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[Intervention Review]

Tocolysis for preventing fetal distress in second stage of labour

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Editorial group: Cochrane Pregnancy and Childbirth Group

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ABSTRACT

Background

Prophylactic tocolysis with betamimetics and other agents has become widespread as a treatment for fetal distress. Uterine relaxation may improve placental blood flow and therefore, fetal oxygenation. However, there may also be adverse maternal cardiovascular effects.

Objectives

The objective of this review was to assess the effects of prophylactic betamimetic therapy during the second stage of labour on perinatal outcome.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (31 March 2011).

Selection criteria

Randomised trials comparing prophylactic intravenous betamimetic therapy during the second stage of labour with placebo or no treatment in uncomplicated pregnancies.

Data collection and analysis

Both authors assessed trial quality independently and extracted data. For dichotomous data, we calculated risk ratios (RR) and 95% confidence intervals (CI). We compared continuous data using mean difference (MD) and 95% CIs.

Main results

One study involving 129 women and one including 35 women were included. Compared to placebo, prophylactic betamimetic therapy was associated with an increase in forceps deliveries in the first trial (RR 1.83, 95% CI 1.02 to 3.29). Umbilical arterial pH values were higher in the tocolysis groups (two trials, 135 women; MD 0.03, 95% CI 0.00 to 0.05). There were no clear effects on postpartum haemorrhage, Apgar scores at two minutes, neonatal irritability, or feeding slowness.

Authors' conclusions

There is no evidence to support the prophylactic use of betamimetics during the second stage of labour. Future research should address the use of tocolysis for the management of fetal distress in the second stage of labour, avoiding the supine position.

PLAIN LANGUAGE SUMMARY

Tocolysis for preventing fetal distress in second stage of labour

Betamimetic tocolytics are drugs that reduce contractions and delay labour, which can improve placental blood flow and fetal oxygenation. They may be suggested to a woman during labour if the baby is showing signs of stress, such as an unusual heartbeat. Tocolysis may also be used to prevent fetal distress (prophylactically) during the second stage of labour, the time from when the cervix is fully dilated by the baby's head to actual childbirth.

The review authors searched the medical literature for randomised controlled trials comparing prophylactic intravenous betamimetic therapy with inactive or no treatment for women with uncomplicated pregnancies and whose babies were not showing signs of stress during the second stage of labour. They identified two trials involving 164 women, both conducted in the 1970s. One trial reported on clinical outcomes and found no beneficial differences in clinical neonatal outcome or Apgar scores at two minutes with tocolysis. The mean umbilical arterial pH values were slightly higher in the treatment groups of the two trials and intravenous betamimetics may prevent the deterioration of fetal arterial pH levels during the second stage of labour, possibly related to use of the supine position in these trials. Women receiving betamimetic drugs were more likely to have forceps delivery, which is the use of surgical tongs to assist the baby through the birth canal. Both trial protocols required forceps to be used if the second stage of labour, or time from initiation of the betamimetic infusion, exceeded 30 minutes. There were no clear differences in postpartum haemorrhage. The authors found inadequate evidence of benefit to recommend the prophylactic use of tocolytics in the second stage of labour.

BACKGROUND

Intravenous tocolytics have been used therapeutically for fetal distress during labour in an attempt to improve the fetal condition (see review 'Tocolytics for suspected intrapartum fetal distress' (Kulier 1998)). This review examines the prophylactic use of betamimetic agents during the second stage of labour.

OBJECTIVES

To assess the effects of prophylactic tocolytic therapy during the second stage of labour on perinatal outcome, according to the best available evidence.

METHODS

Criteria for considering studies for this review

Types of studies

Clinical trials comparing the effect of prophylactic tocolytics during the second stage of labour on clinically meaningful outcomes, with a control group (placebo or no treatment); random allocation to treatment and control groups, with adequate allocation concealment; violations of allocated management and exclusions after allocation not sufficient to materially affect outcomes.

Types of participants

Women with uncomplicated pregnancy in the second stage of labour.

Types of interventions

Tocolytic administration versus placebo or no treatment.

Types of outcome measures

Method of delivery; postpartum haemorrhage; neonatal outcome.

Outcomes included if clinically meaningful; reasonable measures taken to minimise observer bias; missing data insufficient to materially influence conclusions; data available for analysis according to original allocation, irrespective of protocol violations; data available in format suitable for analysis.

Search methods for identification of studies

Electronic searches

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator (31 March 2011).

The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

1. quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. weekly searches of MEDLINE;
3. weekly searches of EMBASE;
4. handsearches 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.

Details of the search strategies for CENTRAL, MEDLINE and EMBASE, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the 'Specialized Register' section within the editorial information about the [Cochrane Pregnancy and Childbirth Group](#).

Trials identified through the searching activities described above are each assigned to a review topic (or topics). The Trials Search Co-ordinator searches the register for each review using the topic list rather than keywords.

We did not apply any language restrictions.

Data collection and analysis

Selection of studies

Two review authors independently assessed for inclusion all the potential studies we identified as a result of the search strategy. There were no disagreements, but we would have resolved any disagreement through discussion or, if required, by consulting a third person.

Data extraction and management

We designed a form to extract data. For eligible studies, two review authors extracted the data using the agreed form. There were no disagreements, but we would have resolved discrepancies through discussion or, if required, by consulting a third person. Data were entered into Review Manager software ([RevMan 2008](#)) and checked for accuracy.

If information regarding any of the above had been unclear, we would have attempted to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies

Two review authors independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2008](#)). Any disagreement would have been resolved by discussion or by involving a third assessor.

(1) Sequence generation (checking for possible selection bias)

We described for each included study the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.

We assessed the method as:

- low risk (any truly random process, e.g. random number table; computer random number generator);
- high risk (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 the allocation sequence in sufficient detail and determine whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.

We assessed the methods as:

- low risk (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- high risk (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear risk of bias.

(3) Blinding (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. Studies were judged at low risk of bias if they were blinded, or if we judged that the lack of blinding could not have affected the results. Blinding was assessed separately for different outcomes or classes of outcomes.

We assessed the methods as:

- low risk, high risk, unclear risk of bias for participants;
- low risk, high risk, unclear risk of bias for personnel;
- low risk, high risk, unclear risk of bias for outcome assessors.

(4) Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations)

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, the numbers included in the analysis at each stage (compared with the total 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 would have re-included missing data in the analyses which we undertook. We assessed methods as:

- low risk;
- high risk (more than 20% missing data);
- unclear risk of bias.

(5) Selective reporting bias

We described for each included study how the possibility of selective outcome reporting bias was examined by us and what we found.

We assessed the methods as:

- low risk (where it is clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported);
- high risk (where not all the study's pre-specified outcomes have been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest are reported incompletely and so cannot be used; study fails to include results of a key outcome that would have been expected to have been reported);
- unclear risk of bias.

(6) Other sources of bias

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;
- high risk;
- unclear risk of 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 (Higgins 2008). With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias and whether we consider it is likely to impact on the findings. We would explore the impact of the level of bias through undertaking sensitivity analyses - see [Sensitivity analysis](#).

Measures of treatment effect

Dichotomous data

For dichotomous data, we present results as summary risk ratio with 95% confidence intervals.

Continuous data

For continuous data, we use the mean difference if outcomes are measured in the same way between trials. We would use the standardised mean difference to combine trials that measure the same outcome, but use different methods.

Unit of analysis issues

No cluster-randomised trials nor crossover trials are expected.

Dealing with missing data

For included studies, levels of attrition were noted. The impact of including studies with high levels of missing data in the overall assessment of treatment effect would be explored by using sensitivity analysis if there were sufficient trials for this.

For all outcomes, analyses were carried out, as far as possible, on an intention-to-treat basis, i.e., we attempted to include all participants randomised to each group in the analyses. The denominator for each outcome in each trial was the number randomised minus any participants whose outcomes were known to be missing.

Assessment of heterogeneity

We used the I^2 statistic to measure heterogeneity among the trials in each analysis. If we identified substantial heterogeneity ($I^2 > 50\%$), we would explore it by pre-specified subgroup analysis.

Assessment of reporting biases

Where we suspected reporting bias (see 'Selective reporting bias' above), we would attempt to contact study authors asking them to provide missing outcome data. Where this is not possible, and the missing data are thought to introduce serious bias, the impact of including such studies in the overall assessment of results would be explored by a sensitivity analysis.

Data synthesis

We carried out statistical analysis using the Review Manager software (RevMan 2008). We used fixed-effect inverse variance

meta-analysis for combining data where trials were examining the same intervention, and the trials' populations and methods are judged sufficiently similar. Where we suspect clinical or methodological heterogeneity between studies sufficient to suggest that treatment effects may differ between trials we would use random-effects meta-analysis.

If substantial heterogeneity is identified in a fixed-effect meta-analysis, this would be noted and the analysis repeated using a random-effects method.

Subgroup analysis and investigation of heterogeneity

We plan to carry out the following subgroup analyses:

- supine versus non-supine posture during second stage of labour.

The following outcomes would be used in subgroup analysis:

- neonatal condition.

For fixed-effect meta-analyses we would conduct planned subgroup analyses classifying whole trials by interaction tests as described by [Deeks 2001](#). For random-effects meta-analyses we would assess differences between subgroups by inspection of the subgroups' confidence intervals; non-overlapping confidence intervals indicate a statistically significant difference in treatment effect between the subgroups.

Sensitivity analysis

If there were sufficient trials, the impact of including trials with moderate or high risk of bias would be explored by sensitivity analysis.

RESULTS

Description of studies

Two studies involving 164 women were included - see table of [Characteristics of included studies](#) and [Characteristics of excluded studies](#) for details.

Risk of bias in included studies

See table of [Characteristics of included studies](#), particularly the 'Methods' and 'Notes' sections.

[Campbell 1978](#) used double-blind placebo-controlled methodology, but 29 of the 129 participants enrolled were excluded from the analysis because of incomplete data. As the remaining groups appear similar in size and baseline characteristics (except for a greater variation in birthweight in the betamimetic group), the exclusions may not have materially biased the comparisons made, but this remains a possibility.

[Humphrey 1975](#) do not describe the method of allocation concealment, but the study is double-blind, placebo-controlled. No

clinical outcomes are given, other than noting that there were no cases of postpartum haemorrhage.

The overall risk of bias was assessed as moderate for [Campbell 1978](#) (more than 20% loss to follow up); and moderate for [Humphrey 1975](#) (poorly described methodology).

Effects of interventions

Both trial protocols required forceps to be used if the second stage of labour or time from initiation of the infusion exceeded 30 minutes. In [Campbell 1978](#), there were more forceps deliveries in the tocolytic group (100 women; risk ratio 1.83, 95% confidence interval (CI) 1.02 to 3.29), and no differences in clinical neonatal outcome or Apgar scores at two minutes. The mean umbilical arterial pH values were borderline significantly higher in the treatment group (two trials, 135 women; mean difference 0.03, 95% CI 0.00 to 0.05). The occurrence of postpartum haemorrhage in two women in the study group can easily be ascribed to the play of chance.

DISCUSSION

The position of the women during the second stage of labour is not specified in [Campbell 1978](#), and in [Humphrey 1975](#) was supine. There is evidence that deteriorating fetal blood gas status during the second stage may occur in the supine position but be avoided by lateral tilting.

AUTHORS' CONCLUSIONS

Implications for practice

There is no evidence from this review of reduction of clinically important morbidity to support the routine use of intravenous tocolytics during the second stage of labour.

Implications for research

The findings in these studies that intravenous betamimetics may prevent the deterioration of fetal arterial pH levels during the second stage of labour, (possibly related to use of the supine position in these trials), may be relevant to the management of fetal distress during the second stage. Research into the use of intravenous betamimetics should be directed towards their use in the management of fetal distress, not uncomplicated pregnancies. Use of the supine position should be avoided in such research.

ACKNOWLEDGEMENTS

The initial version of this review was made possible through a fellowship grant supported by Shell Petroleum International (UK). The funders do not take any responsibility for the data presented or the views expressed.

As part of the pre-publication editorial process, this updated review has been commented on by two peers (an editor and referee who is external to the editorial team) and the Group's Statistical Adviser.

REFERENCES

References to studies included in this review

Campbell 1978 {published data only}

Campbell J, Anderson I, Chang A, Wood C. The use of ritodrine in the management of the fetus during the second stage of labour. *Australian and New Zealand Journal of Obstetrics and Gynaecology* 1978;**18**:110-3.

Humphrey 1975 {published data only}

Humphrey M, Chang A, Gilbert M, Wood C. The effect of intravenous ritodrine on the acid-base status of the fetus during the second stage of labour. *British Journal of Obstetrics and Gynaecology* 1975;**82**:234-45.

References to studies excluded from this review

Briozzo 2007 {published data only}

Briozzo L, Martinez A, Nozar M, Fiol V, Pons JE, Alonso JG. Tocolysis and delayed delivery versus emergency delivery in cases of non-reassuring fetal status during labor. *Journal of Obstetric and Gynecological Research* 2007;**33**:264-71 .

Gerris 1980 {published data only}

Gerris J, Thiery M, Bogaert M, De Schaepdryver A. Randomized trial of two beta-mimetic drugs (ritodrine and fenoterol) in acute intra-partum tocolysis. *European Journal of Clinical Pharmacology* 1980;**18**:443-8.

References to studies awaiting assessment

Rosegger 1988 {published data only}

Rosegger H. Trial to assess the effects of tocolysis (betamimetic infusion) during delivery on preterm birth. Personal communication 1988.

Additional references

Deeks 2001

Deeks JJ, Altman DG, Bradburn MJ. Statistical methods for examining heterogeneity and combining results from several studies in meta-analysis. In: Egger M, Davey Smith G, Altman DG editor(s). *Systematic reviews in health care: meta-analysis in context*. London: BMJ Books, 2001.

Higgins 2008

Higgins JPT, Green S, editors. *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.0.1 [updated September 2008]. The Cochrane Collaboration, 2008. Available from www.cochrane-handbook.org.

Kulier 1998

Kulier R, Hofmeyr GJ. Tocolytics for suspected intrapartum fetal distress. *Cochrane Database of Systematic Reviews* 1998, Issue 2. [DOI: [10.1002/14651858.CD000035](https://doi.org/10.1002/14651858.CD000035)]

RevMan 2008 [Computer program]

The Nordic Cochrane Centre, The Cochrane Collaboration. Review Manager (RevMan). Version 5.0. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2008.

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Campbell 1978

Methods	Double-blind, placebo-controlled random allocation.
Participants	Normal obstetric women selected during the first stage of labour.
Interventions	Infusion of ritodrine 5 micrograms per Kg per minute commencing when the second stage of labour was diagnosed, compared with placebo infusion (dextrose water).
Outcomes	Forceps delivery; neonatal 'irritability'/feeding slowness; postpartum haemorrhage; umbilical arterial pH.
Notes	29 of the original 129 women excluded because of incomplete data. When only those delivered according to protocol within 30 minutes were considered, the umbilical arterial pH of the treatment group was significantly greater than that of the control group (7.29 SD 0.06, n = 30, versus 7.25 SD 0.07, n = 33).
Risk of bias	
Bias	Authors' judgement Support for judgement

Campbell 1978 (Continued)

Random sequence generation (selection bias)	Low risk	
Allocation concealment (selection bias)	Low risk	Double-blind placebo controlled.
Blinding (performance bias and detection bias) All outcomes	Low risk	
Incomplete outcome data (attrition bias) All outcomes	High risk	29 of 129 participants excluded because of inadequate data.
Other bias	Low risk	

Humphrey 1975

Methods	Women were 'randomly allocated'. The method was not specified. The trial was double-blind, placebo-controlled.
Participants	Women between 36 and 42 weeks' gestation with uncomplicated pregnancies; second stage of labour. exclusion criteria: clinical evidence of fetal distress or fetal scalp pH < 7.2.
Interventions	Intravenous infusion of ritodrine 1.5 mcg per kg per minutes versus 3 mcg per kg per minute, versus placebo. Women were delivered in the supine position. Forceps delivery was performed if undelivered 30 minutes after commencement of the infusion.
Outcomes	Time to delivery; umbilical arterial and venous blood gas values.
Notes	Cord arterial pH values re-calculated from values given separately for labour < and > 15 minutes, and for low-dose and high-dose tocolysis. SD approximated as the mean of the SD of the subgroups.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	Double-blind placebo controlled.
Blinding (performance bias and detection bias) All outcomes	Low risk	
Other bias	Low risk	

SD: standard deviation

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Briozzo 2007	This trial relates to the therapeutic use of tocolysis for the treatment of fetal distress.

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Study	Reason for exclusion
Gerris 1980	Randomised comparison of two tocolytic drugs in healthy women in first stage of labour without fetal distress. The objective was to compare the physiological tocolytic effect of the drugs, not to prevent fetal distress.

DATA AND ANALYSES

Comparison 1. Prophylactic tocolytics in 2nd stage of labour

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Forceps delivery	1	100	Risk Ratio (M-H, Fixed, 95% CI)	1.83 [1.02, 3.29]
2 Neonatal 'irritability'/feeding slowness	1	100	Risk Ratio (M-H, Fixed, 95% CI)	1.0 [0.21, 4.72]
3 Postpartum haemorrhage	2	135	Risk Ratio (M-H, Fixed, 95% CI)	5.0 [0.25, 101.58]
4 Umbilical arterial pH	2	135	Mean Difference (IV, Fixed, 95% CI)	0.03 [0.00, 0.05]
5 Apgar scores at 2 minutes	1	100	Mean Difference (IV, Fixed, 95% CI)	-0.30 [-0.79, 0.19]

Analysis 1.1. Comparison 1 Prophylactic tocolytics in 2nd stage of labour, Outcome 1 Forceps delivery.

Analysis 1.2. Comparison 1 Prophylactic tocolytics in 2nd stage of labour, Outcome 2 Neonatal 'irritability'/feeding slowness.

Analysis 1.3. Comparison 1 Prophylactic tocolytics in 2nd stage of labour, Outcome 3 Postpartum haemorrhage.

Analysis 1.4. Comparison 1 Prophylactic tocolytics in 2nd stage of labour, Outcome 4 Umbilical arterial pH.

Analysis 1.5. Comparison 1 Prophylactic tocolytics in 2nd stage of labour, Outcome 5 Apgar scores at 2 minutes.

FEEDBACK

Alonso, 21 March 2009

Summary

Please note the following randomized trial:

[Tocolysis for preventing fetal distress in second stage of labour \(Review\)](#)

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Briozzo L, Martnez A, Nozar M, Fiol V, Pons JE, Alonso JG. Tocolysis and delayed delivery versus emergency delivery in cases of non-reassuring fetal status during labor. *Journal of Obstetric and Gynecological Research* 2007, 33:264-271.

(Submitted by Justo Alonso, March 2009)

Reply

Thank you for your feedback. This review considers trials of prophylactic tocolysis in the absence of fetal distress. The trial referred to relates to the therapeutic use of tocolysis for the treatment of fetal distress.

Contributors

Justus Hofmeyr

WHAT'S NEW

Date	Event	Description
31 March 2011	New search has been performed	New search conducted. No new trial reports identified. Reply to feedback added.

HISTORY

Protocol first published: Issue 2, 1996

Review first published: Issue 2, 1996

Date	Event	Description
2 July 2010	Amended	Contact details edited.
10 May 2010	Feedback has been incorporated	Feedback received from Justo Alonso.
28 April 2009	New search has been performed	Search updated but no new trials identified. Two trials in Studies awaiting classification assessed: Humphrey 1975 included; Gerris 1980 excluded.
12 November 2008	Amended	Converted to new review format.
27 October 2004	New search has been performed	Search updated. Three trial reports added to Awaiting classification: Humphrey 1975 ; Gerris 1980 ; Rosegger 1988 .

CONTRIBUTIONS OF AUTHORS

GJ Hofmeyr prepared the original version, and is responsible for maintaining the review. R Kulier quality-checked and revised the review.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- University of the Witwatersrand, South Africa.
- Department of Obstetrics and Gynaecology, Geneva University Hospital, Switzerland.

External sources

- South African Medical Research Council, South Africa.
- Shell International Petroleum Company Limited, UK.

INDEX TERMS**Medical Subject Headings (MeSH)**

*Tocolysis; Adrenergic beta-Agonists [therapeutic use]; Fetal Distress [*prevention & control]; Labor Stage, Second; Tocolytic Agents [therapeutic use]

MeSH check words

Female; Humans; Pregnancy