

Magnesium sulphate versus lytic cocktail for eclampsia (Review)

Duley L, Gulmezoglu AM



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ABSTRACT

Background

Eclampsia, the occurrence of a seizure in association with pre-eclampsia, is a rare but serious complication of pregnancy. A number of different anticonvulsants are used to control eclamptic fits and to prevent further seizures.

Objectives

The aim of this review was to compare the effects of magnesium sulphate with those of lytic cocktail when used for the care of women with eclampsia.

Search strategy

The register of trials held by the Cochrane Pregnancy and Childbirth Group was searched for relevant trials. The Cochrane Controlled Trials Register in The Cochrane Library Issue 2, 2000 was also searched.

Selection criteria

Randomised trials recruiting women with eclampsia, and comparing any use of magnesium sulphate with any use of lytic cocktail.

Data collection and analysis

Data were extracted from each report without any blinding of the results or of the treatments which women received.

Main results

Two trials with 199 women were included in the review. These were both small and of average quality. Magnesium sulphate was better than lytic cocktail at preventing further fits (relative risk (RR) 0.09, 95% confidence interval (CI) 0.03-0.24; risk difference (RD) 0.43, 95% CI -0.53, -0.34; number needed to treat (NNT) 3, 95% CI 2-3) and was associated with less respiratory depression (RR 0.12, 95% CI 0.02-0.91). Magnesium sulphate was also associated with fewer maternal deaths than lytic cocktail, but the difference was not statistically significant (RR 0.25, 95% CI 0.04-1.43).

Authors' conclusions

Magnesium sulphate is the anticonvulsant of choice for women with eclampsia. Lytic cocktail should be abandoned.

PLAIN LANGUAGE SUMMARY

Magnesium sulphate is more effective than lytic cocktail in preventing further fits for pregnant women with eclampsia.

Eclampsia is when a pregnant woman with pre-eclampsia has one or more convulsions (fits). Pre-eclampsia, also known as toxemia, is a condition which leads to high blood pressure and protein in the urine. Eclampsia is a serious threat to the life of both mother and baby. Although the trials were small and of average quality, the review found that magnesium sulphate is better than lytic cocktail at preventing further fits, breathing problems and, possibly, deaths. Magnesium sulphate is also cheap and easy to use.

BACKGROUND

Eclampsia, the occurrence of a seizure in association with pre-eclampsia, remains a rare but serious complication of pregnancy. Estimated to complicate around 1 in 2,000 deliveries in Europe and other developed countries (Douglas 1994), and from 1 in 100 - 1700 deliveries in developing countries (Crowther 1985), eclampsia is associated with around 10% of maternal deaths. An estimated 50,000 women die each year having had an eclamptic convulsion (Duley 1992). In the UK, for every 100 women who have an eclamptic convulsion, on average two will die (Douglas 1994). In the developing world, mortality may be 2-3 times higher (Collab Trial 1995). There are also considerable risks for the baby. In the UK, for example, total mortality for the baby (fetal, neonatal and infant mortality) following eclampsia is 7% (Douglas 1994) and in developing countries around a quarter of babies whose mothers had eclampsia before delivery will die (Collab Trial 1995).

Currently, standard practice is to use an anticonvulsant to control the immediate fit and to prevent further seizures, but the choice of anticonvulsant has been controversial. Until recently, there has been little adequately controlled evidence to support the use of any of the options, and there has been enormous variation in clinical practice. For example, for decades, magnesium sulphate has been the drug of choice in the United States (Gifford 1990), but even a few years ago only 2% of obstetricians in the United Kingdom reported using it (Hutton 1992). Recently, strong evidence from randomised trials has demonstrated that magnesium sulphate is preferable to either diazepam (valium) (Duley 2000a) or phenytoin (Duley 2000). Practice has changed, in the UK (Gülmezoglu 1998) as in other parts of the world, with magnesium sulphate now being recommended as the drug of choice for women with eclampsia.

Lytic cocktail is usually a mixture of chlorpromazine, promethazine and pethidine. First introduced in India (Menon 1961), this combination of drugs became the standard treatment in India and it is still used for the care of women with eclampsia in some parts of the developing world.

The aim of this review is to evaluate the differential effects of magnesium sulphate when compared with lytic cocktail for the care of women with eclampsia.

OBJECTIVES

The aim was to evaluate the differential effects of magnesium sulphate, given either by the intramuscular or the intravenous route, compared with lytic cocktail for the care of women with eclampsia.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

Any randomised trial comparing magnesium sulphate with lytic cocktail for women with eclampsia were eligible. Quasi randomised studies were excluded.

Types of participants

Women with a diagnosis of eclampsia irrespective of delivery status, number of babies or any other medication given before randomisation.

Types of intervention

Any comparison of magnesium sulphate with lytic cocktail. All routes of administration were included, as was any combination of drugs known as 'lytic cocktail', regardless of the constituents or of how they were administered.

Types of outcome measures

The most important outcome is maternal death but as this is relatively rare, even for women with eclampsia, other measures of serious morbidity which could lead to death were also included, such as stroke, renal failure, liver failure and disseminated intravascular coagulation. For women randomised before delivery, additional outcomes were caesarean section, labour < 8 hours, blood loss at delivery > 500ml, mortality for the baby, and morbidity for live-born babies. Measures of use of health service resources were also included, such as need for intensive care, and admission of the baby to a special care nursery.

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: methods used in reviews.

This review has drawn on the search strategy developed for the Pregnancy and Childbirth Group as a whole.

Relevant trials were identified in the Group's Specialised Register of Controlled Trials. See Review Group's details for more information. The Cochrane Library, 2000 issue 2 was also searched using the terms:

- #1. PREGNAN* AND HYPERTENS*
- #2. ECLAMP*
- #3. LYTIC NEAR COCKTAIL
- #4. CHLORPROM*
- #5. #1 OR #2
- #6. #4 OR #3
- #7. #5 AND #6

METHODS OF THE REVIEW

Potentially eligible trials were assessed by both reviewers and evaluated for methodological quality and appropriateness for inclusion. Discrepancies were resolved by discussion. There was no blinding of authorship or results. Whenever possible, unpublished data were sought from investigators.

A quality score for concealment of allocation was assigned to each trial, using the following criteria:

- (A) adequate concealment of allocation;
- (B) unclear whether adequate concealment of allocation;
- (C) inadequate concealment of allocation, quasi-randomisation.

In addition, quality scores for completeness of follow-up and blinding of the assessment of outcome were assigned to each reported outcome using the following criteria:

For completeness of follow-up:

- (A) < 3% of participants excluded;
- (B) 3% - 9.9% of participants excluded;
- (C) 10% - 19.9% of participants excluded.

Excluded: If not possible to enter data based on intention to treat, and/or 20% or more of participants were excluded from that outcome.

For blinding of assessment of outcome:

- (A) double blind, neither investigator nor participant knew or were likely to guess the allocated treatment;
- (B) single blind, either the investigator or the participant knew the allocation. Or, the trial is described as double blind, but side effects of one or other treatment mean that it is likely that for a significant proportion (> 20%) of participants the allocation could be correctly identified;
- (C) no blinding, both investigator and participant knew (or were likely to guess) the allocated treatment. Or, blinding not mentioned.

The data were synthesized and are expressed as relative risks (RR) and risk difference (RD). From 1/RD the number needed to treat (NNT) for benefits and number needed to harm (NNH) for adverse effects, were calculated. For each measure the 95% confidence interval is given.

DESCRIPTION OF STUDIES

See table of included studies.

METHODOLOGICAL QUALITY

For one study (India 1994) the randomisation procedure is described, although it is unclear whether there was any central record

of the envelopes, or whether the envelopes were to be used in a particular sequence. One woman with uncertain diagnosis was excluded from the analysis. The other study (India 1995) is only available as an abstract, and there is no information about concealment of allocation or how outcome was assessed. Some additional information about the interventions and outcomes for this study was obtained by recording data from the poster presentation.

RESULTS

Two trials with 199 women were included in the review. Magnesium sulphate was substantially better at preventing further fits than lytic cocktail (relative risk (RR) 0.09, 95% confidence interval (CI) 0.03-0.24; risk difference (RD) 0.43, 95% CI -0.53, -0.34; number needed to treat (NNT) 3, 95% CI 2-3). Although magnesium sulphate was also associated with fewer maternal deaths than lytic cocktail, the numbers were very small and the difference was not statistically significant (RR 0.25, 95% CI 0.04-1.43). Both trials reported data on respiratory depression, the risk of which was also reduced with magnesium sulphate (RR 0.12, 95% CI 0.02-0.91). There were no cases of respiratory depression in the magnesium sulphate treated group. Other measures of maternal morbidity were only reported by one or other of the two trials.

DISCUSSION

The number of women in this review is relatively small, and the risk of further fits in the lytic cocktail groups for both trials was surprisingly high. Whilst this may be due to the play of chance, or it may reflect bias in the concealment of allocation, another very plausible explanation is that lytic cocktail actually increases the risk of further fits. Convulsions are a well known side effect of chlorpromazine, one of the constituents of lytic cocktail. The number of women with serious morbidity such as coma (0 versus 12), respiratory depression (0 versus 8) and pneumonia (1 versus 11) were also significantly higher in the lytic cocktail group.

For treatment of women with eclampsia, magnesium sulphate has been demonstrated to be better than either diazepam or phenytoin (Duley 2000; Duley 2000a). The data in this review are not conclusive, as the trials were small and of average quality. However, taken alongside the evidence from trials comparing magnesium sulphate with other alternative anticonvulsants, they do confirm magnesium sulphate as the drug of choice for women with eclampsia.

AUTHORS' CONCLUSIONS

Implications for practice

Lytic cocktail should be withdrawn from clinical practice. Mag-

nesium sulphate is relatively cheap and easy to use. It should be made available for treatment of all women with eclampsia.

Implications for research

There is little reliable evidence about dose or how best to administer magnesium sulphate, or the optimum care for women who have eclampsia outside of a hospital setting. Further research is needed to determine the best regimen for administration, and whether magnesium sulphate should be used before transfer to hospital, or in transit.

POTENTIAL CONFLICT OF INTEREST

None known.

ACKNOWLEDGEMENTS

None

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- Medical Research Council UK

Internal sources of support

- UNDP/UNFPA/WHO/World Bank (HRP) SWITZERLAND
- Resource Centre for Randomised Trials UK

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India 1994 *{published data only}*

Bhalla AK, Dhall GI, Dhall K. A safer and more effective treatment regimen for Eclampsia. *Aust N Z J Obstet Gynaecol* 1994;**34**:144–8.

India 1995 *{published and unpublished data}*

Jacob S, Gopalakrishnan K, Lalitha K. Standardised clinical trial of magnesium sulphate regime in comparison with M.K.K. Menon's lytic cocktail regime in the management of eclampsia. Proceedings of the 27th British Congress of Obstetrics and Gynaecology; 4–7 July 1995; Dublin, 1995:303.

References to studies excluded from this review

India 1997

Chatterjee A, Mukherjee J. Comparative study of different anticonvulsants in eclampsia. *J Obstet Gynaecol Res* 1997;**23**:289–93.

Additional references

Collab Trial 1995

The Eclampsia Trial Collaborative Group. Which anticonvulsant for

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Gifford 1990

Gifford RW, August P, Chesley LC, Cunningham G, Ferris TF, Lindheimer MD, et al. National High Blood Pressure Education Program Working Group Report on High Blood Pressure in Pregnancy. *Am J Obstet Gynecol* 1990;**163**:1691–712.

Gülmezoglu 1998

Gülmezoglu AM, Duley L. Use of anticonvulsants for eclampsia and pre-eclampsia: a survey of obstetricians in the United Kingdom and Republic of Ireland. *BMJ* 1998;**316**:975–6.

Hutton 1992

Hutton JD, James DK, Stirrat GM, Douglas KA, Redman CW. Management of severe pre-eclampsia and eclampsia by UK consultants. *Br J Obstet Gynaecol* 1992;**99**:554–6.

Menon 1961

Menon MK. The evolution of the treatment of eclampsia. *J Obstet Gynaecol Br Commonw* 1961;**68**:417–26.

T A B L E S**Characteristics of included studies**

Study	India 1994
Methods	Sealed numbered opaque envelopes. Stratified in groups of 8. One woman excluded due to uncertain diagnosis.
Participants	91 women with eclampsia.
Interventions	MgSO ₄ : 4 g IV (20% solution) + 8 g IM (50% solution) loading dose, then 4 g 4 hourly until 24 hours after delivery. If recurrent fits, 1.5 g IV. Lytic cocktail: pethidine, promethazine and chlorpromazine 'as described by Menon'.
Outcomes	Women: further fits, death, aspiration, respiratory depression, difficulty with BP control, sudden hypotension, oliguria, postpartum psychosis, caesarean section, induction of labour. Babies: stillbirth, neonatal death, asphyxia, 'permanent sequelae'.
Notes	All women had nifedipine for BP control. MgSO ₄ new intervention.
Allocation concealment	B – Unclear

Study	India 1995
Methods	'Randomly allocated'. No other information.
Participants	108 women with eclampsia.
Interventions	MgSO ₄ : 4 g IV + 10 g IM loading dose, then 5 g 4 hourly up to 24 hours after delivery. Lytic cocktail: 100 mg pethidine + 25 mg chlorpromazine IV and 50 mg chlorpromazine + 25 mg promethazine IM loading dose. 100mg pethidine in 1 litre 20% dextrose over 24 hours, 25 mg promethazine 4 hourly, 50 mg chlorpromazine 8 hourly for 48 hours.

Outcomes	Women: further fits, death, pneumonia, stroke, coma > 24 hours, respiratory failure, cardiac failure, renal failure, HELLP. Babies: stillbirth and neonatal death (for babies > 1 kg).
Notes	Published as abstract only. Additional data taken from poster presentation. MgSO ₄ new intervention.
Allocation concealment	B – Unclear
BP = blood pressure, HELLP = haemolysis elevated liver enzymes and lowered platelets, IM = intramuscular, IV = intravenous, MgSO ₄ = magnesium sulphate	

Characteristics of excluded studies

Study	Reason for exclusion
India 1997	Not a randomised trial. Participants: 100 women with eclampsia. Interventions: Magnesium sulphate (16 women), lytic cocktail (28 women), diazepam (16 women), phenytoin (40 women). Outcomes: Further fits, maternal death, aspiration, perinatal death, neonatal asphyxia.

ANALYSES

Comparison 01. Magnesium sulphate versus lytic cocktail

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Maternal death	2	198	Relative Risk (Fixed) 95% CI	0.25 [0.04, 1.43]
02 Recurrence of convulsions	2	198	Relative Risk (Fixed) 95% CI	0.09 [0.03, 0.24]
03 Coma > 24 hours	1	108	Relative Risk (Fixed) 95% CI	0.04 [0.00, 0.74]
04 Respiratory depression	2	198	Relative Risk (Fixed) 95% CI	0.12 [0.02, 0.91]
05 Pneumonia	1	108	Relative Risk (Fixed) 95% CI	0.10 [0.01, 0.76]
07 Mechanical ventilation	1	90	Relative Risk (Fixed) 95% CI	0.20 [0.01, 4.05]
08 Renal failure	1	108	Relative Risk (Fixed) 95% CI	0.22 [0.01, 4.54]
09 Oliguria	1	90	Relative Risk (Fixed) 95% CI	0.50 [0.10, 2.59]
10 Stroke	1	108	Relative Risk (Fixed) 95% CI	0.22 [0.01, 4.54]
11 HELLP syndrome	1	108	Relative Risk (Fixed) 95% CI	3.35 [0.14, 80.36]
12 Placental abruption	1	108	Relative Risk (Fixed) 95% CI	0.84 [0.20, 3.57]
14 Cardiac failure	1	108	Relative Risk (Fixed) 95% CI	0.22 [0.01, 4.54]
16 Admission to intensive care unit	0	0	Relative Risk (Fixed) 95% CI	Not estimable
17 Postpartum psychosis	1	90	Relative Risk (Fixed) 95% CI	1.00 [0.15, 6.79]
18 Caesarean section	2	183	Relative Risk (Fixed) 95% CI	0.83 [0.49, 1.41]
21 Death of the fetus or infant (subgroups by stillbirth, perinatal and neonatal death)			Relative Risk (Fixed) 95% CI	Subtotals only
22 Any death of the fetus or infant	2	177	Relative Risk (Fixed) 95% CI	0.45 [0.26, 0.79]

INDEX TERMS

Medical Subject Headings (MeSH)

Anticonvulsants [*therapeutic use]; Chlorpromazine [administration & dosage]; Drug Combinations; Eclampsia [*drug therapy]; Magnesium Sulfate [*therapeutic use]; Meperidine [administration & dosage]; Promethazine [administration & dosage]; Randomized Controlled Trials

MeSH check words

Female; Humans; Pregnancy

COVER SHEET

Title	Magnesium sulphate versus lytic cocktail for eclampsia
Authors	Duley L, Gulmezoglu AM
Contribution of author(s)	Both reviewers extracted, entered and double checked data. Both reviewers contributed to writing of the review.
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Review first published	2001/1
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Date of most recent SUBSTANTIVE amendment	21 March 2000
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Date new studies found but not yet included/excluded	Information not supplied by author
Date new studies found and included/excluded	Information not supplied by author
Date authors' conclusions section amended	Information not supplied by author
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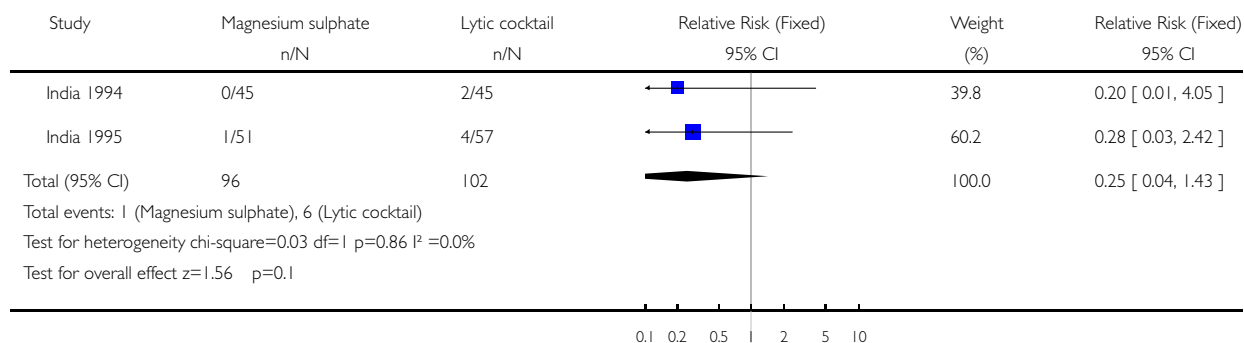
GRAPHS AND OTHER TABLES

Analysis 01.01. Comparison 01 Magnesium sulphate versus lytic cocktail, Outcome 01 Maternal death

Review: Magnesium sulphate versus lytic cocktail for eclampsia

Comparison: 01 Magnesium sulphate versus lytic cocktail

Outcome: 01 Maternal death

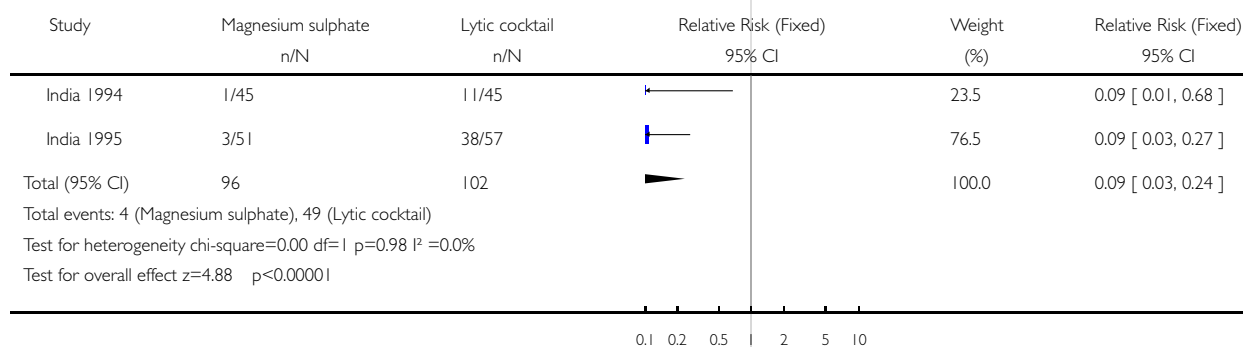


Analysis 01.02. Comparison 01 Magnesium sulphate versus lytic cocktail, Outcome 02 Recurrence of convulsions

Review: Magnesium sulphate versus lytic cocktail for eclampsia

Comparison: 01 Magnesium sulphate versus lytic cocktail

Outcome: 02 Recurrence of convulsions

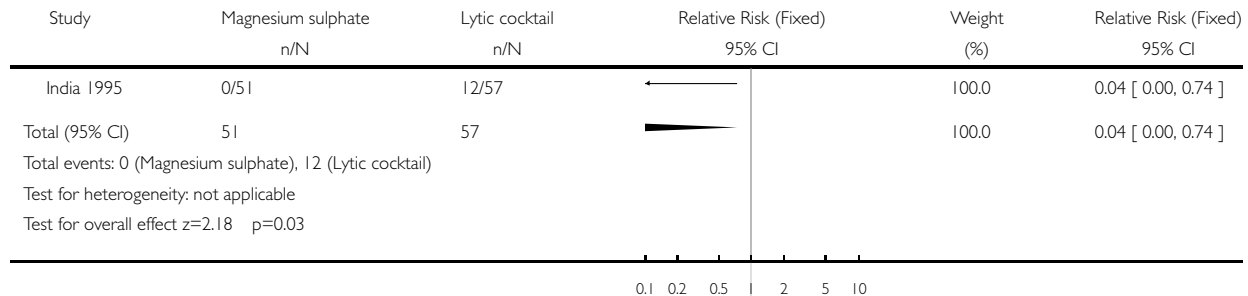


Analysis 01.03. Comparison 01 Magnesium sulphate versus lytic cocktail, Outcome 03 Coma > 24 hours

Review: Magnesium sulphate versus lytic cocktail for eclampsia

Comparison: 01 Magnesium sulphate versus lytic cocktail

Outcome: 03 Coma > 24 hours

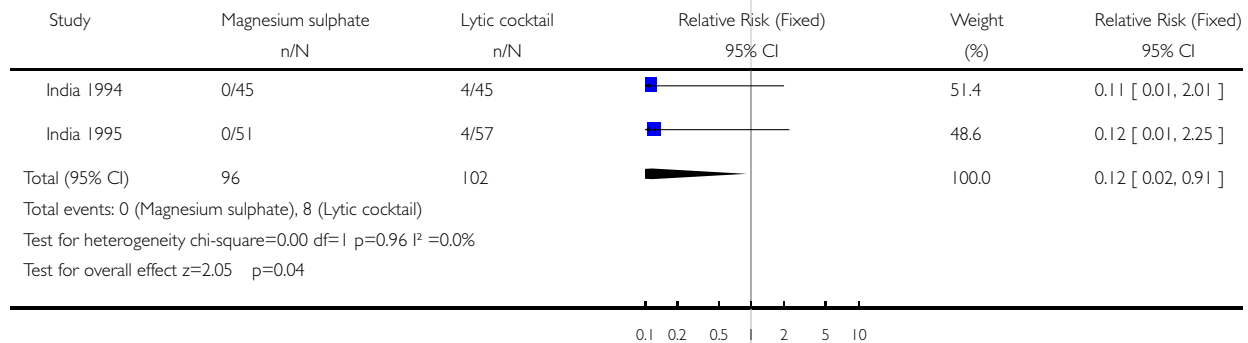


Analysis 01.04. Comparison 01 Magnesium sulphate versus lytic cocktail, Outcome 04 Respiratory depression

Review: Magnesium sulphate versus lytic cocktail for eclampsia

Comparison: 01 Magnesium sulphate versus lytic cocktail

Outcome: 04 Respiratory depression

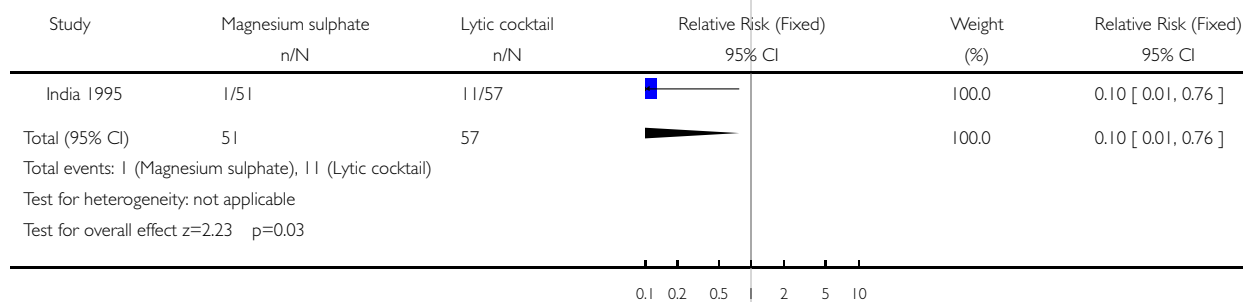


Analysis 01.05. Comparison 01 Magnesium sulphate versus lytic cocktail, Outcome 05 Pneumonia

Review: Magnesium sulphate versus lytic cocktail for eclampsia

Comparison: 01 Magnesium sulphate versus lytic cocktail

Outcome: 05 Pneumonia

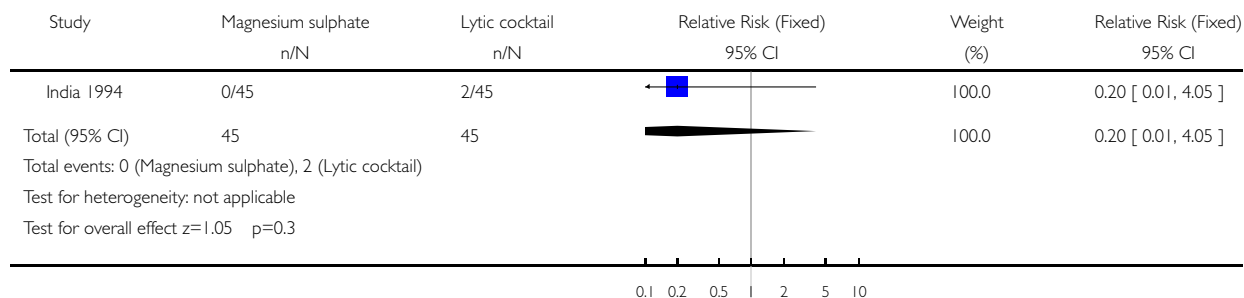


Analysis 01.07. Comparison 01 Magnesium sulphate versus lytic cocktail, Outcome 07 Mechanical ventilation

Review: Magnesium sulphate versus lytic cocktail for eclampsia

Comparison: 01 Magnesium sulphate versus lytic cocktail

Outcome: 07 Mechanical ventilation

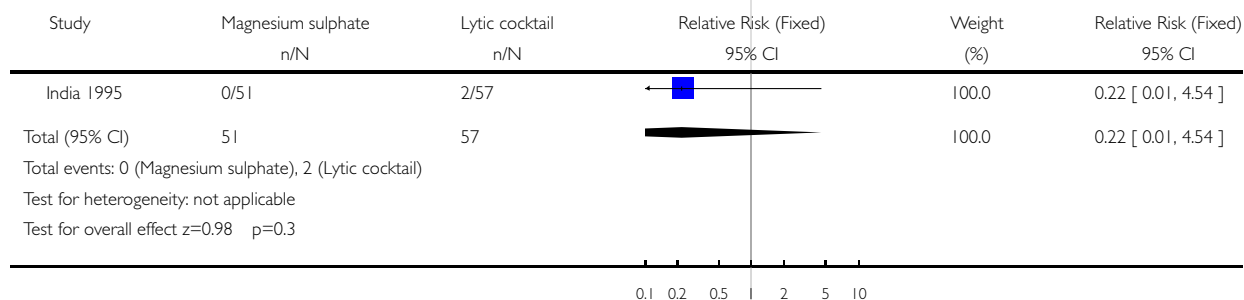


Analysis 01.08. Comparison 01 Magnesium sulphate versus lytic cocktail, Outcome 08 Renal failure

Review: Magnesium sulphate versus lytic cocktail for eclampsia

Comparison: 01 Magnesium sulphate versus lytic cocktail

Outcome: 08 Renal failure

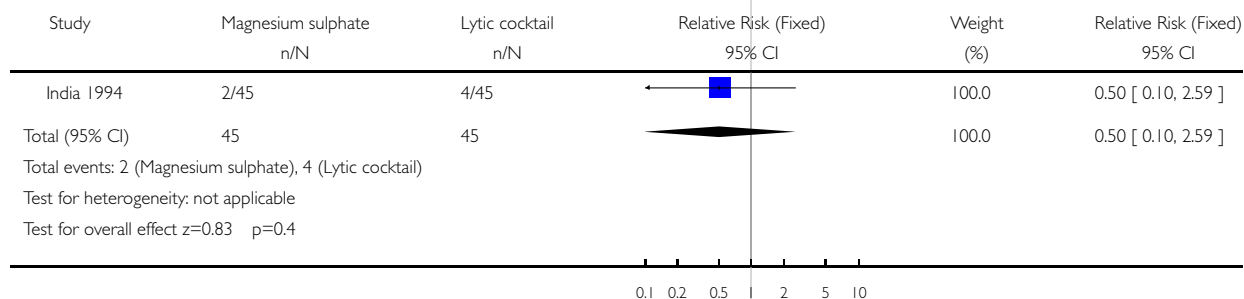


Analysis 01.09. Comparison 01 Magnesium sulphate versus lytic cocktail, Outcome 09 Oliguria

Review: Magnesium sulphate versus lytic cocktail for eclampsia

Comparison: 01 Magnesium sulphate versus lytic cocktail

Outcome: 09 Oliguria

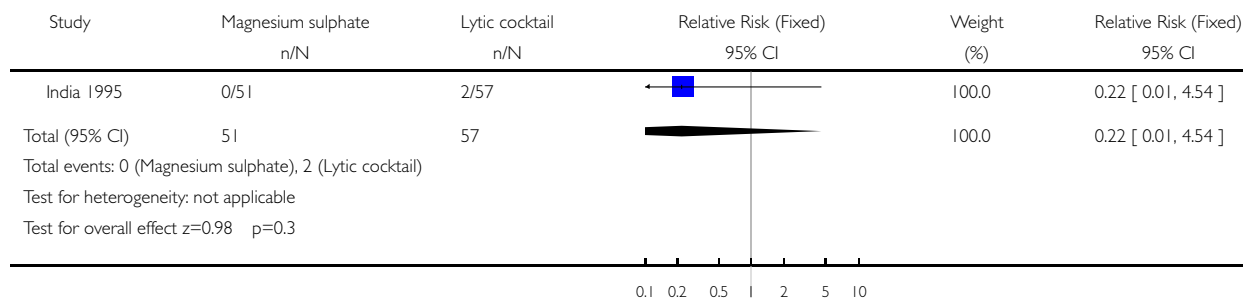


Analysis 01.10. Comparison 01 Magnesium sulphate versus lytic cocktail, Outcome 10 Stroke

Review: Magnesium sulphate versus lytic cocktail for eclampsia

Comparison: 01 Magnesium sulphate versus lytic cocktail

Outcome: 10 Stroke

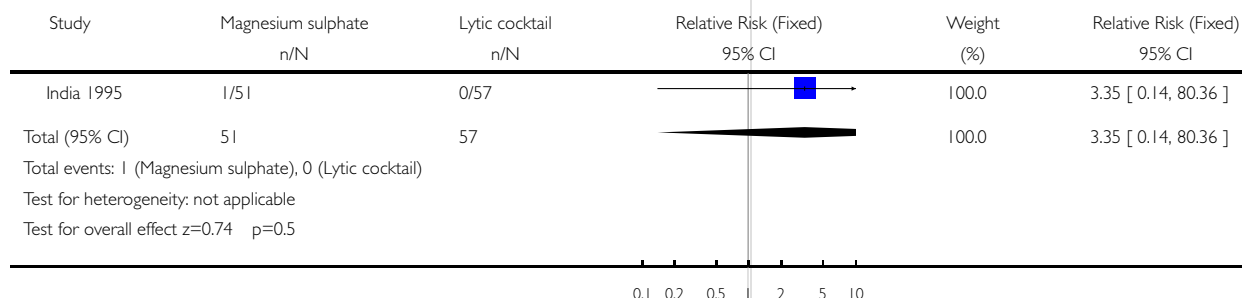


Analysis 01.11. Comparison 01 Magnesium sulphate versus lytic cocktail, Outcome 11 HELLP syndrome

Review: Magnesium sulphate versus lytic cocktail for eclampsia

Comparison: 01 Magnesium sulphate versus lytic cocktail

Outcome: 11 HELLP syndrome

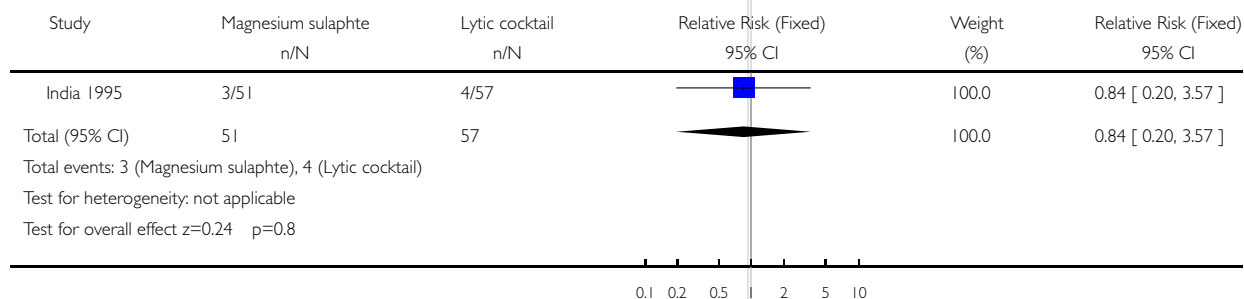


Analysis 01.12. Comparison 01 Magnesium sulphate versus lytic cocktail, Outcome 12 Placental abruption

Review: Magnesium sulphate versus lytic cocktail for eclampsia

Comparison: 01 Magnesium sulphate versus lytic cocktail

Outcome: 12 Placental abruption

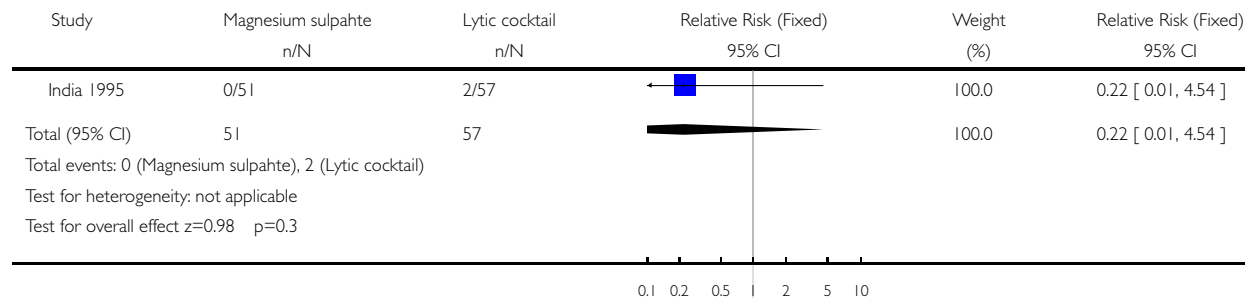


Analysis 01.14. Comparison 01 Magnesium sulphate versus lytic cocktail, Outcome 14 Cardiac failure

Review: Magnesium sulphate versus lytic cocktail for eclampsia

Comparison: 01 Magnesium sulphate versus lytic cocktail

Outcome: 14 Cardiac failure

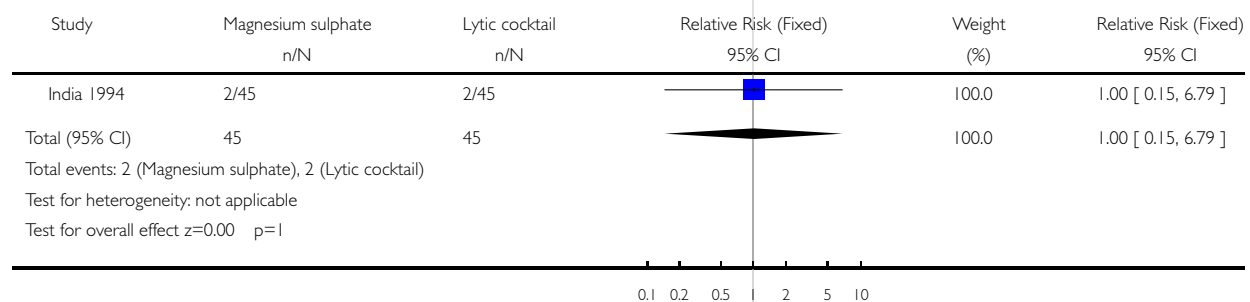


Analysis 01.17. Comparison 01 Magnesium sulphate versus lytic cocktail, Outcome 17 Postpartum psychosis

Review: Magnesium sulphate versus lytic cocktail for eclampsia

Comparison: 01 Magnesium sulphate versus lytic cocktail

Outcome: 17 Postpartum psychosis

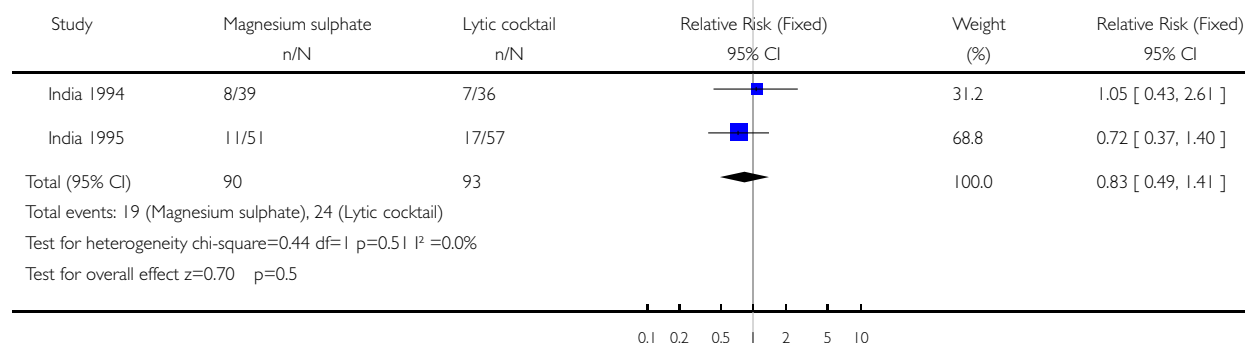


Analysis 01.18. Comparison 01 Magnesium sulphate versus lytic cocktail, Outcome 18 Caesarean section

Review: Magnesium sulphate versus lytic cocktail for eclampsia

Comparison: 01 Magnesium sulphate versus lytic cocktail

Outcome: 18 Caesarean section

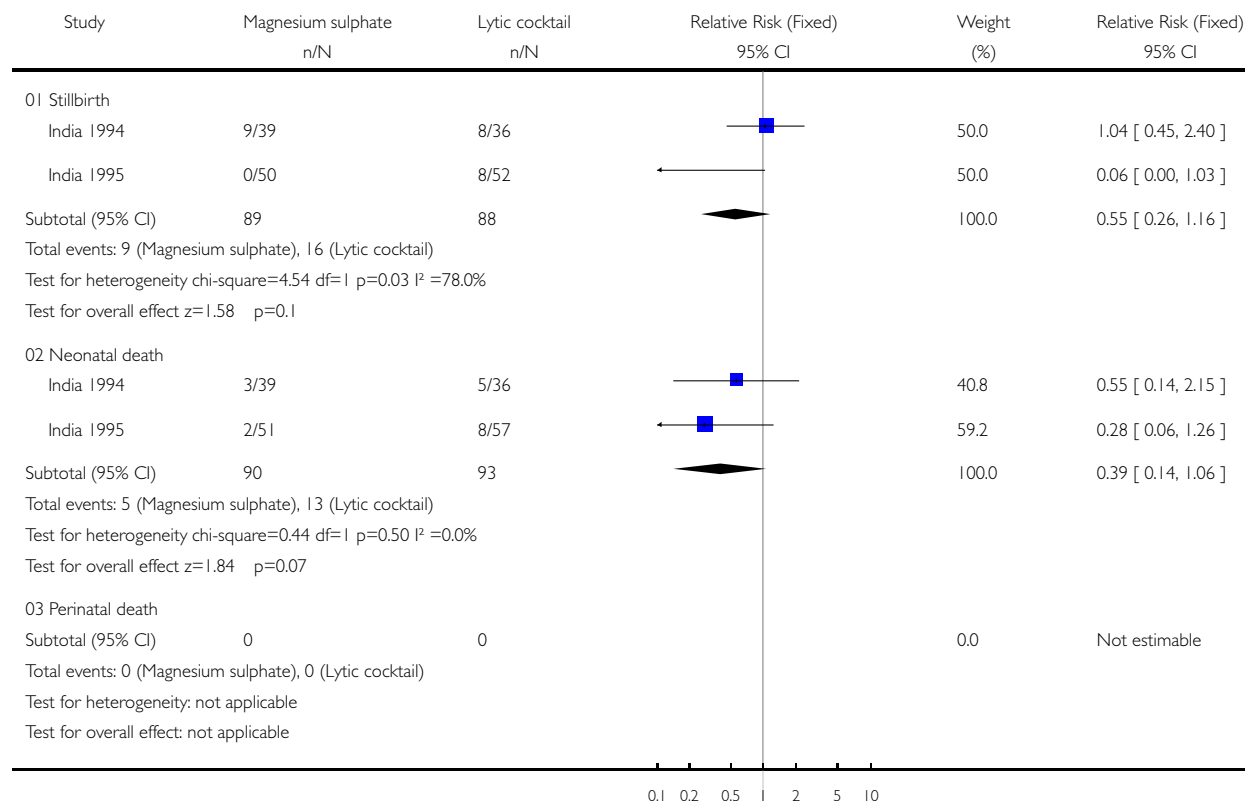


Analysis 01.21. Comparison 01 Magnesium sulphate versus lytic cocktail, Outcome 21 Death of the fetus or infant (subgroups by stillbirth, perinatal and neonatal death)

Review: Magnesium sulphate versus lytic cocktail for eclampsia

Comparison: 01 Magnesium sulphate versus lytic cocktail

Outcome: 21 Death of the fetus or infant (subgroups by stillbirth, perinatal and neonatal death)



Analysis 01.22. Comparison 01 Magnesium sulphate versus lytic cocktail, Outcome 22 Any death of the fetus or infant

Review: Magnesium sulphate versus lytic cocktail for eclampsia

Comparison: 01 Magnesium sulphate versus lytic cocktail

Outcome: 22 Any death of the fetus or infant

