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A Comparative Study of Intravenous and Intramuscular Administration of Magnesium Sulfate in Eclampsia

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Abstract: ***Introduction: Hypertensive disorder of pregnancy (HDP) is a common pregnancy complication involving the activation and injury of maternal endothelial cells. The Pritchard regimen is the standard protocol for managing eclampsia, and magnesium sulfate is the most popular anticonvulsant. This study aimed to evaluate the efficacy and advantages of intravenously administered magnesium sulfate for control of convulsion and prevention of its recurrence in women with eclampsia. Methodology: The study aimed to compare the efficacy and safety of an intravenous (Zuspan) and intramuscular (Pritchard's) magnesium sulfate regimen for pregnant patients presenting with eclampsia. The study population consisted of 80 pregnant patients above 20 weeks presenting with eclampsia at a tertiary care center. The study used a single blind randomized comparative study, with a sample size of 40 subjects in each group. The patients were divided into two groups: Group A, given the standard Pritchard's regimen (intramuscular), and Group B, given the standard Zuspan regimen (intravenous). Results: The study analyzed 80 pregnant patients above 20 weeks presenting with eclampsia at a tertiary care center. The majority of cases were primigravida's, with 63.8% being multigravidas. The majority of cases were primigravida's, with 63.7% being preterm. The study found no statistical difference in the control of convulsions or the need for additional doses after receiving the standard dose of MgSo4. Conclusion: Both intramuscular and intravenous magnesium sulfate regimens were effective in preventing convulsions in eclampsia cases. However, intramuscular magnesium sulfate has a higher incidence of magnesium toxicity, leading to complications like respiratory depression.***

Keywords: Eclampsia, Hypertensive disorder of pregnancy, Maternal mortality, Pregnancy complications, Pritchard, Zuspan

1. Introduction

Hypertensive disorder of pregnancy (HDP) is a common complication of pregnancy that poses significant risks to both the mother and the fetus during pregnancy. HDP is a multi - organ, heterogeneous disorder associated with significant maternal and neonatal morbidity and mortality. The National High Blood Pressure Education Program (NHBPEP) Working Group on High Blood Pressure in Pregnancy proposed the most widely accepted definition and classification of HDP, which uses blood pressure of 140/90 mm Hg or higher on two separate occasions at least four hours apart during the pregnancy as the diagnostic criterion (1) .

The incidence of HDP varies in different populations and is affected by the definition used in reporting the incidence. It is also influenced by parity, age, and race. In a hospital - based study conducted in India in 2006, the incidence of HDP was reported to be 5.38%. The disease comprises preeclampsia and eclampsia, with preeclampsia affecting 4%–5% of pregnancies and eclampsia causing seizures in women with preeclampsia (2) .

The pathogenesis of HDP is not completely clear, but it is a multifactorial disease with a central pathogenesis involving the systemic activation and injury of maternal endothelial cells. This manifests as raised blood pressure, proteinuria, systemic inflammatory response, and accumulation of antiangiogenic factors. Termination of pregnancy reverses the clinical manifestations of the disease, suggesting that trophoblastic invasion probably plays a central role in the pathogenesis of preeclampsia (3) .

Management includes anticonvulsants, antihypertensives, fluid and electrolyte balance, and termination of pregnancy. Various drugs and regimens have been advocated for the management of eclampsia and imminent eclampsia, with magnesium sulfate being the most popular anticonvulsant. The Pritchard regimen, published by Dr. J. A Prichard, is considered the standard protocol for managing eclampsia (4)

In India, most medical centers prefer intramuscular administration due to non - availability of infusion sets, busy nursing staff, and cost - effective sampling for serum magnesium levels. This study aimed to evaluate the efficacy and advantages of intravenously administered magnesium sulfate for control of convulsion and prevention of its recurrence in women with eclampsia compared to conventionally administered intramuscular regimens.

2. Aim and objectives

1) To find out the effectiveness of intravenous and intramuscular magnesium Sulfate in the management of eclampsia.
2) To compare the efficacy of intravenous and Intramuscular magnesium Sulfate for prevention of

recurrence of eclampsia.
3) To compare the maternal and fetal outcome in intramuscular and intravenous administration of magnesium Sulfate.
4) To compare the safety margin, side effects and complications of intravascular and intramuscular administration of Magnesium sulfate.

3. Material and Methods

A total of eighty Eclampsia patients admitted in of static and gynecology department CPR hospital Maharashtra. A total of duration of the study was 15months (from7th December 2019 to 7th March 2021)

Inclusion Criteria
All Pregnant patients (Primigravida / multigravida) with antepartum, intrapartum and postpartum eclampsia presenting in obstetric emergency.

Exclusion Criteria
1) Patients who is ak/c/o epilepsy.
2) Patients with massive pulmonary edema with respiratory failure.
3) Patients in whom magnesium sulfate is contraindicated like renal failure (severe oliguria or anuria), myasthenia gravis, hypocalcaemic states, cardiac conduction disorders etc.
4) Patients with cerebrovascular accidents.

4. Methodology of the data collection

1) Written informed consent was obtained in all the cases.
2) All the 80 patients included in the study were subjected to detailed history and thorough clinical examination including general examination, obstetrical and systemic examination.
   a) History was elicited from the patient and her attendants.
   b) History regarding her age, parity, booking status, gestational age, number of eclamptic fits before admission, whether she was a known case of pregnancy induced hypertension or chronic hypertension, whether she was on anti - hypertensive drugs, presence of edema if so, how long, existence of imminent symptoms like headache, vomiting, severe epigastric pain, blurring of vision were all elicited thoroughly.
   c) Any known history of epilepsy, renal failure, cardiac conduction disorders, and myasthenia gravis was also elicited in a detailed manner.
3) All the investigations including ABO and Rh type, complete hemogram including peripheral smear to see any evidence of hemolysis, liver function tests, kidney function tests, coagulation profile, fundus examination and urine analysis for proteinuria were done.
4) All 80 cases were divided in to two groups.
   a) **Group A** received Magnesium sulfate as per Pritchard regimen (intramuscular). This included a loading dose of 4 grams as 20%solution given intravenously at a rate not to exceed 1 g/ min and 5 grams of magnesium sulfate deep IM in each buttock (14 grams). Subsequently5 grams of magnesium sulfate were given deep IMevery4 hourly in alternate buttock.
   b) **Group B** received zuspan regimen which is continuous intravenous infusion consisting of loading dose of 4gm magnesium sulfate in 100 ml Ringer lactate given within 20 minutes followed by maintenance dose 1 gm/hour by infusion pump.

Each case was monitored during and before giving each maintenance dose, for any evidence of magnesium sulfate toxicity by observing knee jerk, urinary output and respiratory output hourly in intravenous (zuspan regimen) and 4 hourlies in intramuscular (Pritchard's regimen) respectively. Maintenance dose was skipped if patellar reflexes were absent, respiratory rate was <12 per minuteorurinaryoutputwaslessthan100ml/hr. over preceding four hours
. Serum magnesium was also sent for detecting magnesium toxicity.

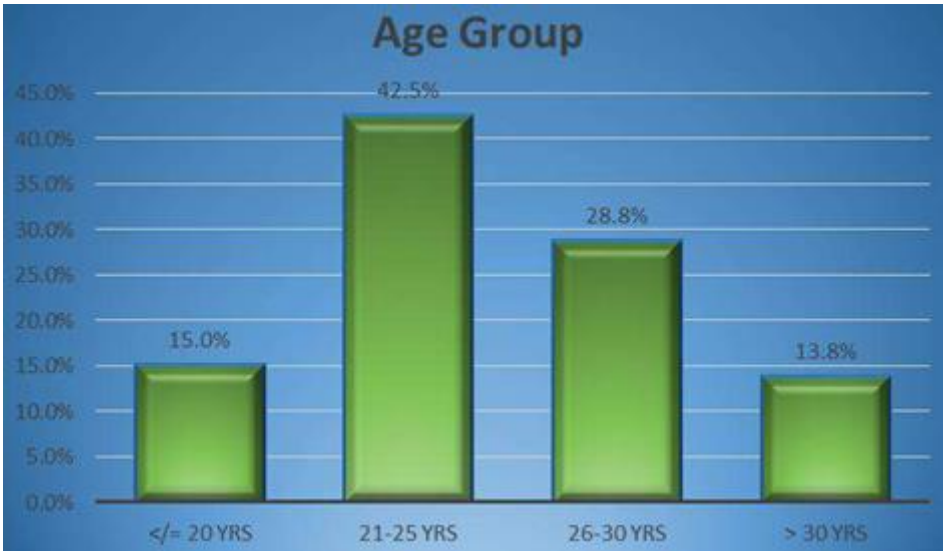
In both the groups, if convulsions occurred within four hours after loading dose, then it was said to be recurrence of convulsions and an additional dose of 2 gm IV slowly has to be given and previous dose schedule has to be continued. If convulsion is still not controlled with this, IV phenytoin was given. Termination of pregnancy was considered in all cases of eclampsia. Delivery was expedited in the form of induction/ augmentation of labouror L. S. C. S depending upon Bishop's score, gestational age and viability of the fetus.

The primary objective of the study was to compare the efficacy and safety of Intravenous regimen (Zuspan regimen) as compared to intramuscular (standard Pritchardregimen). Maternal complications and perinatal outcome were taken as a secondary objective in both groups. Baby was managed by paediatrician following vaginal delivery or caesarean section till discharge.

Statistical Analysis
The quantitative data was represented as their mean ± SD. Categorical and nominal data was expressed in percentage. Thet – test was used for analyzing quantitative data, or else non parametric data was analyzed by Mann Whitney test and categorical data was analyzed by using chi – square test. The significance threshold of p value was set at <0.05. All analysis was carried out by using SPSS software version 21.

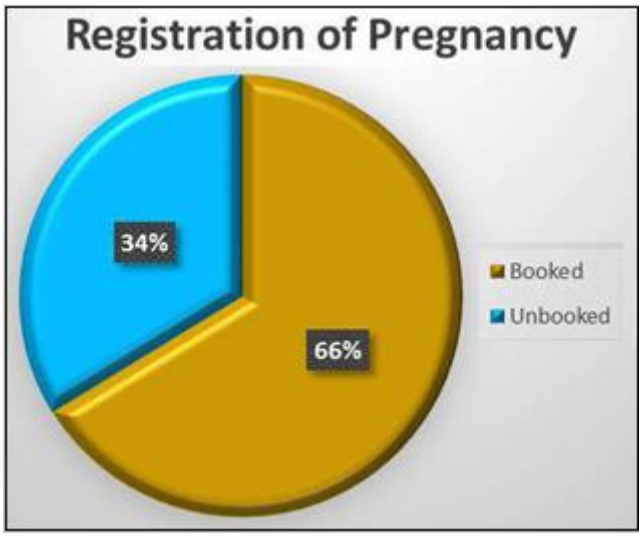
5. Results and Observations

Mean age of the females in the studywas 25.68 years with most of them (71.3%) were between 21 - 30 years of age.



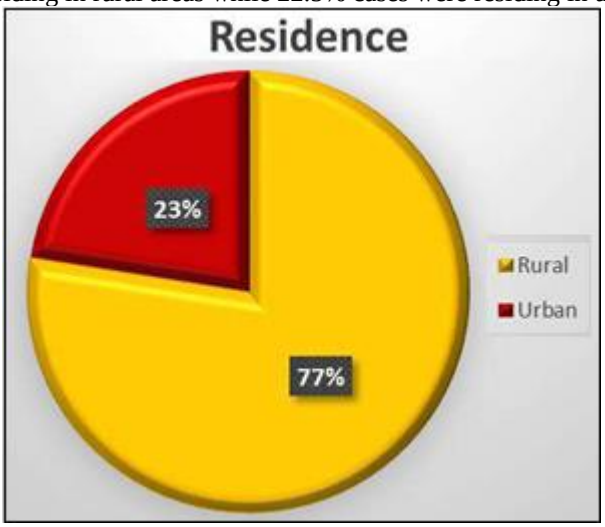
Graph 1: Distribution of study cases as per age group

Registration of pregnancy was done in 66.3% cases while remaining 33.7% cases came to our hospital unregistered.



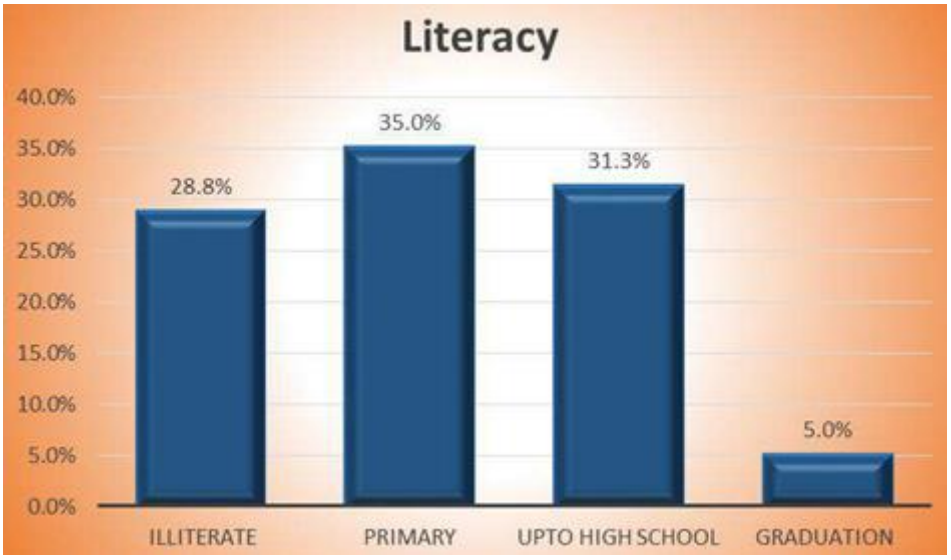
Graph 2: Distribution of study cases as per registration of pregnancy

Majority of cases (77.5%) were residing in rural areas while 22.5% cases were residing in urban areas.



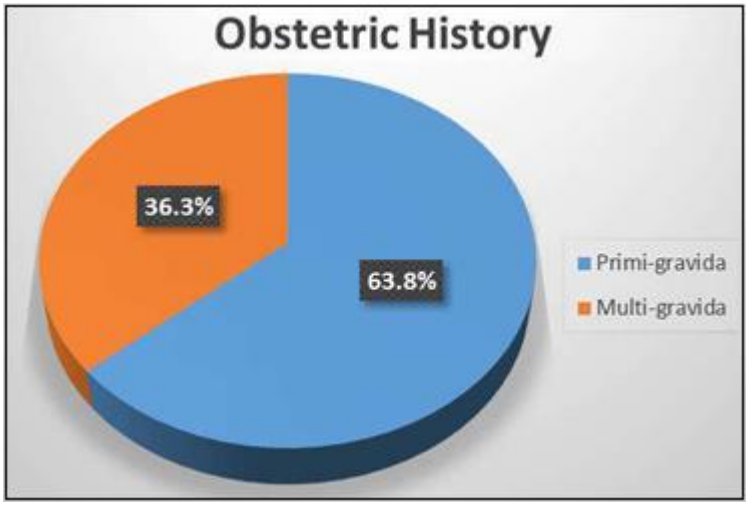
Graph 3: Distribution of study cases as per residence

Low literacy was found among study cohort (illiterates were 28.8%. Rest was educated up to primary35%, high school 31.3% while only 5% cases were graduates)



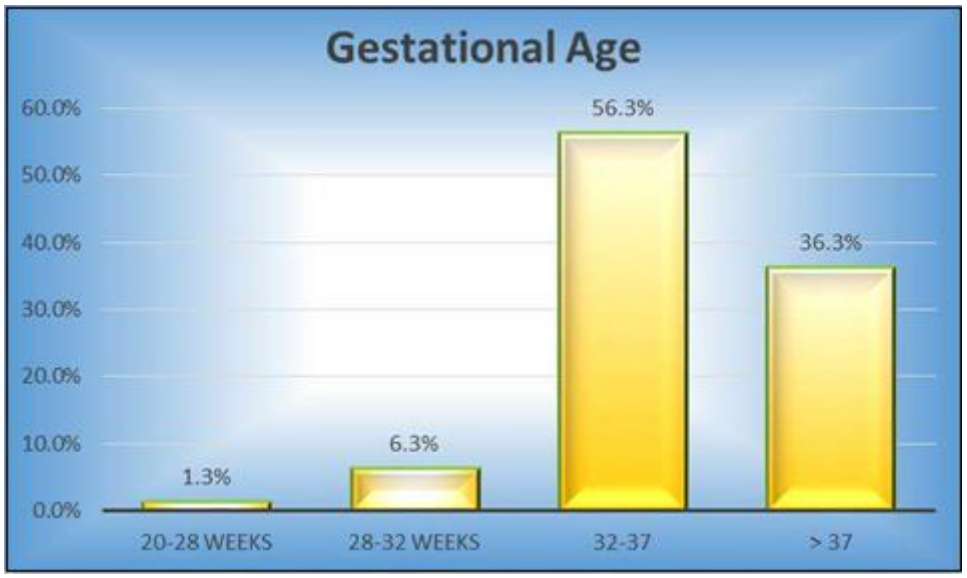
Graph 4: Distribution of study cases as per literacy level

Out of the total 80cases, 63.8% were primigravida's while remaining 36.3% were multigravidas.



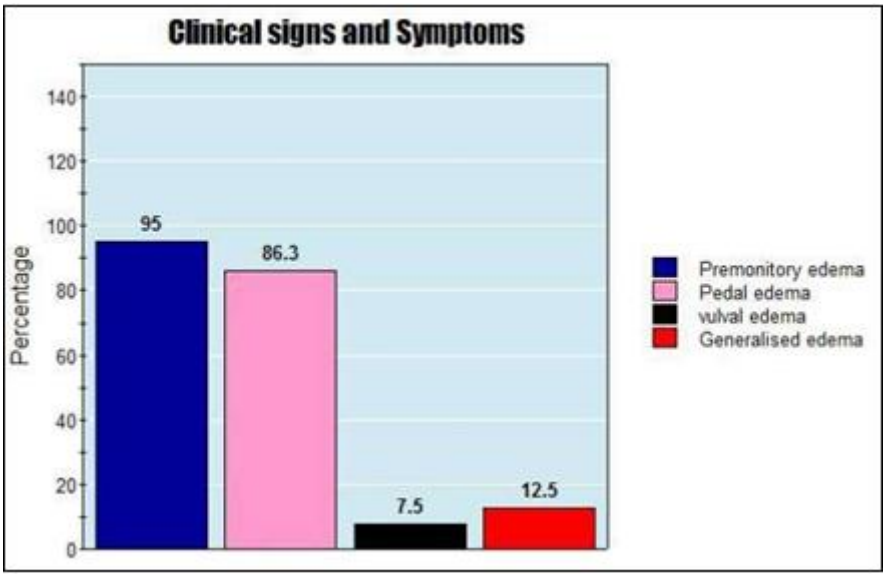
Graph 5: Distribution of study cases as per obstetric history

Out of the 80 eclampsia cases studied, majority were preterm 63.7%, in which 1.3% belonged to 20 - 28 wks, 6.3% belonged to 28 - 32wks, 56.3% belonged to 32 - 37 wks. While 36.3% cases were term eclampsia cases.



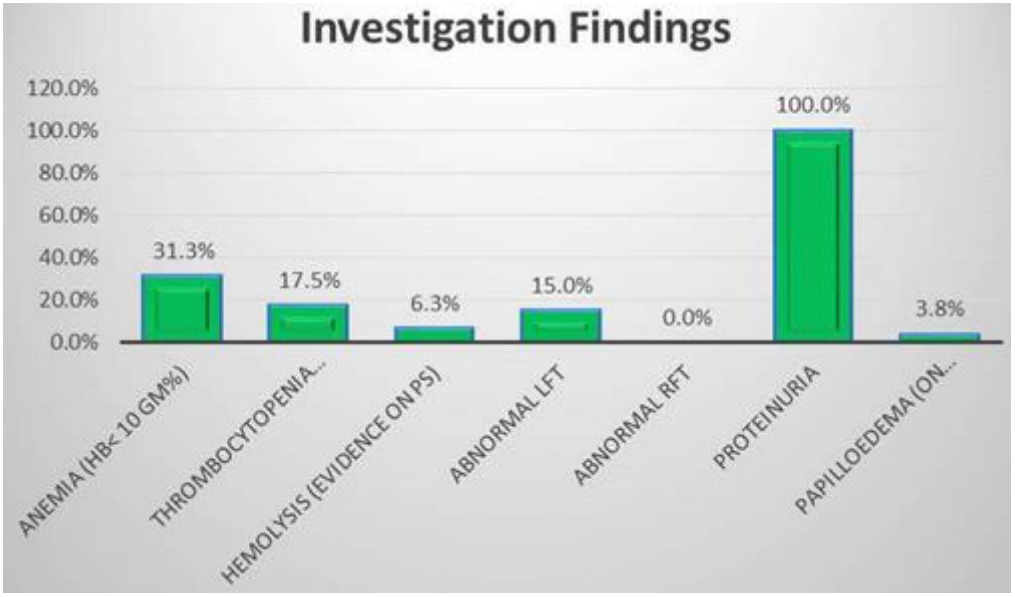
Graph 6: Distribution of study cases as per gestational age

Pre - monitory Symptoms were seen in 95% cases. Pedal edema, vulval edema and generalized edema was seen in 86.3%, 7.5% and 12.5% cases respectively.



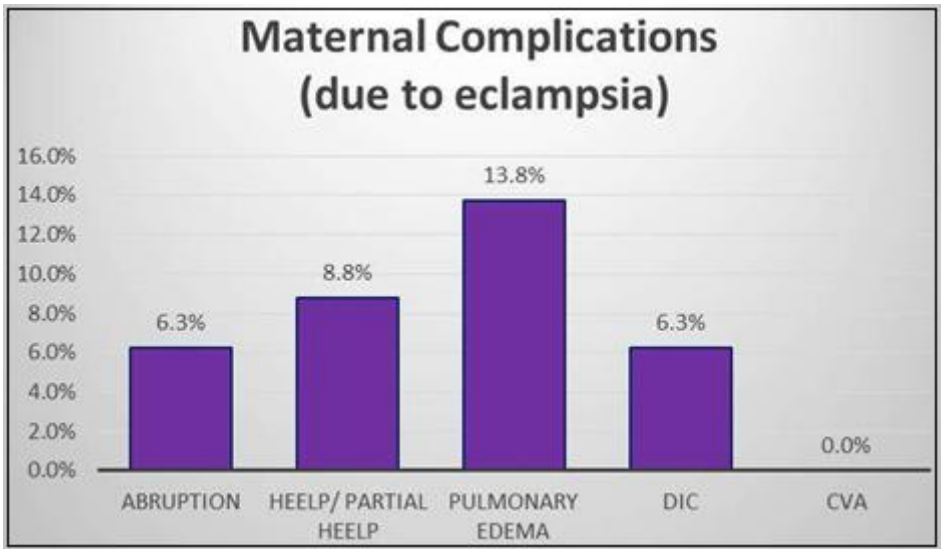
Graph 7: Distribution of study cases as per clinical signs and symptoms

Hb<10 gm% (31.3%), Thrombocytopenia (17.5%), peripheral smears/o hemolysis (6.3%) Derangement of LFT (15%) were the abnormal laboratory findings noted in study group. Proteinuria was commonly found in all cases. Papilledema on fundoscopy was found only in 3.8%.



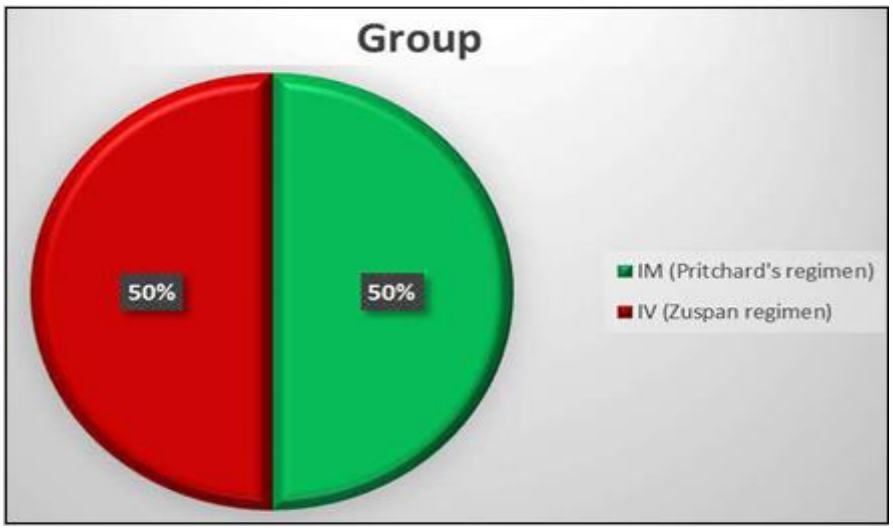
Graph 8: Distribution of study cases as per investigation details

Maternal complications due to eclampsia, observed in present study were: Abruption (6.3%), HELLP/partial HELLP (8.8%), pulmonary edema (13.8%), DIC (6.3%) and CVA (0%).



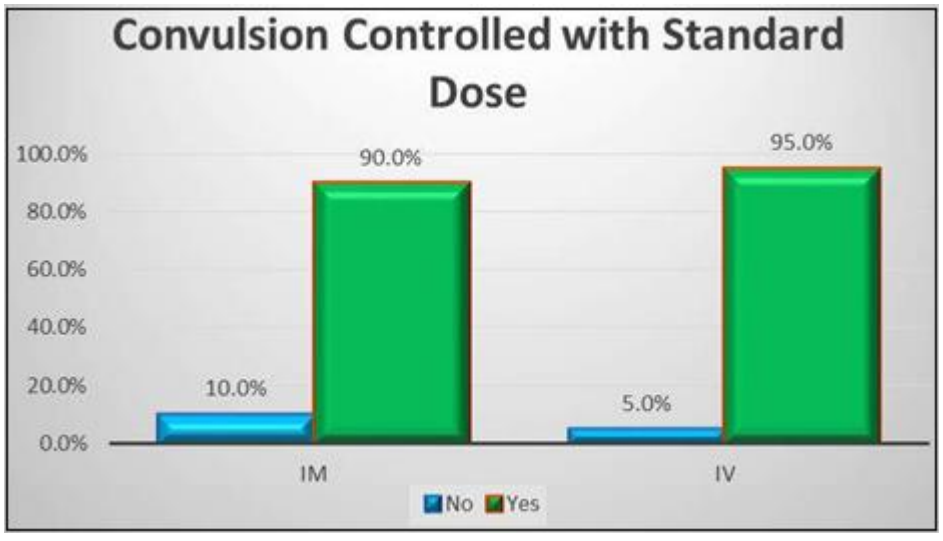
Graph 9: Distribution of study cases as per maternal complications associated with eclampsia

A total of 80 cases presenting with eclampsia at our hospital were randomly divided into one of the following two groups (40 each) using computer generated random numbers: **Group IM -** Given standard Pritchard's regime and; **Group IV -** Given Zuspan regimen.

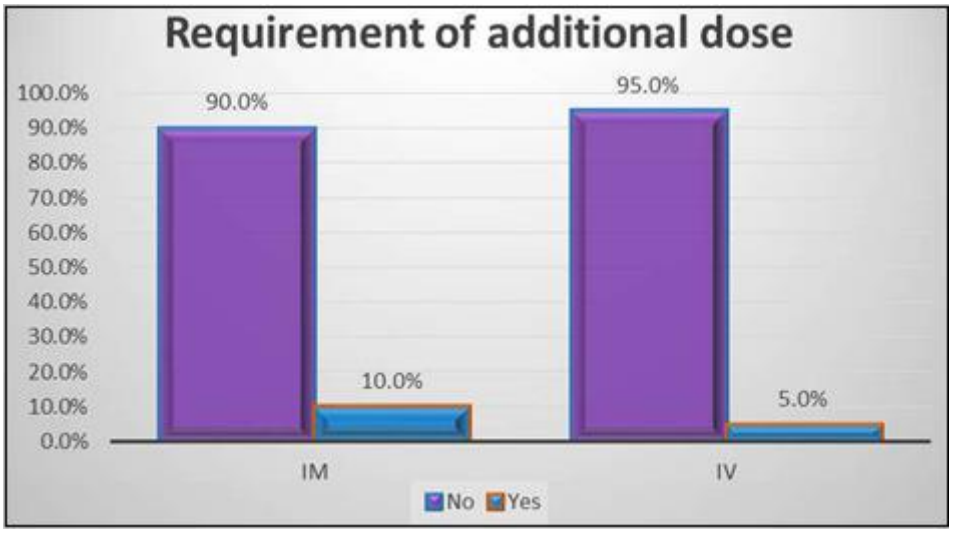


Graph 10: Distribution of cases as per route of administration of study drug

Convulsions were controlled with standard dose in 90% cases of IM regimen and 95% cases of IV regimen. No statistical difference was observed among study groups in terms of control of convulsions (p - 0.675).

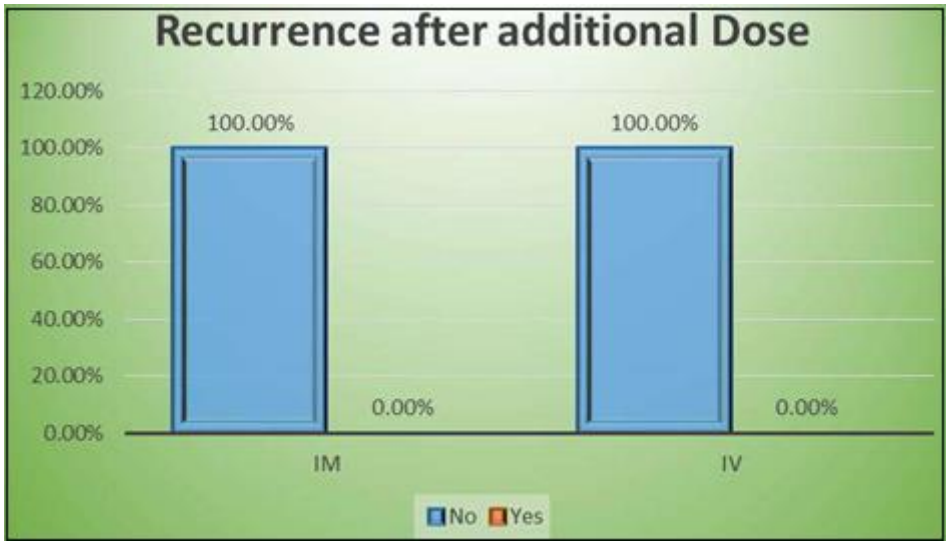


Additional dose to control convulsion was required in 10% and 5%cases of IM and IV regimen respectively. The results were statistically comparable (p - 0.676).



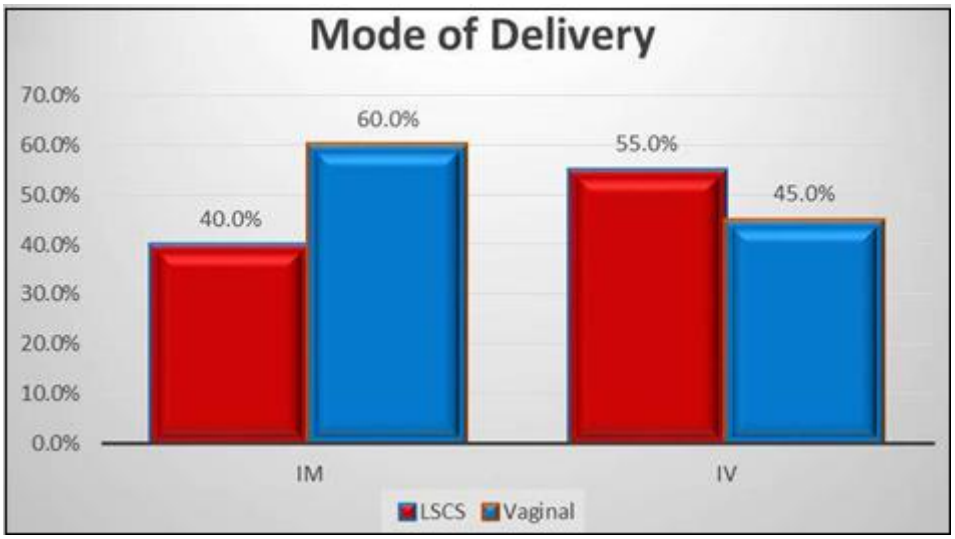
Graph 12: Association of study groups with requirement of additional dose after receiving standard dose of MgSo4

No recurrence of convulsions after additional dose was seen in any of the group.



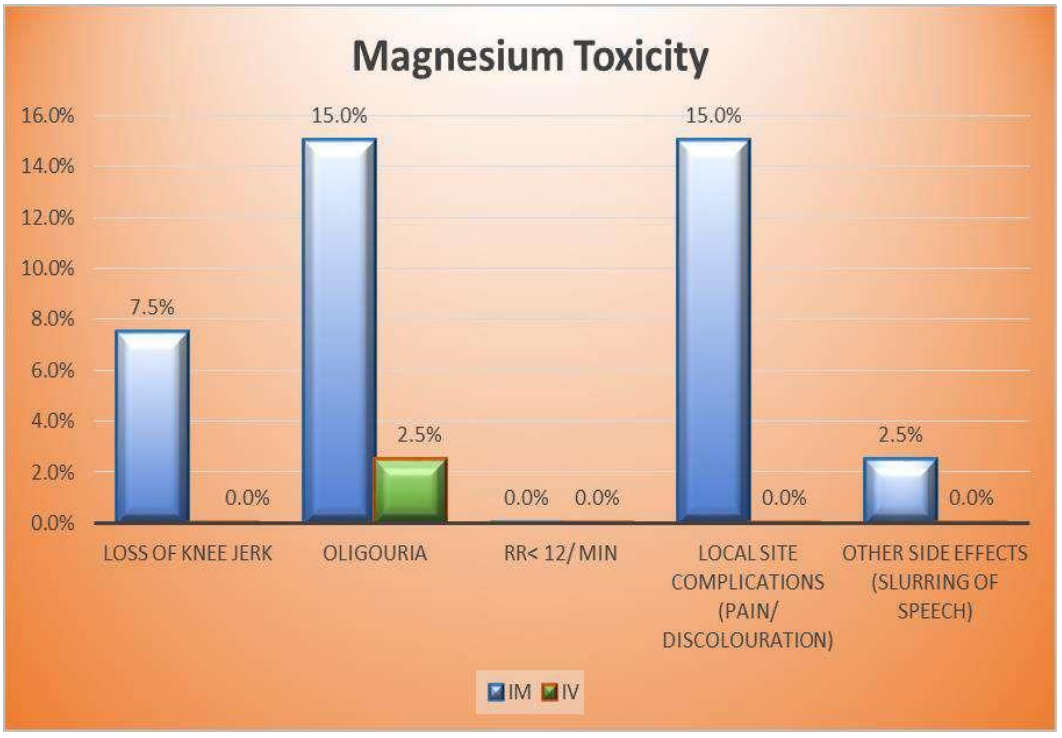
Graph 13: Recurrence of convulsions after additional dose

Mode of delivery as caesarean section was noted in 40% cases of IM regimen and 55% cases of IV regimen. The difference was statistically insignificant (p - 0.27).



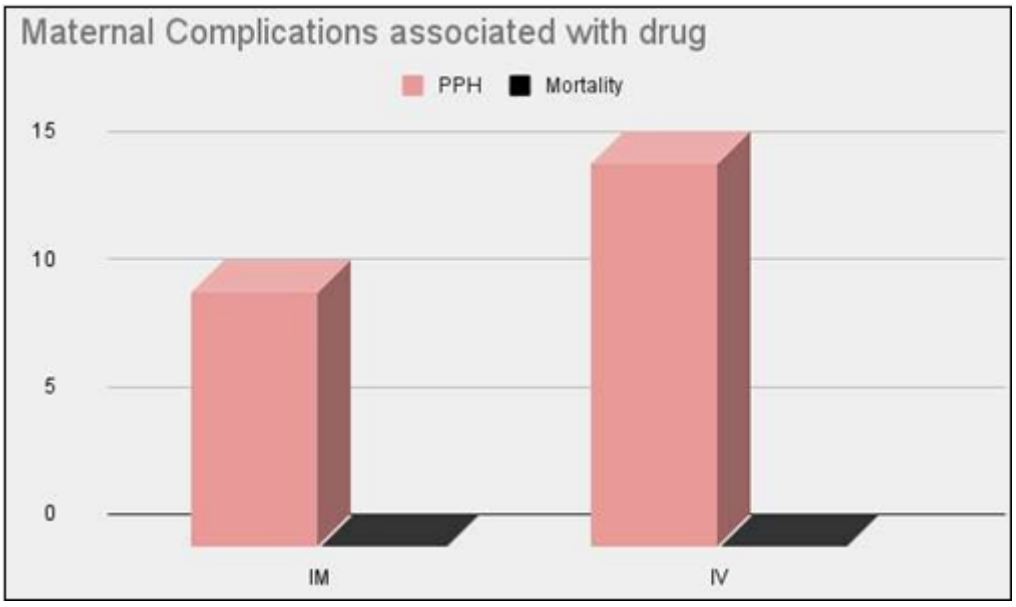
Graph 14: Association of study drug with mode of delivery

Incidence of magnesium toxicity was observed to be higher with IM dose. Loss of knee jerk was seen in 7.5% cases in IM group as compared to none in IV group (p - 0.24). Oliguria was seen in 15% cases and 2.5% cases of IM and IV group respectively (p - 0.11). Local site complications like pain and discoloration were exclusively associated with IM injections (15%; p<0.01). Slurring of speech and drowsiness was seen in 2.5% cases of IM group as compared to none in IV group.



Graph 15: Association of study drug with magnesium toxicity

No difference was observed among study groups in terms of incidence of PPH (10% vs 15%) and maternal mortality (0% vs 0%) in IM and IV group respectively.



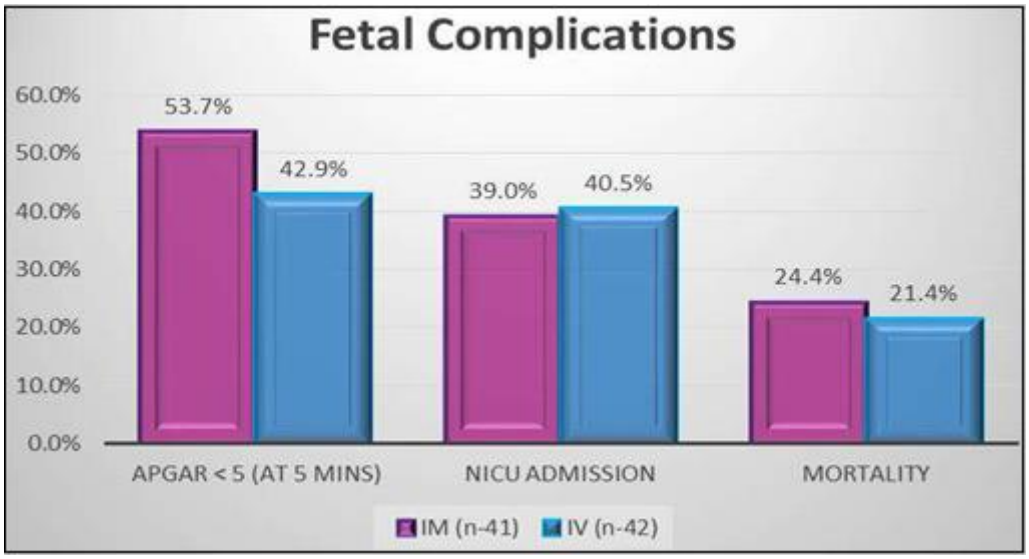
Graph 16: Association of study drug with maternal complications

Mean birth weight was 2.32Kg and 2.45Kg in IM and IV groups respectively. The difference was non - significant statistically (p - 0.28).

Graph 17: Association of study drug with mean birth weight

* Include NND, still birth & IUD

No difference was observed among study groups in terms of neonatal findings like low APGAR at 5 min (53.7% vs 42.9%), requirement of NICU admissions (39%vs 40.5%) and neonatal mortality (24.4%vs 21.4%) in IM and IV group respectively.



Graph 18: Association of study drug with fetal complications

6. Discussion

Hypertensive disorders are important cause of maternal and fetal morbidity and mortality. It is the most common medical complication of pregnancy and can occur at any time during the second half of pregnancy or the first few weeks after delivery. Unlike preeclampsia, eclampsia can be considered as a preventable condition. Magnesium sulfate (MgSO4) is the first choice for the prevention and the treatment of eclampsia. The efficacy of magnesium sulfate in the prevention and control of eclamptic convulsions has been validated in various randomized controlled trials performed worldwide. Since the introduction of Pritchard regimen there has been a constant discussion in literature regarding the route of magnesium sulfate and therapeutic serum magnesium levels to reduce magnesium related toxicities.

Zuspan and SibaiBaha (5) both have proposed protocol which consists of continuous infusion of magnesium sulfate in which toxicity caused due to magnesium Sulfate (MgSO4) can be kept under control and complications due to toxicity could be prevented. In the Zuspan regimen, the loading dose consists of an initial intravenous dose of 4 g slowly over 5 - 10 min followed by a maintenance dose of 1 - 2 g every hour given by an infusion pump.

In this present hospital based comparative study, we aimed to find out the efficacy of intravenous and Intramuscular magnesium sulfate (MgSO4) in management of eclampsia, in preventing recurrence of convulsion and to compare the maternal and fetal outcome in intramuscular and intravenous administration of magnesium sulfate (MgSO4). A total of 80 cases presenting with eclampsia at our hospital were randomly divided into one of the following two groups (40 each) using computer generated random numbers: **Group IM -** Given standard Pritchard's regime **and; Group IV –** Given standard Zuspanregimen.

Baseline Characteristics

Mean age of the females in the study was 25.68 years with most of the females (71.3%) were between 21 - 30 years of age. Registration of pregnancy was done in 66.3% cases while remaining 33.7% cases were unregistered. Outof the total 80 cases, 63.8% were primigravida while remaining 36.3% were multigravida. Low literacy (63.8%) was noted among study cohort while only 5%cases were graduates. Majorityof cases were residing in rural areas (77.5%) while 22.5% cases were from urban areas. These socio demographic findings could be reflection of the location in which the study was conducted but the it clearly signifies that rural life and educational status has a bearing on their understanding of need for regular antenatal checkups and their treatment seeking behaviorin due time. The other point noted was that eclampsia was more common in young and primigravida's.

Similar demographic pattern was also observed by other studies. In the study by Ranjana et al. (6) , mean age of the patients was 25.7±3.53 years. Mean body mass index of 20.31±1.34 kg/m^2. Nautiyal et al. (7) in their study observed mean age of the patients of eclampsia/ pre - eclampsia as 25.5 years while Sharmaetal. (8) observed the mean age as 25.9 years in their study group. Kumar S et al. (9) in their study too, observed mean age of 123 such cases as 25.07 (range 19 - 40) years, mostly in the age group of 21 - 25 years (51.21%), followed by the age groups of 26 - 30 years (35.78%).

Uzma Kauser et al (10) in their studyfound that majority of eclampsia patients belonged to 20 - 25 years age group (63%) followed by above 30 years of age (22%) Eclampsia is diseases of primigravida which was seen in this study as well (63.8% cases were primi - gravida). Ranjana et al. (7), Bangal et al. (11) and Sardesai et al. (12) in their studies observed 70%, 75% and 79% of eclampsia cases in primigravida's respectively.

Control of Convulsions

The yardstick used to measure the efficacy of magnesium sulfate was the number of convulsions that occurred after the patient was started on magnesium sulfate. In present study, convulsions were controlled with standard dose in 90% cases of IM regimen and 95% cases of IV regimen. No significant difference was observed among both study groups in terms of control of convulsions (p - 0.675). Recurrence of convulsions after standard dose of magnesium was observed among 10% and 5% cases of IM and IV regimen respectively. No recurrence was seen after additional dose.

Singh S et al. (13) in their study observed that both the treatment regimens were comparable with regard to recurrence of convulsions.3 (6%) patientsinGroupIMand2 (4%) patients in Group IV developed convulsions after initiation of treatment, p value 0.646. Rashmi Verma et al. (14) observed that incidence of recurrence of convulsions was comparable in both the groups.8% patients in Group IM and 4% patients in Group IV developed convulsions after initiation of treatment. Chissell S et al. (15) randomized patients with severe pre - eclampsia to receive magnesium sulfate according to an intramuscular or an intravenous regimen. Seizure was controlled in all cases with no recurrence. Vaibhav Kanti et al. (16) also observed similar level of control with both IV and IM regimen. UzmaKauser et al (10) conducted in their study found that nearly16%patientsin IM magnesium sulfate (MgSO4) group and 12% patients in IV magnesium Sulfate (MgSO4) received recurrence of seizure after starting of treatment (p value >0.5).

Magnesium Toxicity

Incidence of magnesium toxicity was observed to be higher with IM dose. Loss of knee jerk was seen in 7.5% cases in IM group as compared tonone in IV group (p - 0.24). Oliguria was seen in 15% cases and 2.5% cases of IM and IV group respectively (p - 0.11). Slurred speech and drowsiness were noted in 2.5% cases of IM group as compared to none in IV group. Local site complications like pain and discoloration were exclusively associated with IM injections (15%; p<0.01).

Singh S et al. (13) observed incidence of loss of knee jerk was significantly higher in Group IM as compared to group IV; 7 (14%) in Group IM versus 1 (2%) in Group IV, p value 0.027. Incidence of other parameters of toxicity was comparable between the groups. Rashmi Verma et al. (14)

in their study also observed that incidence of loss of knee jerk was significantly higher in Group IM as compared to group IV. Incidence of other parameters of toxicity were comparable between the groups. Vaibhav Kanti et al. (16) observed statistically higher incidence of sign of impending toxicity such as loss of patellar reflex was seen in IM group as compared to IV group. Other signs of toxicity such as oliguria, respiratory rate depression though more in IM group, were statistically insignificant. Jeffrey Michael Smith et al (17) conducted a study in a low - or middle - income country, and the study included the recording of the incidence of any adverse side effect resulting from magnesium sulfate use. It was found that about 26%patientsin IM magnesium sulfate (MgSO4) group and 18%patientsin IV magnesium Sulfate (MgSO4) group had mild side effects of MgSO4 but no patients in both the group had major side effects of magnesium sulfate (MgSO4).

The study thus observed that intramuscular injection of magnesium is painful and there can be local complications like discoloration, because of which compliance to IM injection may not be very good as compared to IV dose. Another important point of consideration was that oliguria is an element of disease process and not an adverse effect of the magnesium use. As magnesium is eliminated via kidneys, oliguria less than 30 cc per hour is usedas a level for withholding the scheduled dose, to prevent toxic levels. Higher incidence of oliguria in IM group showed that higher serum magnesium concentrations were produced by the IM regimens as compared to IV regimen.

Mode of Delivery

Mode of delivery as caesarean section was noted in 40% cases of IM regimen and 55% cases of IV regimen. The difference was statistically non - significant (p - 0.27). Moreover, the mode of deliverywas decided upon factors like Bishop's score, prolonged induction - delivery interval, fetal and maternal wellbeing and associated factors such as elderly primigravida, contracted pelvis, malpresentations.

Koech Irene et al (18) concluded in their study that there is no benefit of emergency caesarean section for women with eclampsia. This study showed that induction of labour and vaginal delivery can be successfully achieved in pregnant women with eclampsia. Maternal and perinatal mortality from eclampsia can be prevented through prompt and effective care.

Maternal Complications

Maternal complications due to disease observed in present study were: Abruption (6.3%), HELLP (8.8%), pulmonary edema (13.8%), DIC (6.3%), CVA (0%). No difference was observed among study groups in terms of maternal morbidities like PPH (10% vs 15%) and maternal mortality (0% vs 0%) in IM and IV group respectively.

Singh S et al. (13) in their study observed that maternal outcome was poor in both the groups but were comparable and no significant differences were observed between the groups. Chissell S et al. (15) in a similar study observed no significant differences between groups with regard to clinical outcome of mothers. VaibhavKanti et al. (16) also observed that there was statistically no significant difference in maternal morbidities between the two groups and no mortality in IV group. Similar results were also observed in the study by RashmiVerma et al. (14) Jeffrey Michael smith et al (17) in their study found that there was only one maternal death that was attributed by the study authors to the use of magnesium sulfate among the 9556 women in the 24 studies.

Koech Irene et al (18) in their study found that there was no maternal death; however, 5.7% of mothers were admitted to the ICU. Additionally, 20.8% of patients had true HELLP) syndrome while 11.3% had incomplete HELLP syndrome; 15.1% others had acute kidney injury (AKI); and 1.9% developed stroke. All patients recovered from the disease within 6 weeks post - delivery of follow up, including follow up after discharge from hospital.

Fetal Complications

Mean birth weight was 2.32 Kg and 2.45 Kg in IM and IV groups respectively. The difference was non - significant (p - 0.28). No difference was observed among study groups in terms of neonatal findings like low APGAR at 5 min (53.7% vs 42.9%), requirement of NICU admissions (39% vs 40.5%) and neonatal mortality (24.4% vs 21.4%) in IM and IV group respectively.

Singh S et al. (13) in their study observed that fetal outcome was poor in both the groups but were comparable and no significant differences were observed between the groups. Chissell Setal. (15) in a similar study observed no significant differences between groups with regard to clinical outcome of neonates. Similar results were also observed in the study by Rashmi Verma et al. (14) and Vaibhav Kanti et al. (16)

Koech Irene et al (18) also studied regarding perinatal outcomes. The following were the findings that 34.0% of newborns were admitted to the newborn unit (NBU). Mortality was reported in 9.4% of cases, and 7.5% were fresh stillbirths. The majority of newborns (73.6%) were born with a good Apgar score of >7 at 5min, whereas only 20.8% of newborns had an Apgar score<7 at 5min. The score was not applied for 7.5% of stillbirths.

Thus, to summarize, both IM and IV groups are comparable in terms of control and prevention of recurrence of convulsions, maternal and perinatal morbidity and mortality. IM Magnesium Sulfate regimen is associated with high incidence of magnesium toxicity as evidenced by higher incidence of loss of knee jerk and oliguria which can be a preceding sign of respiratory depression and renal failure. Local complications like pain and injection site discoloration were also more in IM group.

7. Conclusion

In present study, we observed that both IM and IV regimens are equally effective in preventing recurrence of convulsion in eclampsia cases. IM Magnesium Sulfate regimen is associated with high incidence of magnesium toxicity as evidenced by higher incidence of loss of knee jerk and oliguria which are the primitive signs of magnesium Sulfate toxicity preceding life - threatening complications like

respiratory depression. Local complications like pain and discoloration were noted in IM group. Maternal and fetal outcomes were comparable in both the regimens. The present study thus conclude that Intravenous magnesium Sulfate should be a preferred mode if facilities of IV infusion and frequent monitoring exist, otherwise in resource deficient setups, IM magnesium Sulfate can be used.

Another important point of consideration is that the total dose of magnesium sulfate by intramuscular and intravenous route is different. It was found that the total dose was more in intramuscular group (44gm) as compared to intravenous group (28gm). Thus, intravenous administration of magnesium sulfate is suitable and equally effective in Indian women who on an average weigh much less than the western counterparts to control convulsions in eclampsia with no increase in maternal mortality & morbidity and perinatal morbidity and mortality with the added benefit of reducing the side effects related to magnesium Sulfate.

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