest, use of a mechanical ventilator, admission to intensive care unit)
- Maternal infection
- Women's satisfaction

Neonatal
- Time to delivery
• Neonatal morbidity
• Neonatal infection
• Respiratory distress syndrome
• Use of mechanical ventilation
• Intraventricular haemorrhage
• Neonatal jaundice
• Neonatal sepsis
• Neonatal death

Health service
• Neonatal length of hospital stay
• Maternal admission to intensive care unit
• Total hospital costs
• Use of health services

Electronic searches
We searched the Cochrane Pregnancy and Childbirth Group’s Trials Register by contacting the Trials Search Co-ordinator (11 April 2012). The Cochrane Pregnancy and Childbirth Group’s Trials Register is maintained by the Trials Search Coordinator and contains trials identified from:
1. monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. weekly searches of MEDLINE;
3. weekly searches of EMBASE;
4. hand searches of 30 journals and the proceedings of major conferences;
5. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Trials identified through the searching activities described above were each assigned to a review topic (or topics).
The Trials Search Coordinator searched the register for each review using the topic list rather than keywords.
In addition, we searched PubMed (1966 to 7 March 2012) using the search terms detailed in Appendix 1.
We did not apply any language restrictions.

Data collection and analysis

Selection of studies
Two review authors, PF Jansen (PJ) and JJH Bakker (JB), independently assessed all the potential studies identified as a result of the search strategy. BY van der Goes (BG) was asked to assess the Bakker 2010 trial as she was not involved in the conducting or writing up of this study. Disagreements were resolved through discussion.
Data extraction and management

We designed a form to extract data. For eligible studies, two review authors PJ and JB independently extracted the data using the agreed form. For the Bakker 2010 trial, co-author BG was asked to extract data from the trial. We resolved discrepancies through discussion. We used the Review Manager software (RevMan 2011) to double enter all the data, or a subsample. When information regarding any of the above was unclear, we attempted to contact the authors of the original reports for them to provide additional information or data.

Assessment of risk of bias in included studies

Two authors (PJ and JB) independently assessed the risk of bias for each study using the criteria outlined in section 8 of the Cochrane Handbook for Systematic Reviews of Interventions. There was no disagreement. We considered two major sources of potential bias and the methods of avoidance of these biases when assessing trial quality. Moreover, we looked specifically at declared sample size calculations, defined inclusion and exclusion criteria, baseline comparability and whether a conflict of interest was present, absent or unclear.

(1) Random sequence generation (checking for possible selection bias)

We described for each included study the method used to generate the allocation sequence to allow an assessment of whether it should produce comparable groups. We assessed the method as:
• low risk of bias (any truly random process, e.g. random number table; computer random number generator);
• high risk of bias (any non-random process, e.g. odd or even date of birth; hospital or clinic record number); or
• unclear risk of bias.

(2) Allocation concealment (checking for possible selection bias)

We described for each included study the method used to conceal allocation to interventions prior to assignment and assessed whether intervention allocation could have been foreseen in advance of or during recruitment, or changed after assignment. We assessed the methods as:
• low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
• high risk of bias (open random allocation; unsealed or nonopaque envelopes; alternation; date of birth);
• unclear risk of bias.
(3.1) Blinding of participants and personnel (checking for possible performance bias)

We described for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We considered that studies were at low risk of bias if they were blinded, or if we judged that the lack of blinding would be unlikely to affect results. We assessed blinding separately for different outcomes or classes of outcomes. We assessed the methods as:
- low, high or unclear risk of bias for participants;
- low, high or unclear risk of bias for personnel

(3.2) Blinding of outcome assessment (checking for possible detection bias)

We described for each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received. We assessed blinding separately for different outcomes or classes of outcomes.

We assessed methods used to blind outcome assessment as:
- low, high or unclear risk of bias.

(4) Incomplete outcome data (checking for possible attrition bias due to the amount, nature and handling of incomplete outcome data)

We described for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported and the numbers included in the analysis at each stage (compared with the total number of randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported, or could be supplied by the trial authors, we re-included missing data in the analyses which we undertook.

We assessed methods as:
- low risk of bias (e.g. no missing outcome data; missing outcome data balanced across groups);
- high risk of bias (e.g. numbers or reasons for missing data imbalanced across groups; ‘as treated’ analysis done with substantial departure of the intervention received from that assigned at randomisation);
- unclear risk of bias.

(5) Selective reporting (checking for reporting bias)

We described for each included study how we investigated the possibility of selective outcome reporting bias and what we found.

We assessed the methods as:
- low risk of bias (where it was clear that all of the study’s pre-pecified outcomes and all expected outcomes of interest to the review have been reported);
• high risk of bias (where not all the study’s pre-specified outcomes have been reported; one or more reported primary outcome was not pre-specified; outcomes of interest were reported incompletely and so cannot be used; study failed to include results of a key outcome that would have been expected to have been reported);
• unclear risk of bias.

(6) Other bias (checking for bias due to problems not covered by (1) to (5) above)
We described for each included study any important concerns we had about other possible sources of bias.
We assessed whether each study was free of other problems that could put it at risk of bias:
• low risk of other bias;
• high risk of other bias;
• unclear whether there was a risk of other bias.

(7) Overall risk of bias
We made explicit judgements about whether studies were at high risk of bias, according to the criteria given in the Handbook for Systematic Reviews of Interventions. 22 With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias and whether we considered it likely to impact on the findings. We explored the impact of the level of bias through undertaking sensitivity analyses (see Sensitivity analysis).

Measures of treatment effect
We carried out statistical analysis using the Review Manager software (RevMan 2011). We used fixed-effect model meta-analysis for combining data in the absence of significant heterogeneity if trials were sufficiently similar. If heterogeneity was found, this was explored by sensitivity analysis followed by use of a random-effects model if required. Probable causes of heterogeneity could be the body mass index (BMI) of the woman in labour, parity, gestational age and birthweight. For dichotomous data, we presented results as summary relative risk with 95% confidence interval.
For continuous data, we used the median as outcomes were measured in the same way between trials.

Dealing with missing data
For included studies, we noted levels of attrition. We explored the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis. For all outcomes we carried out analyses, as far as possible, on an intention-to-treat basis. That is, we attempted to include all participants randomised to each group in the analyses, and all participants were analysed in the group to which
they were allocated regardless of whether or not they received the allocated intervention. The denominator for each outcome in each trial was the number randomised minus any participants whose outcomes were known to be missing.
We assessed statistical heterogeneity in each meta-analysis using the $T^2$, $I^2$ and $\chi^2$ statistics. We regarded heterogeneity as substantial if $I^2$ was greater than 30% and either $T^2$ was greater than zero or there was a low $P$ value (less than 0.10) in the $\chi^2$ test for heterogeneity.

Assessment of reporting biases
In future updates of this review, if there are 10 or more studies in the meta-analysis we will investigate reporting biases (such as publication bias) using funnel plots. We will assess funnel plot asymmetry visually, and also use formal tests for funnel plot asymmetry. For continuous outcomes we will use the test proposed by Egger, and for dichotomous outcomes we will use the test proposed by Harbord. If asymmetry is detected in any of these tests or is suggested by a visual assessment, we will perform exploratory analyses to further investigate the causes.

Data synthesis
We carried out statistical analysis using the Review Manager software. We used fixed-effect model meta-analysis for combining data where it was reasonable to assume that studies were estimating the same underlying treatment effect; that is where trials were examining the same intervention, and the trials’ populations and methods were judged sufficiently similar. If there was clinical heterogeneity sufficient to expect that the underlying treatment effects would differ between trials, or if substantial statistical heterogeneity was detected, we explored the reason for the heterogeneity by subgroup analysis. We discussed the clinical implications of treatment effects differing between trials. If the average treatment effect was not clinically meaningful we did not combine trials.

Subgroup analysis and investigation of heterogeneity
If we identified substantial heterogeneity, we investigated it using subgroup analyses and sensitivity analyses. We considered whether an overall summary was meaningful and, if it was, used random-effects model meta-analysis to produce it. We planned to carry out the following subgroup analyses for the outcome ‘duration of labour’:
1. induction of labour;
2. augmentation of labour.
We planned to carry out subgroup analysis in the group of women with a previous caesarean section.
For fixed effect model inverse variance meta-analyses we assessed differences between subgroups by interaction tests.
For random effects and fixed effect model meta-analyses using methods other than inverse variance, we assessed differences between subgroups by inspection of the confidence intervals; non-overlapping confidence intervals indicate a statistically significant difference in treatment effect between the subgroups.

Sensitivity analysis

In future updates of this review, as more data become available, we will carry out sensitivity analysis to explore the effect of trial quality if trials of differing quality are included in the review. This will involve analysis based on our assessment of whether trials are at risk of selection bias or attrition bias. Studies of poor quality (those rated as ‘high’ or ‘unclear’ risk of bias for sequence generation, allocation concealment, or incomplete outcome data) will be excluded in the analysis in order to assess any substantive difference compared to the overall result.

RESULTS

Description of studies

Results of the search

The search of the Pregnancy and Childbirth Group Trials Register found 14 reports and our search of Pub Med found 189. After screening the titles and abstracts we selected 25 reports of 19 studies. We included three and excluded 16 titles. Two review authors (PJ and JB) independently assessed all the potential studies identified as a result of the search strategy. Both authors used a data form to assess the quality of the studies and extract data from the included studies. There were four potentially eligible randomised controlled trials with a randomised comparison of external tocodynamometry (ET) and internal tocodynamometry (IT). We found no unpublished or ongoing studies on this subject.

Included studies

We included three studies (Chua 1990; Chia 1993; Bakker 2010) involving 1945 women. Furthermore we used the report of van Halem 2011, a follow up of the randomised controlled trial of Bakker 2010, that contained data for the infection outcome. The two studies of Chia and Chua were performed in Singapore, and the third study was performed in the Netherlands. All studies were in hospital settings. The methodological quality of the trials was considered good. The three randomised controlled trials had good comparable methods and outcomes. In the trials of Chia 1993 and Chua 1990, it remained unclear whether the study population included women with a previous caesarean section. In the trial of Bakker 2010 women with a previous caesarean section were excluded.

For details of the included studies, see the table Characteristics of included studies.
### Excluded studies

We excluded 16 studies. There were many publications about intra- and extramembranous placement of the catheter, differences between different types of catheters and case reports about adverse events. We did not include these studies in this review but focused on the randomised comparison of ET and IT. We agreed to exclude one study that compared ET and IT, the study of Panayotopoulos 29, because of the invalid randomisation method, which involved selecting every second case and ended up with two unequal study groups. We did not identify any studies comparing tocodynamometry with no monitoring. For details of excluded studies, see the table Characteristics of excluded studies.

### Risk of bias in included studies

#### Allocation

The Bakker 2010 trial used a central, computerised randomisation program that provided the allocation of included women at the different study sites, so it was ensured that the sequence was concealed. Women in the studies of Chia 1993 and Chua 1990 were randomly allocated to the different methods of tocography by using a random number table; this method was acceptable at the time and has a low risk of selection bias. Chia 1993 and Chua reported no losses to follow up and they did not keep a record of eligible non-randomised women. The trial by Bakker 2010 reported no losses to follow up cases but had a substantial number of non-participants. More than 72% of the eligible women declined participation or were not informed about the trial due to various reasons, mostly workload of the caregivers (information first author). We judged adequate generation of the randomisation sequence in all three trials and the risk for bias was low.

#### Blinding

Due to the nature of the interventions, in all included studies the allocation was not blinded for the doctor or the women. Although it is highly unlikely that women or caregiver knowledge of the allocation could influence outcomes, the lack of blinding down-graded the level of quality assessment of findings. In the study of van Halem 2011, the assessor of the medical files was blinded to the allocation.

#### Incomplete outcome data

The trial by Bakker 2010 reported the outcomes according the intention-to-treat principle, that is the women were analysed in the group they were allocated to; and also according to the per protocol principle, that is the women were analysed in the group with the treatment they actually received. Chia 1993 and Chua 1990 reported no crossover in their study groups. For the pooled risk we used the data from the intention-to-treat analysis.

#### Selective reporting

The included studies had clear and specific pre-specified outcomes and so appeared to be free of selective reporting. The trial by Bakker 2010 did not report the outcome
hyperstimulation. In the study protocol published in the trials register this outcome was not planned.

**Effects of interventions**

*Primary outcomes*

*Uterine rupture* did not occur in any of the three trials. *Hyperstimulation* was reported in two of the included trials, Chia 1993 and Chua 1990 (involving 489 women), but was not different between the study groups (risk ratio (RR) 1.21, 95% confidence interval (CI) 0.78 to 1.88; Analysis 1.2).

The neonatal outcome was no different between the control group which used ET and the intervention group which used an intrauterine pressure catheter. An *Apgar score less than seven at five minutes* was reported in all included trials and was not statistically significantly different between groups (RR 1.78, 95% CI 0.83 to 3.83; N = 1945; Analysis 1.3). *Umbilical artery pH less than 7.15* was reported in one trial (Bakker 2010) (RR 1.31, 95% CI 0.95 to 1.79; N = 1456; Analysis 1.4); *pH less than 7.16* was reported in the trial of Chia 1993 (RR 1.23, 95% CI 0.39 to 3.92; N = 239; Analysis 1.6). *Admission to the neonatal intensive care unit* was reported in two studies (Chua 1990; Chia 1993) and was not statistically significantly different between groups (RR 0.34, 95% CI 0.07 to 1.67; N = 489; Analysis 1.7). One study (Bakker 2010) reported *more than 48 hours hospitalisation* instead (RR 0.92, 95% CI 0.71 to 1.20; N = 1456; Analysis 1.8).

*Secondary outcomes*

There were no *serious complications*, like placenta or vessel perforation, or abruptio placentae, reported in the trials from the use of the intrauterine pressure catheter, and no neonatal deaths or serious maternal complications (defined as death, coma, cardiac arrest, respiratory arrest, use of a mechanical ventilator, admission to intensive care unit) occurred in either study group. All three studies reported rates of instrumental vaginal delivery and caesarean section. The pooled risk for *instrumental delivery* (caesarean section, ventouse and forceps extraction) was not statistically significant different (RR 1.05, 95% CI 0.9 to 1.2; three studies, N = 1945; Analysis 1.11). There was variance between the studies. The differences in crude percentages between the studies were probably due to the different policies and increasing interventions in obstetrics over time (1993 versus 2010), but most of all the variance was due to different aetiology: induced labour versus augmented labour in cases of arrest of labour. Therefore, we performed a subgroup analysis. The pooled risk for instrumental delivery for women with induced labour was more in favour of IT yet not statistically significantly different (RR 0.91, 95% CI 0.75 to 1.1; two studies, N = 1195; Analysis 1.11).

The pooled risk for instrumental delivery for women with augmented labour, however, was in favour of ET and just statistically significantly different (RR 1.25, 95% CI 1.02 to 1.5; two studies, N = 750; Analysis 1.11). The interaction test for subgroup differences was significant for this subgroup analysis (P = 0.02; Analysis 1.11) suggesting a difference between the
induced and augmented subgroups. When the risk for instrumental delivery was specified as vaginal instrumental delivery or operative delivery (that is caesarean section) the difference between the augmented group women and the induced group women disappeared. The pooled risk for a caesarean section was not statistically significant between study groups (RR 1.04, 95% CI 0.85 to 1.29; three studies, N = 1945; Analysis 1.13). This CI corresponds to a plausible reduction of the caesarean section rate of 15% up to a nearly 30% increase. The risk for caesarean section was not different between the subgroups. The pooled risk for vaginal instrumental deliveries (ventouse or forceps extraction) was not statistically significant different (RR 1.06, 95% CI 0.85 to 1.32; three studies, N = 1945; Analysis 1.12). There was no increased risk of infection when an intrauterine catheter was used: infection during labour (RR 0.69, 95% CI 0.44 to 1.08; one study, N = 1456; Analysis 1.17), and no increased risk of infection in mother or child up to three weeks postpartum (van Halem 2011) (RR 0.84, 95% CI 0.61 to 1.16; one study, N= 1435; Analysis 1.16). For the outcome “infection up to three weeks postpartum”, women with an indication for prophylactic antibiotic during labour (i.e. for known positive Group B Streptococcus (GBS) status, heart disease, or other reasons for prophylaxis) were excluded for analysis. Median times to delivery in the subgroups induced and augmented labour were not statistically significantly different between study groups (see Table 1). Mean time to delivery was extracted for this review from the dataset of the Bakker 2010 trial, no statistically significant difference was found between the groups (mean difference (MD) -15.60 minutes, 95% CI -40.99 to 9.79; 1 study, N = 1456; Analysis 1.14). Other secondary outcomes were not reported (antepartum or postpartum haemorrhage, duration of hospital stay for mother or child, women’s satisfaction; specified neonatal outcomes like respiratory distress syndrome, use of mechanical ventilation, intraventricular haemorrhage, neonatal jaundice or sepsis; total hospital costs, use of health service). No subgroup analysis could be performed for women with a previous caesarean section.

DISCUSSION

The aim of this review was to compare the effectiveness of IT compared with ET. We included three randomised controlled studies (1945 women) of moderate quality. The results suggest no benefit for the routine use of internal tocodynamometry (IT) for monitoring contractions in women with induced or augmented labour with intravenous oxytocin. However, there is insufficient evidence to recommend the use of one form of tocodynamometry over another form for women where intravenous oxytocin is administered for induction or augmentation of labour.
Chapter 7

Summary of main results

Three studies were included in this review. Although on theoretical grounds one might expect a better neonatal outcome and a more effective stimulation when the contractions are accurately measured, the robust results of the included studies do not support this concept. The pooled risk for instrumental delivery was not statistically different between study groups, however in the subgroup of women with augmented labour there was a just statistically significant difference in favour of ET. When the variable instrumental delivery was specified into instrumental vaginal delivery or caesarean section, this benefit for ET was not found; moreover we lack a clinical explanation for a possible advantage of external registration of contractions when labour is augmented.

This review found insufficient evidence for a benefit of the routine use of IT on rates of adverse neonatal outcomes, rates of instrumental deliveries, use of analgesia, infection, or time to delivery. Moreover, case reports state that IT has rare but serious risks, including placental or fetal-vessel damage, infection and anaphylactic shock. In this review involving 922 women who were monitored with IT, no such events occurred.

Overall completeness and applicability of evidence

In the Bakker 2010 trial, 12% of the women assigned to external monitoring were nonetheless treated with an intrauterine pressure catheter at the physician’s discretion. The protocol of this study permitted crossover if cervical progression was absent for two hours, the frequency of uterine contractions was not sufficient, or caesarean section was being considered. These 12% of women were more likely to be primiparous (82.6% versus 63.2%), had a higher mean pre-pregnancy BMI (27.4 versus 25.3), and were more likely to have hypertension or pre-eclampsia (33.8% versus 10.3%); they were also more likely to have a caesarean section (33.0% versus 16.0%). Analysis per protocol, for example according to the treatment actually given, had similar results in the rate of operative deliveries and for adverse neonatal outcomes. The two smaller studies (Chua 1990; Chia 1993) did not report crossover between study groups.

The study population of this review included women who were treated with intravenous oxytocin to stimulate contractions but did not involve women with a previous caesarean section. Whether an intrauterine pressure catheter should be used in these women is still controversial. Some clinicians state that the risk for uterus rupture is increased because of insertion of the catheter; others advocate the use of IT in women with a previous caesarean section, because they expect that the diagnosis of uterus rupture is easier. This review does not answer this question for this subgroup of women.

Quality of the evidence

The methodological quality of the trials was considered moderate.
Potential biases in the review process

We acknowledge that there is always a possibility of introducing bias at every stage of the review process. We attempted to minimise bias in a number of ways; two review authors independently assessed eligibility for inclusion and risk of bias, and carried out data extraction; moreover, assessment and data extraction of the largest trial (Bakker 2010) was done by a review co-author (BG) who was not involved in the trial.

Agreements and disagreements with other studies or reviews
The three included studies agree in their conclusion that there is no benefit with routine IT.

AUTHORS’ CONCLUSIONS

Implications for practice
There is insufficient evidence to recommend the use of one form of tocodynamometry over another for women where intravenous oxytocin is administered for induction or augmentation of labour.
In women with lack of progress of labour, cervical progression absent for two hours, or unclear frequency of uterine contractions, one-to-one observation of the labouring woman and her contractions is a realistic alternative to IT in the absence of a non-invasive alternative.

Implications for research
Future trials could focus on examining the strength of contractions during labour by improving the quality of extra-abdominal methods. These trials should include hyperstimulation and women’s satisfaction.

ACKNOWLEDGEMENTS

We thank Dr R Scholten from the Dutch Cochrane Centre for his advice during preparation of the review.
We thank Dr JM van Lith for contributing to the protocol.
We acknowledge the Cochrane Childbirth and Pregnancy group for their valuable feedback. As part of the pre-publication editorial process, this review has been commented on by three peers (an editor and two referees who are external to the editorial team), a member of the Pregnancy and Childbirth Group’s international panel of consumers, and the Group’s Statistical Adviser.
‘This review is published as a Cochrane Review in the Cochrane Database of Systematic Reviews 2012, Issue 12. Cochrane Reviews are regularly updated as new evidence emerges and in response to comments and criticisms, and the Cochrane Database of Systematic Reviews should be consulted for the most recent version of the Review.’

REFERENCE LIST


Chapter 7


### Characteristics of Studies [ordered by year of study]

#### Chua 1990

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Include Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methods</strong></td>
<td>Randomised controlled trial.</td>
</tr>
<tr>
<td><strong>Participants</strong></td>
<td>250 women with spontaneous onset of labour, slow progress and the indication for augmentation with oxytocin</td>
</tr>
<tr>
<td><strong>Interventions</strong></td>
<td>Intervention: 125 women were allocated to internal tocodynamometry. Control: 125 women were allocated to external tocodynamometry</td>
</tr>
<tr>
<td><strong>Outcomes</strong></td>
<td>Length of labour. Dose of oxytocin. Rate of caesarean section. Vaginal instrumental deliveries. Apgar score &lt; 4 at 1 minute. Apgar score &lt; 6 at 5 minutes. Neonatal admission for asphyxia. Birthweight. The number of times the dose of oxytocin had to be reduced for reasons of hyperstimulation (i.e. more than seven contractions in 15 minutes) or fetal heart rate changes</td>
</tr>
<tr>
<td><strong>Notes</strong></td>
<td>Women with a caesarean section were likely to be excluded (personal communication Prof Arulkumaran). No primary outcome defined. Sources of funding not stated.</td>
</tr>
</tbody>
</table>

#### Risk of Bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: “Randomly assigned using a random number table”.</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>No report of method of concealment.</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>Unclear risk</td>
<td>Not reported but due to the kind of intervention we expect no blinding</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) All outcomes</td>
<td>Unclear risk</td>
<td>Not reported.</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Unclear risk</td>
<td>Not reported, no crossover reported so we assume the participants were analysed in the group they were assigned to</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>No missing relevant outcomes.</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>None</td>
</tr>
</tbody>
</table>

#### Chia 1993

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Include Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methods</strong></td>
<td>Randomised controlled trial.</td>
</tr>
<tr>
<td><strong>Participants</strong></td>
<td>239 women with induced labour.</td>
</tr>
<tr>
<td><strong>Interventions</strong></td>
<td>Intervention: 118 women were allocated to internal tocodynamometry. Control: 121 women were allocated to external tocodynamometry</td>
</tr>
<tr>
<td><strong>Outcomes</strong></td>
<td>Length of labour. Dose of oxytocin. Rate of caesarean section. Vaginal instrumental deliveries. Apgar score &lt; 5 at 1 minute. Apgar score &lt; 7 at 5 minutes. Cord arterial blood pH &lt; 7.16. Neonatal admission for asphyxia. Birthweight. The number of times reduction in oxytocin was needed for hyperstimulation or cardiotocographic changes. Hyperstimulation was defined as a contraction frequency &gt; 7 contractions in 15 minutes or a rise in baseline tone between contractions for more than 3 minutes</td>
</tr>
<tr>
<td><strong>Notes</strong></td>
<td>Women with a caesarean section were likely to be excluded (personal communication Prof Arulkumaran). No primary outcome defined. Sources of funding not stated. Calculation error in percentages in table 3, arterial blood pH</td>
</tr>
</tbody>
</table>
**Risk of bias**

<table>
<thead>
<tr>
<th>Bias</th>
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<th>Support for judgement</th>
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<tr>
<td>Random sequence generation (selection bias)</td>
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</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>No report of method of concealment.</td>
</tr>
<tr>
<td>Blinding of participants and personnel (performance bias) All outcomes</td>
<td>Unclear risk</td>
<td>Not reported but due to the kind of intervention we expect no blinding</td>
</tr>
<tr>
<td>Blinding of outcome assessment (detection bias) All outcomes</td>
<td>Unclear risk</td>
<td>Not reported.</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Unclear risk</td>
<td>Not reported, no crossover reported so we assume the participants were analysed in the group they were assigned to</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>No missing relevant outcomes.</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>None</td>
</tr>
</tbody>
</table>

Bakker 2010

- **Methods**: Randomised controlled trial.
- **Participants**: 1456 women with a singleton pregnancy and gestational age beyond 36 weeks, a child in cephalic position and an indication for either induction or augmentation of labour with intravenous oxytocin.
- **Interventions**: Intervention: 734 women were allocated to internal tocodynamometry. Control: 722 women were allocated to external internal tocodynamometry.
- **Outcomes**: Operative deliveries, including both caesarean sections and instrumental vaginal deliveries. Use of antibiotics during labour. Length of labour. Adverse neonatal outcomes (defined as any of the following: an Apgar score at 5 minutes of less than 7, umbilical artery pH of less than 7.05, and neonatal hospital stay of longer than 48 hours).

Notes: Follow-up trial van Halem 2011.

**Risk of bias**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Quote: “Randomisation was done by a computer program”.</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Allocation was concealed because of the computerized method of randomisation with use of a minimisation method. Sequence was generated at a central location in the department of epidemiology.</td>
</tr>
</tbody>
</table>

Characteristics of excluded studies [ordered by study ID]

<table>
<thead>
<tr>
<th>Study</th>
<th>Reason for exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arulkumaran 1991</td>
<td>No comparison.</td>
</tr>
<tr>
<td>Bsat 1992</td>
<td>No comparison between extraterine and intraterine registration</td>
</tr>
<tr>
<td>Chua 1992</td>
<td>No randomised comparison.</td>
</tr>
<tr>
<td>Chua 1998</td>
<td>No randomised comparison.</td>
</tr>
<tr>
<td>Lemus 1997</td>
<td>No use of oxytocin.</td>
</tr>
<tr>
<td>Panayotopoulos 1998</td>
<td>Quasi-RCT; answers the research question but was excluded because the randomisation method was not valid</td>
</tr>
<tr>
<td>Sciscione 2005</td>
<td>No randomised comparison.</td>
</tr>
</tbody>
</table>
### DATA AND ANALYSES

Monitoring of contractions with internal tocodynamometry compared to external tocodynamometry

<table>
<thead>
<tr>
<th>Outcome or subgroup title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Uterine rupture</td>
<td>3</td>
<td>1945</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.0 [0.0, 0.0]</td>
</tr>
<tr>
<td>2 Hyperstimulation</td>
<td>2</td>
<td>489</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>1.21 [0.78, 1.88]</td>
</tr>
<tr>
<td>3 Apgar less than 7 at 5 minutes</td>
<td>3</td>
<td>1945</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>1.78 [0.83, 3.83]</td>
</tr>
<tr>
<td>4 Umbilical artery pH &lt; 7.15</td>
<td>1</td>
<td>1456</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>1.31 [0.95, 1.79]</td>
</tr>
<tr>
<td>5 Umbilical artery pH &lt; 7.05</td>
<td>1</td>
<td>1456</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.90 [0.40, 2.03]</td>
</tr>
<tr>
<td>6 Umbilical artery pH &lt; 7.16</td>
<td>1</td>
<td>239</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>1.23 [0.39, 3.92]</td>
</tr>
<tr>
<td>7 Admission to NICU</td>
<td>2</td>
<td>489</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.34 [0.07, 1.67]</td>
</tr>
<tr>
<td>8 Neonatal admission &gt; 48 hours</td>
<td>1</td>
<td>1456</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.92 [0.71, 1.20]</td>
</tr>
<tr>
<td>9 Perinatal mortality</td>
<td>3</td>
<td>1945</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.0 [0.0, 0.0]</td>
</tr>
<tr>
<td>10 Serious maternal outcomes*</td>
<td>3</td>
<td>1945</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.0 [0.0, 0.0]</td>
</tr>
<tr>
<td>11 Instrumental delivery</td>
<td>3</td>
<td>1945</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>1.05 [0.91, 1.21]</td>
</tr>
<tr>
<td>11.1 Induced labour</td>
<td>2</td>
<td>1195</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.91 [0.75, 1.10]</td>
</tr>
<tr>
<td>11.2 Augmented labour</td>
<td>2</td>
<td>750</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>1.25 [1.02, 1.53]</td>
</tr>
<tr>
<td>12 Instrumental vaginal delivery</td>
<td>3</td>
<td>1945</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>1.06 [0.85, 1.32]</td>
</tr>
<tr>
<td>12.1 Induced labour</td>
<td>2</td>
<td>1195</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.90 [0.66, 1.24]</td>
</tr>
<tr>
<td>12.2 Augmented labour</td>
<td>2</td>
<td>750</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>1.25 [0.91, 1.73]</td>
</tr>
<tr>
<td>13 Caesarean section</td>
<td>3</td>
<td>1945</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>1.04 [0.85, 1.29]</td>
</tr>
<tr>
<td>13.1 Induced labour</td>
<td>2</td>
<td>1195</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.91 [0.68, 1.21]</td>
</tr>
<tr>
<td>13.2 Augmented labour</td>
<td>2</td>
<td>750</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>1.25 [0.91, 1.71]</td>
</tr>
<tr>
<td>14 Mean time to delivery</td>
<td>1</td>
<td>1456</td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>-15.60 [-40.99, 9.79]</td>
</tr>
<tr>
<td>14.1 Induced labour</td>
<td>1</td>
<td>956</td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>-25.78 [-58.57, 7.01]</td>
</tr>
<tr>
<td>14.2 Augmented labour</td>
<td>1</td>
<td>500</td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>-0.35 [-40.47, 39.77]</td>
</tr>
<tr>
<td>15 Placental or fetal vessel damage</td>
<td>3</td>
<td>1945</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.0 [0.0, 0.0]</td>
</tr>
<tr>
<td>16 Indication of infection up to three weeks postpartum in mother or child</td>
<td>1</td>
<td>1435</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.84 [0.61, 1.16]</td>
</tr>
<tr>
<td>17 Signs intrauterine infection during labor</td>
<td>1</td>
<td>1456</td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>0.69 [0.44, 1.08]</td>
</tr>
</tbody>
</table>

*defined as death, coma, cardiac arrest, respiratory arrest, use of a mechanical ventilator, admission to intensive care unit*
Analysis 1.2. Comparison 1 Monitoring of contractions with internal tocodynamometry compared to external tocodynamometry, Outcome 2 Hyperstimulation.

Analysis 1.3. Comparison 1 Monitoring of contractions with internal tocodynamometry compared to external tocodynamometry, Outcome 3 Apgar score less than seven at five minutes.

Analysis 1.7. Comparison 1 Monitoring of contractions with internal tocodynamometry compared to external tocodynamometry, Outcome 7 Admission to neonatal intensive care.
Analysis 1.12. Comparison 1 Monitoring of contractions with internal tocodynamometry compared to external tocodynamometry, Outcome 12 Instrumental vaginal delivery

Analysis 1.13. Comparison 1 Monitoring of contractions with internal tocodynamometry compared to external tocodynamometry, Outcome 13 Caesarean section.