Magnesium sulphate prevented eclampsia better than phenytoin


Objective
To compare magnesium sulphate (MgS) with phenytoin to prevent seizures in women with hypertension who were hospitalised in labour.

Design
Randomised controlled trial with scheduled interim analyses.

Setting
A labour and delivery unit of a U.S. hospital.

Patients
2138 women (62% black race) in labour admitted to the hospital with systolic blood pressure ≥ 140 mm Hg and diastolic blood pressure ≥ 90 mm Hg. Exclusion criteria were birth or imminent birth, epilepsy, and eclamptic convulsions.

Intervention
1049 women were allocated to MgS (10-g intramuscular loading dose and a maintenance dose of 5 g every 4 hours continued for 24 h after delivery). Women with severe pre-eclampsia were given an additional intravenous loading dose of 4 g. 1089 women were allocated to phenytoin (1000-mg loading dose infused over 1 hour and a 500-mg oral dose 10 hours later). All convulsions were treated with intravenous MgS. Follow-up was complete.

Main Outcome Measures
The main outcome was the development of eclampsia (witnessed generalized tonic-clonic seizures with characteristic postictal reduced consciousness and amnesia). Secondary outcomes included induction or augmentation of labour, type of delivery, and infant outcomes.

Main Results
Analysis was by intention to treat. The study was stopped early based on an interim analysis. 139 women (13%) assigned to phenytoin did not receive it and 17 women (2%) were unable to tolerate phenytoin. MgS led to fewer seizures than phenytoin (0% vs 0.9%, P = 0.004). (This absolute risk reduction of 0.92% converts to a number of women who need to be treated with MgS (rather than phenytoin) to prevent 1 seizure of 109 (95% CI 67 to 281; the relative risk reduction was 100%). Women allocated to MgS had a higher rate of caesarean delivery (27% vs 22%, P = 0.047). The groups did not differ for rates of post-term delivery, induction or augmentation of labour, or infant outcomes (stillbirth, neonatal or perinatal death, Apgar scores, arterial cord-blood pH, birth weight, and admission to the special-care nursery).

Conclusion
Magnesium sulphate was better than phenytoin at preventing eclampsia in women with hypertension who were hospitalised for labour and delivery.

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*Numbers calculated from data in article.
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References

Author's Response
Saunders and Hammersley (1) described these 2 articles as "the victory of pragmatism over theory." We agree with Dr. Young that, in theory, "unnecessary intervention" should be avoided.

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Reference