

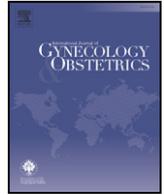


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CLINICAL ARTICLE

Facility and personnel factors influencing magnesium sulfate use for eclampsia and pre-eclampsia in 3 Indian hospitals

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ABSTRACT

Objective: To identify factors at the health facility and health professional levels that might hinder or facilitate the appropriate use of magnesium sulfate for the treatment of pre-eclampsia and eclampsia. **Methods:** Seven focus group discussions were conducted with a purposively sampled group of obstetricians/gynecologists, medical residents, and nurses at 3 hospitals in Nagpur, India. Data were collected on facility and drug availability, criteria for diagnosis and management of pre-eclampsia and eclampsia, attitudes about magnesium sulfate use, and perceived barriers to the treatment of pre-eclampsia and eclampsia. **Results:** Senior gynecologists seemed to encourage the use of magnesium sulfate, especially management prior to transfer to a higher facility. However, clinicians noted a lack of specific institutional guidelines on dose, timing, and indications, particularly in cases in which delivery was not imminent. In all facilities, service providers noted that their clinical care decisions were sometimes influenced by political and social factors, making management of eclampsia and pre-eclampsia cases difficult. Care was further challenged by limited drug availability, particularly at the tertiary-care center. **Conclusion:** Limited drug supply and lack of specific institutional guidelines, equipment, and trained staff hinder the translation of evidence-based policy on magnesium sulfate into practice.

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1. Introduction

Pre-eclampsia is a condition unique to pregnancy; it is characterized by raised blood pressure and proteinuria. Advancing disease is associated with multiple organ system involvement, including renal failure; cerebral edema and hemorrhage; hepatic failure and rupture; and thrombocytopenia. Eclampsia, which is characterized by maternal seizures, is a serious complication that increases the risk of morbidity and maternal/infant mortality. Eclampsia probably accounts for 50 000 deaths per year worldwide and approximately 10% of direct maternal deaths [1]. In India, nearly 5% of maternal deaths can be attributed to pre-eclampsia and eclampsia [2].

Magnesium sulfate is the drug of choice for the treatment and prevention of eclampsia. The risk of convulsion is halved when women with pre-eclampsia are treated with magnesium sulfate [3] but, despite convincing data regarding its safety and efficacy for treatment of eclampsia and pre-eclampsia, use of the compound remains low in many settings [4].

There are significant regional and national differences in the barriers to magnesium sulfate use. In India, the policy environment is supportive of the use of magnesium sulfate for the treatment of severe pre-eclampsia and eclampsia. In 2003, the compound was added to the national Essential Medicines List for the “management of convulsions” [5]. The National Rural Health Mission and Emergency Obstetric Guidelines stipulate that “magnesium sulfate should be available at the sub-centre level facility and the auxiliary nurse midwife/lady health visitor should be trained to administer magnesium sulfate for the treatment of eclampsia” [6].

Still, many Indian women in need do not receive this life-saving treatment. Experience from a clinical study conducted at 3 facilities in a city in Maharashtra in western India showed that, although the use of magnesium sulfate is well-accepted and routine for women with eclampsia, it is not universally used in cases of pre-eclampsia. Owing to concerns about the safety of the drug, providers frequently omit the loading dose, reduce the size of the maintenance dose, or increase the interval between maintenance doses [7]. However, there is insufficient evidence about the efficacy of these modified regimens [8].

Identifying barriers to the availability and use of magnesium sulfate is an important step in the development of strategies to encourage and improve its use. Thus, the primary goal of the present study was to

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identify factors at the health facility and health professional levels that might influence the treatment of pre-eclampsia and eclampsia.

2. Materials and methods

The present data were collected at 3 hospitals in Nagpur, India, as the qualitative component of a project conducted from April 2008 to April 2010 testing the safety, acceptability, and feasibility of a low-tech spring-loaded pump (Springfusor; Go Medical, Australia) for the delivery of magnesium sulfate to women with pre-eclampsia (NCT Registry: NCT00666133 and NCT01030627). The sites included a teaching institute (tertiary-care referral hospital), a women's hospital, and a trust hospital (both lower-level secondary-care hospitals). Both the teaching and the women's hospitals performed approximately 1000 deliveries each and treated approximately 100–120 cases of pre-eclampsia and eclampsia per month. The trust hospital was smaller and performed approximately 100 deliveries per month. Ethics approval was obtained for the project from the relevant Institutional Review Boards at the 3 facilities.

From August 1 to 31, 2010, focus group discussions (FGDs) were conducted with a purposively sampled group of 3 types of service provider: nurses; clinicians (i.e. residents); and obstetricians/gynecologists. Seven FGDs were carried out: 3 at the teaching institute (1 with consultants, 1 with residents, and 1 with nurses); and 2 each (1 with gynecologists and 1 with nurses) at the women's and trust hospitals. Each FGD included 8–10 people. Semi-structured interview guides focused on: facility and drug availability; criteria for diagnosis and management of pre-eclampsia and eclampsia; attitudes about magnesium sulfate use in management of pre-eclampsia and eclampsia; and perceived barriers to the treatment of pre-eclampsia and eclampsia. Providers were asked about the following: shortcomings in the care of patients at their facility; when women were identified as being at risk; available drugs and diagnostic technologies; and standards of care for management of pre-eclampsia and eclampsia (including drug regimens, duration of therapy, perceived risks, and barriers to use of specific medications). Providers were also asked to assess their experience in the clinical trial of the Springfusor delivery system for administration of magnesium sulfate. All participants provided written informed consent. Interviews were conducted in English (with obstetricians and gynecologists) or Marathi (with nurses) by a medical professional (AB) trained in qualitative research methods. All FGDs were audiotape recorded and transcribed into English. Each discussion lasted approximately 45 minutes.

The interviews were designed, implemented, and analyzed according to grounded-theory methods. Grounded theory involves the collection of data that detail participants' views, feelings, intentions, and actions, as well as the contexts and structures of their lives [9]. The researcher constantly reviews the data to identify emerging patterns and new avenues of inquiry. Three investigators (AB, SM, HB) conducted a content analysis of the FGD transcripts to identify common themes and domains.

3. Results

Participants at all facilities generally agreed about the signs and symptoms that led to the diagnosis of pre-eclampsia and eclampsia, and those symptoms considered serious enough to indicate a fatal prognosis or when women were at risk. However, respondents at all 3 institutions found managing pre-eclampsia and eclampsia cases a challenge. Both physicians and nurses acknowledged that many women delayed seeking care owing to lack of knowledge about the condition, absence of affordable transportation, and difficulties in accessing services. Most women from rural and peripheral areas attended in acute emergency conditions and their obstetric history; past clinical history; and current history of illness, investigation, and treatment were unknown. The failure to diagnose pre-eclampsia and

eclampsia (or even take routine blood pressure measures) at lower levels of care also complicated case management at the tertiary-care facilities.

While acknowledging the beneficial role of magnesium sulfate in the management of pre-eclampsia, gynecologists from the teaching and women's hospitals still expressed their reservations about extensive use of the drug, particularly without the ability to monitor serum magnesium levels. Clinicians and nurses at all 3 facilities mentioned that the absence of institutional guidelines about the indications for magnesium sulfate use led to confusion in treatment practice. Gynecologists at the teaching hospital were also confused about the indications for use among women with pre-eclampsia and women with ongoing convulsions. At this hospital, each unit followed a different protocol for management—often resulting in confusion among junior staff.

Service providers were concerned about risks to the fetus, as well as the safety of the mother, particularly when magnesium sulfate was administered concurrently with anesthesia during cesarean delivery. In fact, a senior gynecologist (a unit-in-charge) at the teaching hospital did not use magnesium sulfate precisely for this reason—preferring, instead, antihypertensives and anticonvulsants such as phenytoin. A lack of cooperation among specialists exacerbated these difficulties. Gynecologists at the women's and teaching hospitals complained that anesthesiologists at their hospitals advised against the use of magnesium sulfate in case of impending cesarean—thus, further inhibiting the use of the drug even when clinically indicated.

There were often gaps in referral and transfer. Service providers at the women's and trust hospitals complained that many women refused to transfer to a tertiary-care facility, even when the hospital lacked the requisite emergency care facilities needed to manage the case. Many women and their families associated intractable complications, poor management, and prognosis with the tertiary-care facility (teaching hospital). At the same time, gynecologists at the lower-level hospitals were reluctant to treat pre-eclampsia cases on site, usually referring such cases to tertiary-care hospital. This reluctance stemmed, in part, from concern about the effect of adverse patient outcomes on the hospital's reputation.

The service providers, under the circumstances, were required to handle the clinical emergency, counsel the relatives, and manage public opinion at a time when maternal mortality is perceived as being indicative of negligence in care. Inevitably, women and their families sometimes took matters into their own hands. A nurse at the trust hospital explained that some cases would discharge themselves and go directly to the tertiary-care hospital for care.

Clinicians and nurses at all 3 facilities felt that their hospitals lacked the requisite manpower and equipment to manage pre-eclampsia and eclampsia cases according to recommended clinical procedures. The women's and trust hospitals lacked adequate emergency facilities and were even required to outsource their routine laboratory examinations. These hospitals did regularly have magnesium sulfate in stock, especially for the provision of a loading dose prior to transfer to a tertiary-care hospital. However, these hospitals lacked enough staff to manage even the routine cases. Under the National Rural Health Mission, a new junior doctor's post was added at the women's hospital but this proved inadequate for meeting demands after routine office hours.

By contrast, service providers at the teaching hospital—a tertiary-care referral hospital charged with managing the most critical cases—lacked the material to do so: adequate laboratory and diagnostic tools; monitoring facilities; essential medications, including magnesium sulfate; a functioning respirator; and essential staff. Clinicians noted that magnesium sulfate was often not available and they had to ask relatives to purchase the medication from outside the hospital. One service provider indicated that a lot of time was wasted in prescribing and procuring the drug. Even laboratory investigations could not easily be performed on site. As a result, the gynecologists at the hospital had to manage such cases without adequate investigative support. Nurses

reported that residents often could not be reached, particularly at night, making management of emergency cases difficult. The nursing staff were overwhelmed with work; in the morning, they were busy with admissions and managing outpatients. In the evening, the staff numbers were insufficient to handle the treatment of patients and the counseling of relatives.

The nurses at the 3 hospitals stated that they had neither the knowledge nor the skills to manage eclampsia patients. At the same time, they accepted that there was some hesitancy to manage such complicated cases. They feared being blamed for any negative outcomes that could result, even when those outcomes were a natural consequence of the condition. A senior gynecologist at the trust hospital—where the nursing staff comprised auxiliary nurse midwives, rather than staff nurses—was not supportive of training auxiliary nurse midwives, who undergo shorter training than do nurses, to perform these duties. Generally, however, the clinicians at all 3 facilities expected that the management of pre-eclampsia and eclampsia cases would improve if paramedics, particularly those stationed in lower-level facilities, were trained and able to provide a loading dose of magnesium sulfate.

4. Discussion

Since 2003, magnesium sulfate has been included in the national list of essential medicines in India and in the National Rural Health Mission program. However, the present study indicates that this progressive policy was not sufficient to ensure adequate access and rational use of the drug and practice of evidence-based medicine (Table 1). At the 2 lower-level hospitals (trust and women's hospitals), senior gynecologists and hospital leaders seemed to encourage the use of the drug, especially for management prior to transfer to a higher facility. Clinicians noted a lack of specific institutional guidelines on dose, timing, and indications, particularly in cases in which delivery was not imminent. Standards of care were less uniform at the tertiary-care center, where individual units were more autonomous and not open to modifying their views based on current research. In all facilities, service providers noted that their clinical care decisions were sometimes influenced by political and social factors. They found it difficult to explain to family members the difference between complications of the underlying disease and the effects of magnesium sulfate administration.

A tertiary-care/teaching hospital should have everything, including medicines and specialists. However, service providers at the tertiary-care hospital reported that, owing to high case loads, drug stock-outs did happen and patients were required to procure drugs from nearby pharmacies. Other studies have shown that, in some

places, limited drug availability and poorly implemented clinical guidelines constrict use of this life-saving medication [10,11]. Even where the drug is available, utilization may be low [12] because providers are concerned about its safety or lack experience with its use [13]. Given the intensive monitoring required, healthcare providers may be reluctant or lack adequate training to initiate treatment for a condition that may be relatively infrequent [14].

In the present study, manpower available at the tertiary-care facility was not commensurate with the amount of monitoring required for women who were critically ill. There was a lack of support from other medical specialties, resulting in gaps in care. According to reports, patients were not managed at lower-level facilities because of the absence of specialists, but when they reached the tertiary-care center the specialists were not convinced about the urgency of care required, and the anesthesiologists were often reluctant to treat women who had recently received magnesium sulfate.

The main limitation of the present case study was that it involved a small number of facilities in 1 city in western India. The study was also conducted at the conclusion of a clinical trial on the use of magnesium sulfate. As a result, participants were more likely to be aware of the issue of pre-eclampsia/eclampsia, treatment practices, and guidelines; therefore, the findings may not reflect the current situation in other states and regions in India. Furthermore, the study did not reflect the availability and use of magnesium sulfate in the private sector, where many women in India receive their care. Other limitations of the study included a lack of observational data on actual treatment practices and drug availability. Future research will need to assess the availability and use of magnesium sulfate among eligible patients at private-sector health facilities and lower-level public-sector health facilities. The present findings are based on the providers' descriptions of these factors and did not include assessment of community-level data.

Magnesium sulfate availability in Nagpur—at the 3 hospitals—represents the most optimistic picture of the supply-and-use situation in Maharashtra. However, the present assessment indicates that there is a failure to translate progressive evidence-based policy—as reflected in the Essential Medicines List and national policy—into treatment practices. Health system issues (including the adequate and consistent supply of drugs, equipment, and trained staff) are necessary to ensure the elimination of such gaps. Moreover, efforts need to be undertaken to ensure that service providers at all levels of the health system are aware of existing guidelines and that such guidelines are readily accessible. The study findings suggest that personnel and equipment in critical-care units need to be upgraded in referral centers. Efforts to ameliorate the situation must also address service provider attitudes and include regular in-

Table 1
Major barriers and facilitators to the availability and use of magnesium sulfate identified at each level.

Hospital	Barriers identified	Facilitators identified	Outcome
University teaching hospital	Stock-outs of MgSO ₄ Inadequate paramedic staff for management of critical cases No institutional protocol for management of pre-eclampsia cases Nurses not trained in use of MgSO ₄ Specialists unconvinced of the utility and safety of MgSO ₄	Most health professionals aware that MgSO ₄ is first-line treatment for eclampsia	Evidence that MgSO ₄ used for treatment of eclampsia in limited cases, but not severe pre-eclampsia
Women's hospital (secondary-level center)	Medical doctor not available in evening hours Nursing staff not trained in use of MgSO ₄ Anesthesiologist resistant to use of MgSO ₄ in cases where cesarean indicated No emergency care backup Concerns about hospital reputation in the event of maternal death	MgSO ₄ available in hospital stock Most health professionals aware that MgSO ₄ is first-line treatment for eclampsia, and institutional Head supportive of rational use	Evidence that MgSO ₄ used for treatment of eclampsia in limited cases, but not severe pre-eclampsia
Trust hospital (secondary-level center)	Nursing staff not trained in use of MgSO ₄ Fewer medical doctors No emergency care backup Concerns about hospital reputation in the event of maternal death	MgSO ₄ available in hospital stock Most health professionals aware that MgSO ₄ is first-line treatment for eclampsia	Evidence that MgSO ₄ used for treatment of eclampsia in limited cases, but not severe pre-eclampsia

service, as well as pre-service, training. These actions should be accompanied by rigorous evaluation at the local level to ensure that such steps provide the desired outcome.

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Conflict of interest

The authors have no conflicts of interest.

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