Effects of early augmentation of labour with amniotomy and oxytocin in nulliparous women:
  a meta-analysis

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Authors' objectives
To estimate the effects among nulliparae of early augmentation with amniotomy and oxytocin on Caesarean delivery, and on other indicators of maternal and neonatal morbidity such as transfusion, an Apgar score of less than 7 at 5 minutes, and admission to the special care nursery.

Searching
Published studies from 1970 to 1996 were identified through handsearches, and by searching MEDLINE using the following keywords: 'oxytocin', 'amniotomy', 'active management of labour' and 'randomised clinical trials'.

Unpublished reports were identified through the Cochrane Pregnancy and Childbirth Database, whilst data from unpublished trials were obtained through direct communication with the authors.

Study selection

Study designs of evaluations included in the review
Randomised trials comparing a policy of early augmentation of labour with amniotomy and oxytocin, with a more conservative form of management.

Specific interventions included in the review
Early augmentation with amniotomy and oxytocin (applied sequentially in the active management of labour).

Participants included in the review
The participants were nulliparous women, since Caesarean section is more frequent among nulliparae. The mean maternal age at admission ranged from 19.7 to 27 years (this information was unavailable in 4 studies) and the mean gestational age ranged from 39.2 to 39.7 weeks (this information was unavailable in 5 studies). The mean cervical dilation ranged from 2.7 cm to 5.2 cm (this information was unavailable in 2 studies). Seven of the trials (prevention) recruited woman with 'normal' labour and 3 of the trials (therapy) recruited woman with dystocia.

Outcomes assessed in the review
The risk of Caesarean section, and indicators of maternal and neonatal morbidity such as transfusion, an Apgar score less than 7 at 5 minutes, and admission to a special care nursery.

How were decisions on the relevance of primary studies made?
All trials were reviewed separately by two independent reviewers, and any disagreements were resolved by consensus.

Assessment of study quality
The trials were reviewed for four types of potential bias: selection, performance, attrition and detection. Studies that the authors perceived to contain bias were not included in the analyses.

The authors also discussed blinding of allocation. All trials were reviewed separately by two independent reviewers, and any disagreements were resolved by consensus. In terms of potential bias, reviewers had 96% agreement (kappa-statistic 0.81).

Data extraction
The data were abstracted independently by two reviewers, and the results were compiled. Any disagreements between evaluators were resolved by consensus.
Methods of synthesis
How were the studies combined?
Odds ratios (ORs) and their 95% confidence intervals (CIs) were calculated for each outcome of interest within the individual studies. A summary estimate of the typical OR was calculated for each outcome measure, using Peto's method (see Other Publications of Related Interest), unless the test for heterogeneity was positive.

How were differences between studies investigated?
A chi-squared test for heterogeneity was used to assess the consistency of treatment effects across the trials for each outcome. The critical alpha-level for these calculations was set at 0.10. Studies were also grouped according to whether they included only women with abnormal progress, or accepted women with normal labour.

Results of the review
Ten randomised trials with a total of 5,111 participants were included in the meta-analysis: 7 prevention trials and 3 therapy trials. Two studies were unpublished. In the prevention trials, there were 2,561 participants involved in early intervention and 2,441 controls. The therapy trials included only women with an established abnormality in the progress of labour. There were 63 participants involved in early intervention and 46 controls.

The heterogeneity tests for the effect estimates on the major outcomes of interest (the typical OR) were non significant, except for the outcome of epidural analgesia where heterogeneity was significant (chi-squared 6, d.f.=18.4, P=0.0053). Consequently, no OR was calculated for epidural analgesia.

There was no support for the hypothesis that early augmentation reduces the risk of Caesarean section (typical OR 0.9, 95% CI: 0.7, 1.1). In a stratified analysis, the typical OR for the prevention trials was similar to that obtained in the unstratified analysis (typical OR 0.9, 95% CI: 0.7, 1.1). In the therapy trials, there was a non significant reduction in the rate of Caesarean section with early intervention (typical OR 0.6, 95% CI: 0.2, 1.4). However, there was a small number of women in the therapy trials, resulting in a large CI.

Six trials reporting the proportion of women with prolonged labour (duration greater than 9 or 12 hours) found that prolonged labour was markedly reduced by early augmentation (typical OR 0.3, 95% CI: 0.2, 0.4).

An analysis of operative vaginal delivery (both prevention and therapy trials) showed no difference between early augmentation and expectant management (typical OR 0.9, 95% CI: 0.8, 1.1).

Two trials reporting the frequency of postpartum fever found a reduction in the frequency of maternal postpartum fever with early augmentation (typical OR 0.4, 95% CI: 0.3, 0.7). In contrast, 2 trials reporting the frequency of the need for maternal blood transfusion found an increase in transfusion associated with early intervention (typical OR 3.8, 95% CI: 1.2, 11.8). This effect was thought to be mainly due to the effects of one study.

There was no evidence of any difference between the experimental and control groups in the outcome for infants. The typical ORs for the various indicators of neonatal morbidity were reported in the paper.

Two studies found that early augmentation was associated with a reduction in hyperstimulation (typical OR 0.7, 95% CI: 0.5, 1.0), although this effect was observed primarily in only one trial.

Authors’ conclusions
Early augmentation does not appear to be more beneficial than more conservative forms of management for nulliparous women with mild delays in the progress of labour. When there is an established delay in labour, augmentation may reduce the risk of Caesarean section. The latter conclusion should be treated with caution, because only three small trials were performed in this context, and they had inadequate power to allow firm conclusions to be drawn.

CRD commentary
This is a comprehensive review with a clear review question. The authors performed a reasonably thorough literature search which involved handsearching, searches of MEDLINE and an identification of unpublished reports through the Cochrane Pregnancy and Childbirth Database.

The inclusion criteria were clearly stated, data pooling was appropriate, and the validity of the included studies was adequately assessed.

There was a substantial amount of information missing from the initial patient characteristics, e.g. the mean maternal and gestational ages were unavailable in four and five studies, respectively.

The authors’ conclusions follow logically from the results presented and the limitations of the individual studies are discussed.

**Implications of the review for practice and research**

Obstetricians should refrain from using early augmentation for mild delay in labour, as it is unlikely to result in benefits to woman or their infants. However, for established delay in labour, augmentation of labour may reduce the risk of Caesarean section. The degree of delay which is sufficient to justify intervention remains to be defined.

The authors state that future research is required to investigate whether early augmentation is associated with an increase in the requirement for blood transfusion. The current review found that there was a positive association between these variables, but this was mainly the result of a single trial.

The authors also suggest that future research may benefit from using cluster randomisation, whereby centres are located either to the implementation of a new policy or to usual care. They point out that a major shortcoming of several of the studies in the review is the similarity between the experimental and the control groups. Obstetricians who have strong beliefs concerning care in labour may have difficulty in reaching the desired degree of contrast in the interventions administered. The authors argue that participation in a randomised control trial may alter treatment in the control group, such as to diminish the effect of the experimental treatment (Hawthorne effect). This could lead to an underestimation of the magnitude of the benefit of early intervention. A cluster randomisation would allow researchers to optimise compliance while minimising contamination.

The authors suggest that future research should assess the effects of amniotomy alone to treat delays in labour, and should compare early augmentation of labour with expectant management in two situations:

1. In established delay in labour or other situations where the risk of Caesarean is high, such as small stature, obesity or closed cervix.
2. In institutions with a high Caesarean section rate, where cluster randomisation should be used.

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**Other publications of related interest**

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.