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Examining the use of magnesium sulfate use to treat pregnant women with pre-eclampsia and eclampsia: results of a program assessment of emergency obstetric care (EmOC) training in India

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Abstract:	Background: The aim of this study is to examine rates of magnesium sulfate utilization by emergency obstetric care trainees to treat preeclampsia-eclampsia in India. Secondarily, structural barriers are identified which limit the use of magnesium sulfate, highlighting limitations of emergency obstetric care training, which is a commonly implemented intervention in resource-poor settings. Methods: Trainees' curriculum specified magnesium sulfate treatment for eclampsia and severe preeclampsia. Case records were analyzed for preeclampsia-eclampsia diagnosis, magnesium sulfate utilization, delivery route, and maternal and neonatal outcomes from 13,238 reported deliveries between 2006 and 2012 across seventy-five district hospitals in twelve Indian states. Results: Of 1,320 cases of preeclampsia-eclampsia, 322 (24.4%) had eclampsia. Magnesium sulfate was given to 12.9% of preeclamptic and 54.3% of eclamptic women, with lower usage rates in rural communities. Among the 1,308 women with preeclampsia-eclampsia, only 24 deaths occurred (1.8%). In contrast, among the 17,179 women without preeclampsia-eclampsia, there were 95 reported deaths (0.6%). Both maternal mortality ratios were found to be much higher than the Millennium Development Goal target of 0.15%. Magnesium sulfate administration was associated with a higher death rate in preeclamptic but not eclamptic women, representing possible confounding by severity. Conclusion: To optimize monies spent on emergency obstetric care training, the consistent availability of magnesium sulfate

	should be improved in India. Increasing drug availability, implementing clinical guidelines around its administration, and training health care providers on the identification and treatment of preeclampsia-eclampsia could lead to notable improvements in maternal and infant mortality.

Title Page

Title: Examining the use of magnesium sulfate use to treat pregnant women with pre-eclampsia and eclampsia: results of a program assessment of emergency obstetric care (EmOC) training in India

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Compliance with Ethical Standards

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CONTRIBUTION TO AUTHORSHIP

NAC was responsible for hypothesis formulation, data analysis and initially drafting the manuscript. AB contributed to the development, implementation and management of the training program described, and revised the manuscript critically. CNP contributed to the development, administrative support for program implementation and reviewing the manuscript. SD and PB conceptualized the EmOC program and developed partnerships with the Government and other agencies for the national scale up of the program and reviewed the manuscript. DB provided GOI led program support and reviewed the manuscript. HBu provided the public health perspective, coordinated communication between UAB and AVNI, and revised the manuscript critically. PS was one of the key program implementer and revised the manuscript critically.

INTRODUCTION

India is home to almost one fifth of the world's population[1], but suffers from a health care provider shortage which directly affects health care access and utilization, impacting the well-being of vulnerable populations, such as pregnant women and those residing in rural communities.[2, 3] Specifically, 69% of Indians live in rural areas, and 49% of community health centers (CHCs) which are located in rural areas did not have an obstetrician/gynecologist on staff.[4] These shortages have a direct effect on maternal health care utilization, and subsequently maternal mortality in India. The current Indian maternal mortality ratio (MMR) is about 167 per 100,000 live births, which is higher than the United Nations Millennium Development Goal 5, which aimed to reduce MMR to 150 by 2015.[5-6] Hypertensive disorders complicate 5% of Indian pregnancies [7] and are responsible for 5% of their maternal mortality.[7,8] Thus, treating pre-eclampsia and eclampsia PE-E (hypertensive disorders) with magnesium sulfate (magnesium) could positively impact India's MMR. Unfortunately, magnesium utilization is less than optimal and this lower-than-necessary utilization is due to supply shortages, lack of institutional clinical guidelines, and lack of knowledge about its usage by health care workers.[9] In addition to challenges with the administration of magnesium to treat PE-E, lack of emergency obstetric and neonatal care contributes critically to persistently high rates of maternal and neonatal morbidity and mortality.[7,11] Interventions promoting institutional delivery have been able to reduce India's MMR, but other gaps in care, such as sub-optimum quality of services during institutional deliveries and lack of knowledge around the treatment of PE-E, persist.[12,13,14,15]

To address this deficit, a competency-based certificate program to train Indian non-specialist public-sector physicians in emergency obstetric care (EmOC) was developed through a partnership between the Ministry of Health and Family Welfare, Government of India (GOI), the

Federation of Obstetric and Gynaecological Societies of India (FOGSI), and its academic wing, the Indian College of Obstetricians and Gynaecologists (ICOG). Non-specialist public-sector physicians were those who minimally held an Medicinae Baccalaureus, Baccalaureus Chirurgiae (MBBS) and were posted in public health facilities run by the Indian government. This EmOC training program was managed and implemented by Avni Health Foundation (AVNI), conducted in medical colleges and district hospitals, and intended to increase the provision of comprehensive EmOC in underserved areas. Details of this program have been documented elsewhere.[14] The aim of this study is to examine rates of magnesium utilization by EmOC trainees to treat PE-E in India. We examine rates of maternal and neonatal mortality among pregnant women who receive care from an EmOC-trained non-specialist physician and explore associations between mortality, magnesium administration, and caesarean delivery. We hypothesize that magnesium administration varies and is associated with PE-E severity.

MATERIALS AND METHODS

EmOC trainees maintained logbooks of clinical encounters, including primary and secondary diagnoses, procedures performed, treatments administered, and maternal and neonatal outcomes. These deidentified case records were entered in a centralized repository; 18,528 patient entries (13,238 deliveries) from 75 district hospitals in 12 states between 2006 and 2012 were included. Women with a pregnancy-related hypertensive disorder were identified as those with the diagnosis of pregnancy-induced hypertension (PIH), preeclampsia, or eclampsia. Those with PIH or preeclampsia were subsumed as “preeclampsia,” in view of their common pathophysiology and risk for eclampsia. Records containing a PE-E diagnosis and a diagnosis or procedure unique to the first half of pregnancy (N=13) were excluded. Additional variables included in this

analysis were: route of delivery, receipt of magnesium, maternal mortality, and neonatal mortality. Univariate and multivariate analyses were conducted. Logistic regressions were performed with SAS JMP Pro 10.0 software. A p-value less than 0.05 was taken as statistically significant. Ethical approval for secondary analysis of these data was obtained by the University of Alabama at Birmingham (UAB) Institutional Review Board.

RESULTS

There were 1,320 identified cases of PE-E (7.1% of records, 10.0% of deliveries), of which 322 (24.4%) reported having eclampsia. Comparatively, national estimates show the rate of PE-E is about 8.0% in India[7,15]. The proportion of cases with PE-E and eclampsia differed by state (Table 1); PE-E ranged from 1 to 14%, and eclampsia ranged from less than 1% to 83%. To examine the direct management of PE-E by trainees, health records were aggregated for the seven states reporting thirty or more cases of PE-E (Supplementary Table 1). Trainees directly managed 48% of all reported PE-E cases.

Use of magnesium sulfate

The EmOC training manual used advises treatment with magnesium in eclampsia and severe preeclampsia, employing a loading dose of 4 gm intravenously (IV) and 10 gm intramuscularly (IM), followed by maintenance treatment with 5 gm IM every 4 hr. Trainees received extensive education on the management of PE-E and administration of magnesium which included but was not limited to side effects of magnesium on mother and fetus (e.g. maternal nausea, low calcium levels in fetus) and guidelines for proper use (e.g. loading dose, maintenance dose, and toxicity). Trainees were also informed that, depending on the severity of the PE-E, magnesium alone may

not be a sufficient treatment. Of the 58 training centers with at least one reported PE-E case, 33 (57%) reported at least one use of magnesium in PE-E. "Other anticonvulsants" were reported in only 8 cases overall, 5 of whom had stated PE-E and 4 of whom received magnesium.

With a view to identifying regional and hospital-wise differences in the availability and utilization of magnesium, the number of PE-E cases who received magnesium was examined both by state and by the presence or absence of eclampsia. As shown in Table 2, across the 7 largest-volume states magnesium was given to a mean of 12.9% of preeclamptic and 54.3% of eclamptic women (P<0.001 for difference). The proportion with eclampsia that received magnesium in each state varied from 12% to 76%, with lower rates found in rural communities.

Route of delivery and association with use of magnesium

Of the 1,268 women with PE-E treated in the 7 largest-volume states, a route of delivery was noted for 741 (58.4%). Among these, the overall caesarean delivery rate was 59.0% and the instrumental vaginal delivery rate for non-breech presentations, including forceps and vacuum, was 2.2%. The caesarean rate according to the diagnosis of eclampsia and the use of magnesium is shown in Table 3. The caesarean rate was greater in cases where magnesium was not given (P<0.001); after stratification by eclampsia status, this difference was significant only in the preeclampsia subgroup. The caesarean rate was higher in preeclamptic (63.5%) than eclamptic women (38.9%; P<0.001).

Maternal and neonatal morbidity

PE-E was associated with an excess risk of maternal hemorrhage due to disseminated intravascular coagulopathy (DIC) [9.0% vs. 0.6% without PE-E (P<0.001); RR 15.7 (95%

confidence interval {CI} 12.1–20.3)]. Women with PE-E were also more likely to undergo induction of labor [1.8% vs. 1.1% (P=0.02); RR 1.7 (CI 1.1–2.6)] and to receive an anti-hypertensive medication [8.0% vs. 0.1% (P<0.001); RR 81 (CI 49–135)]. PE-E was not associated with an excess risk of maternal sepsis, hemorrhage from causes other than DIC, or requirement for resuscitation, or with an excess risk of neonatal resuscitation.

Maternal mortality

Among the 1308 women with PE-E for whom maternal vital status was included in the database, there were 24 deaths (1.8%). By contrast, among the 17,179 women without reported PE-E, there were 95 reported deaths (0.6%). Both MMRs, for those with and without PE-E, are much higher than the Millennium Development Goal target of 0.15%. The relative risk for death in women with PE-E was 3.3 (CI 2.1–5.2). The death rate in eclamptic women (5.1%; 16 deaths) was significantly greater than that in preeclamptic women (0.8%; 8 deaths; P<0.001).

Use of magnesium was associated with a higher death rate in preeclamptic (RR for death with magnesium use 6.5, CI 1.6–25.5, P=0.01) but not eclamptic women (RR 1.1, CI 0.4–2.9). This finding is consistent with the trainees' curriculum, which specified magnesium treatment for eclampsia and severe but not mild preeclampsia, and which, if followed, would be expected to produce confounding by severity. Thus, those with severe preeclampsia and eclampsia are at greater risk for death, as well as treatment with magnesium; provision of magnesium may not stop all maternal deaths and its effectiveness is dependent on dosage and time of administration. Indeed, logistic regression of maternal mortality on magnesium use and eclampsia status revealed a significant ($p<0.05$) positive interaction between these two variables. Controlling for the interaction in the regression, the presence of eclampsia and the use of magnesium were

associated with odds ratios (OR) of 3.9 (CI 1.9–7.8) and 2.7 (CI 1.3–5.2) for maternal death, respectively. Performance of caesarean delivery did not alter the maternal mortality rate, before or after adjustment for eclampsia and magnesium use.

Neonatal mortality

Overall, 16 of 797 neonates (2.0%) born to mothers with PE-E died, compared with 148 of 13,049 neonates (1.1%) born to mothers without PE-E (P=0.03); the RR of neonatal death with PE-E was 1.8 (CI 1.1–2.9). The Indian infant mortality rate is 39 per 1,000 live births, or 0.39%; comparatively, outcomes from this dataset, reflecting pregnant women with PE-E show a higher rate of infant deaths as compared to pregnant women without PE-E.

Thirteen of these 16 deaths occurred in Jharkhand. As expected, neonatal mortality was greater in offspring of eclamptic than preeclamptic mothers (9.0% vs. 0.46%; P<0.001). This difference was not found, however, in the subgroup that received magnesium (N=105; P=0.3). When the combined effects on neonatal mortality of magnesium use and eclampsia status are analyzed by logistic regression including an interaction term, eclampsia (OR=9.2 [CI 2.8-48.4]), but not magnesium use, significantly altered mortality. A modest improvement in neonatal mortality was noted with caesarean section among mothers with PE-E (1.1% vs. 3.5% mortality, P=0.023), but this effect was not seen after adjustment for eclampsia status.

DISCUSSION

Consistent with the 8% prevalence of PE-E reported nationwide [7, 15], women in this sample with PE-E represented 7% of the cases logged by the trainees. Eclampsia was reported in 24% of those cases, and they were more likely to receive magnesium (54%, vs. 13% in preeclampsia). In

preeclamptic but not eclamptic women, magnesium receipt was negatively associated with caesarean delivery and positively associated with mortality, pointing to the use of magnesium in more severe cases of preeclampsia. Non-use of magnesium in eclamptic women was associated with greater neonatal mortality. Great variability in magnesium use by state and by facility was observed, pointing to differences in either magnesium availability or in the onsite availability of personnel trained in its use.

Considering the well-documented success of EmOC training programs [16, 17], these less-than-optimal statistics point to structural barriers that persist across India. Being such a populous country, with high levels of poverty, adequate health care for its citizens is lacking. [9] This includes the accessibility of magnesium sulfate.[10] Magnesium provision and appropriate health care was further hindered by limited drug availability, especially at tertiary-care health facilities. [10] These shortages may be due to magnesium being unavailable from pharmaceutical providers [18], gaps in medication management, or because of issues in transporting the drug from urban hubs to more remote communities.

Limitations

Not included in the dataset was information on patient age, timing of a first eclamptic seizure, dosage of magnesium, magnesium initiation relative to delivery, and magnesium-related measures at complementary primary and secondary centers. Parity was not consistently noted. These are significant limitations of our dataset that preclude a better understanding of regional patterns of magnesium utilization and the clinical context of its use. An additional limitation of our findings is that because care and training took place in district hospitals, the patient population in the dataset is not representative of obstetric patients in the states or even districts as

a whole, and likely displays a greater level of acuity and severity. Trainee records from some regions were likely incompletely entered into the database. Despite these limitations, our dataset does allow for examination of the utilization of magnesium for PE-E within the context of the experience of EmOC trainees in tertiary hospitals in disparate regions of India, as well as examination of the maternal and neonatal mortality rates in the seven states for which sufficient case volume is available.

CONCLUSION

Magnesium sulfate is on the World Health Organization's Model List of Essential Medicines [19] and has been included in India's registry of essential medicines since 2003. The Indian Ministry of Health and Family Welfare, as well as curriculum guidelines for our EmOC trainees, state that "MgSO4 is the drug of choice to control convulsions in eclampsia" and that in women laboring with severe (but not mild) preeclampsia, "MgSO4 should be given to prevent eclampsia." [20] Despite these guidelines, magnesium was received by only 54% of eclamptic women, and magnesium was administered at the district hospital level in only 13% of preeclamptic women. Possible reasons for this considerable shortfall include a lack of drug availability, a lack of facility support such as staff training for its use, or a lack of physician education on its indications. [18] Although our dataset cannot inform or distinguish between the first two considerations, it is valuable to juxtapose the well-documented success of EmOC training programs in lowering the MMR and IMR [16,17] against the also-noted shortage of magnesium sulfate in India, with its availability reported in only 39% and 48% of "higher public facilities." [9, 21]

Therefore, to optimize monies spent on provider training, specifically EmOC training, the consistent availability of magnesium sulfate use to treat PE-E in India should be improved. Increasing drug availability, implementing clinical guidelines around its administration, and training health care providers on the identification and treatment of PE-E could lead to notable improvements in maternal and infant mortality. This anticipated reduction in preventable deaths has significant implications for community health and would likely elevate the health standing of India as compared to other low- and middle-income nations.

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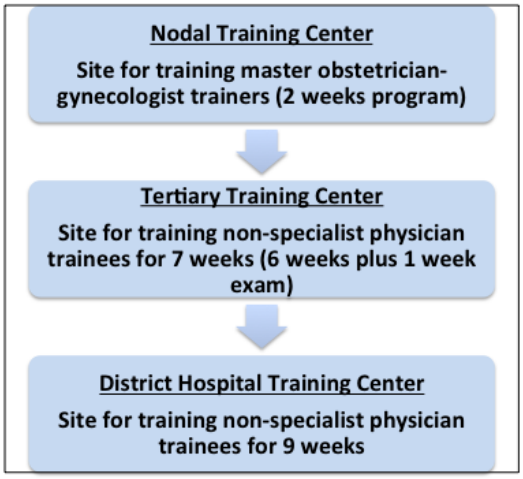
Figure

Figure 1



Table

State	Total cases	Total PE-E	Percent PE-E	Total eclampsia	Percent eclampsia
States with high volume:					
Haryana	2654	60	2.3%	8	13.3%
Jharkhand	2112	228	10.8%	190	83.3%
Karnataka	4998	152	3.0%	25	16.4%
Madhya Pradesh	4113	572	13.9%	4	0.7%
Maharashtra	807	83	10.3%	11	13.2%
Rajasthan	1170	134	11.5%	49	36.6%
Uttar Pradesh	450	39	8.7%	17	43.6%
States with low volume:					
Bihar	19	1	5.3%	0	0%
Chhatisgarh	111	11	9.9%	4	36.4%
Himachal Pradesh	1824	19	1.0%	6	31.6%
Orissa	116	6	5.2%	2	33.3%
Tamil Nadu	154	15	9.7%	6	40.0%
TOTAL	**18528**	**1320**	**7.1%**	**322**	**24.4%**

Table 1. Volume of preeclampsia and eclampsia cases seen by trainees, by state.

Percent eclampsia refers to the proportion of all PE-E cases.

State	Total eclampsia	MgSO4 eclampsia	% got MgSO4	Total preeclampsia	MgSO4 preeclampsia	% got MgSO4
Haryana	8	1	12.5%	49	3	5.8%
Jharkhand	190	96	50.5%	38	7	18.4%
Karnataka	25	17	68.0%	127	9	7.1%
Madhya Pradesh	4	1	25.0%	568	64	11.3%
Maharashtra	11	2	18.2%	72	0	0.0%
Rajasthan	49	35	71.4%	85	26	30.6%
Uttar Pradesh	17	13	76.5%	22	15	68.2%
TOTAL	**304**	**165**	**54.3%**	**964**	**124**	**12.9%**

Table 2. Proportions of women with eclampsia and preeclampsia who received MgSO4 in the 7 largest-volume states.

	Eclampsia	Preeclampsia	All PE-E
MgSO4 given	24/76 (31.6%)	7/21 (33.3%)	31/97 (32.0%)
MgSO4 not given	32/68 (47.1%)[a]	394/610 (64.6%)[b]	426/678 (62.8%)[c]
All women	56/144 (38.9%)	401/631 (63.5%)[d]	457/775 (59.0%)

Table 3. Proportion of delivering women who underwent cesarean delivery, by diagnosis of eclampsia or preeclampsia and receipt of magnesium.

[a]p=0.06; [b]p<0.005; [c]p<0.001 *vs.* magnesium given.

[d]p<0.001 *vs.* eclampsia.

State	No. of centers	No. of centers with PE-E[a]	PE cases managed[b]	Range /center	Eclampsia managed[b]	Range /center
Haryana	8	7	32	0-14	5	0-2
Jharkhand	6	6	7	0-2	71	1-21
Karnataka	7	5	64	1-25	23	1-15
Madhya Pradesh	10	10	325	4-80	1	0-1
Maharashtra	13	8	45	0-25	4	1-3
Rajasthan	6	6	13	0-7	15	1-7
Uttar Pradesh	5	5	3	0-2	5	0-5
Bihar	1	1	0	—	0	—
Chhatisgarh	5	3	3	0-3	4	0-4
Himachal Pradesh	8	5	5	1-4	1	0-1
Orissa	3	1	0	—	0	—
Tamil Nadu	3	3	5	2-3	0	—
TOTAL	**75**	**43**	**502**		**129**	

Supplementary Table 1. Numbers of preeclampsia and eclampsia cases reported as directly managed by trainees, by state, with numbers of cases managed per center.

[a]At least one reported PE-E case. [b]Statewide totals.

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All funding sources supporting the work and all institutional or corporate affiliations of mine are acknowledged in a footnote.

I have had full access to all the data in the study (if applicable) and thereby accept full responsibility for the integrity of the data and the accuracy of the data analysis.

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☒ Author's signature
DR. NICHOLAS CATALDO
17/09/2016
Printed name and date

Completed forms can be scanned and included as a pdf file during the online submission process as a supplemental file not for review.