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LOW DOSE 10 GRAM INTRA MUSCULAR VERSUS CONVENTIONAL DOSE OF MAGNESIUM SULPHATE FOR ECLAMPSIA PROPHYLAXIS

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ABSTRACT Optimum dose, route and duration of magnesium sulfate prophylaxis has always been debatable in HDP .Our objective is to reduce the eclampsia incidence while dealing with low dose ,we compared the efficacy of 10 gram I.M. MgSO4 loading dose only versus conventional dose for seizure prophylaxis over 100 women . With mean age of 24.83 years , 58% being primigravida, none of the patients in both groups developed eclamptic seizures, atonic pph and oliguria was significantly low in low dose group with a p value <0.05 , no maternal mortality observed in both the groups . Neonatal outcomes were statistically insignificant . low dose 10 gram I.M. loading dose only may be considered as an effective alternative for eclampsia prophylaxis , for its potential use in low resource peripheral health centres. With minimal monitoring it can help to reduce maternal morbidity, mortality and improved neonatal outcome .

KEYWORDS : Severe pre eclampsia , Hypertensive disorders of pregnancy (HDP) , Magnesium sulphate(MgSO4).

INTRODUCTION -

Hypertensive disorders during pregnancy(HDP) remain among the most significant and fascinating unsolved problems in obstetrics. These disorders complicate 5-10% of all pregnancies and together they are one of the deadly triad-along with hemorrhage and infection-that contributes greatly to maternal morbidity and mortality. Of hypertensive disorders , the *"pre-eclampsia syndrome*" is the most dangerous[1].

The complication of HDP which are responsible for the maternal morbidity and mortality include cerebro-vascular accidents, acute Renal Failure , pulmonary edema - all of which are potentially preventable They also contribute to iatrogenic prematurity , fetal growth restriction, neonatal morbidity and mortality, however the above mentioned complications could be avoided if health care provider remain alert to the likelihood that pre eclampsia will progress. The WHO (2014) systematically reviews maternal mortality worldwide, in developed countries 16 % and in developing countries 12.9% maternal death were attributed to HDP[2] . Unfortunately, more than half of these hypertension related deaths were deemed preventable.

As per sample registration system(SRS) 2014-2016, MMR in India was 130 and in Rajasthan it was 199 , So HDP although preventable are still contributing to 13% of maternal deaths , implicating their potential role in maternal mortality . Thus the need of the hour is to enable an effective and comprehensive protocol for management of such cases. When a woman develops symptom and sign of impending eclampsia, she should be kept in a quiet room, an intra venous access should be obtained, antihypertensive therapy should be started if blood pressure is high followed by eclampsia prophylaxis. The drug of choice for both prevention and treatment of eclampsia is magnesium sulfate, it has been found to be superior to the other agents to prevent eclampsia in almost all studies[3]

ACOG task force recommended magnesium sulfate in the management of pre eclampsia with severe features. Magnesium Sulfate is used as a first line anticonvulsant in pregnancy .It is highly effective in ameliorating seizure without producing CNS depression. Regular assessment of urine output , deep tendon reflex , respiratory rate , O2 saturation is done as long as Magnesium sulfate is continued to avoid toxicity which include loss of patellar reflex , decrease urine output , drowsiness , respiratory depression . Some proposed mechanisms of action include: (1) reduced presynaptic release of the neurotransmitter glutamate, (2) blockade of glutamatergic *N*-methyl-D-aspartate (NMDA) receptors, (3) potentiation of adenosine action, (4) improved mitochondrial calcium buffering, and (5) blockage of calcium entry via voltage-gated channels. With therapeutic plasma concentration 4-7mq/l(1.8-3.5mmol/l) and renal route of drug excretion , magnesium sulfate toxicity can easily be encountered in patients with impaired renal function. Intravenous Calcium gluconate is used for reversal of toxicity .

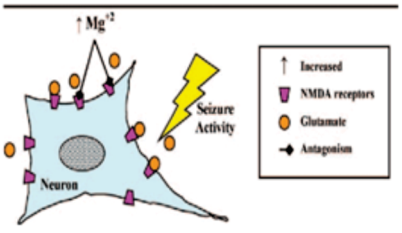

Figure 1. Mechanism of action of MgSo4

Figure 2. Magnesium sulphate ampule, 2% lignocaine & syringe .

OBJECTIVE

The efficacy of low dose (10gm) intramuscular magnesium sulphate only over conventional dose (44gm) of magnesium sulphate for seizure prophylaxis in patients with severe pre eclampsia with least drug toxicity for its potential use at low resource peripheral health centres .

Reduced maternal morbidity and mortality with improved neonatal outcome being the secondary benefit .

METHODOLOGY –

This prospective comparative study was conducted in the dept. of obstetrics and gynaecology, Jay Kay Lon hospital,Govt.medical college Kota, Rajasthan In this study we include 100 patients of Pre Eclampsia with severe features admitting in the hospital during routine and emergency hours (booked / unbooked / referred) since July 2018 to January 2019.

Patients with Gestational Hypertension , Pre Eclampsia without severe features & Ante partum eclampsia were excluded .

Patients were randomly allocated to 2 groups- group 1 & 2 , as per even / odd registration numbers to avoid biasness.

After quick review of patient records, medical and obstetric history, baseline vitals were assessed and management given as:-

1.Magnesium sulfate prophylaxis –

Group 1 received 10 gram Magnesium sulphate intramuscular dose

only - 5 gm of 50% MgSo4 injected deeply in the upper outer quadrant of both buttocks through a 3-inch-long 20-gauge needle together with 1 ml 2% lignocaine in same syringe to minimize discomfort Group 2 received loading dose of 4 gram of 20% MgSo4 intravenous slowly over 5 minutes followed by 10 gm of 50% mgSo4 intramuscularly (5 gm in each buttocks with 1ml of 2% lignocaine in the same syringe to minimize discomfort) injected deeply in the upper outer quadrant of both buttocks through a 3-inch-long 20-gauge needle followed by maintenance dose of 5 gms IM in alternate buttock 4 hourly.

2. Antihypertensive
3. Monitoring fetal status
4. Steroids where ever applicable
5. Definite management i.e. delivery

We compared both the groups, summarized and systematically analyzed the outcomes in terms of mean, standard deviation, chi square test and p value.

Outcomes measured as -

1. Occurrence of eclampsia fits
2. Maternal morbidity – lethargy, confusion, coma, atonic pph, oliguria.
3. Maternal mortality
4. Neonatal outcome – as 5 min Apgar score
5. Neonatal mortality

RESULTS

Table 1: Age

AGE	GROUP 1	GROUP 2
< 20 YEARS	01	00
20-24 YEARS	23	24
25-29 YEARS	14	20
>30 YEARS	12	06
Mean+ SD	25.56 + 3.87	24.1 + 3.01

Mean age in group 1 was 25.56 + 3.87yrs22 while it was 24.1 + 3.01 yrs in group 2 .

Tableno.2 – Demographical & Obstetrical Paremeters

PARAMETER	GROUP 1 (n=50)	GROUP 2 (n=50)
Parity		
Primigravida	28	30
Multigravida	22	20
PERIOD OF GESTATION		
<34 wks	8	6
34-37 wks	18	16
>37 wks	24	18

Pre eclampsia has long been believed to be a disease of primigravida, in our study 58% were primigravida.

Table No.3- Maternal Complications

COMPLICATION	GROUP 1 (n=50)	GROUP 2 (n=50)
CONVULSION	0	0
ATONIC PPH	06	10
OLIGUREA	0	02
MORTALITY	0	0
NEUROLOGICAL DEFICIT – LETHARGY/COMA/CONFUSION	0	0
p value	P<0.05, significant	

None of the patient from both groups developed eclampsia. Atonic pph was observed in 6 versus 10 patients in low dose versus conventional dose group . Oliguria was present in 2 patients of group 2 with p value <0.05, which was statistically significant. No maternal mortality and neurological morbidity observed in both groups.

Table No. 4 Neonatal Outcomes

OUTCOME	NO. OF PATIENTS GROUP1 (n=50)	NO. OF PATIENTS GROUP 2(n=50)
APGAR >8/10	42	40
NICU ADMISSION	O4	06
STILL BIRTHS	04	04
p value	P>0.05 (0.108133), non-significant	

42 newborns in group 1 and 40 newborns in group 2 were having an APGAR score of >8/10 , total 8 newborns were admitted to NICU in view of prematurity / VLBW / TTPN , all the still births were diagnosed IUFD at the time of the admission.

DISCUSSION -

Magnesium sulphate is the drug of choice for seizure prophylaxis in severe pre-eclampsia .The largest comparative study , MAGPIE trial studied more than 10,000 women established the role of Magnesium sulfate in treatment of severe pre eclampsia .women given MgSo4 had a 58% lower risk of eclampsia than those given placebo[4] .

Optimal route , dose and duration of MgSo4 for prophylaxis has been a topic of debate and there are Randomized Control Trials depicting the effectiveness of low dose of Magnesium sulphate than the existing regime for eclampsia prophylaxis . In a study conducted by Shobha Bembalgi et al using 4 gm IV magnesium sulfate in patients with severe pre eclampsia , among 50 studied patients only 1 had eclamptic seizures , no maternal deaths and postpartum convulsions [5].

Similar study conducted by Keepanasseril et al (2018), compared the safety and efficacy of ' low dose Dhaka regime' with ' loading dose only regime' for seizure prophylaxis in severe pre eclampsia using randomized control trial in 402 women . The incidence of eclampsia in low dose Dhaka regime was 1.49% & in low dose only regime was 2.98% , neonatal APGAR score at 5 min was 5% v/s 8.05% , and perinatal mortality was 20.4 % v/s 21.9 %[6] .

Darngwan l et al in 2012 studied a shortened postpartum magnesium sulfate prophylaxis regime in women with pre eclampsia and found that a shortened (6 hour) magnesium sulfate was as effective for seizure prophylaxis as the conventional 24 hours regime with significant benefits in terms of cost & morbidity[7] .

Surya Prasad et al conducted a randomized controlled trial of standard magnesium sulfate regime (Pritchard regime) v/s 14 gm loading dose only in 60 pregnant women with pre eclampsia , and concluded that single dose is equally effective as standard regime in seizure prophylaxis[8] .

A lower dose regime has been tried in several centres of Indian subcontinent considering the low BMI , loading of 4 gm IV & 3 gm in each buttock , followed by a maintenance dose of 2.5 gm 4 hrly [9].

The short regime of Magnesium sulfate using the only loading dose as eclampsia prophylaxis is also an effective alternative to low dose dhaka regime[10] .

A double blind randomized control trial comparing Pritchard's regime with low dose regime in women with severe pre eclampsia by Miriam George fenn in 2014, they concluded that low dose magnesium sulfate can effectively prevent onset / recurrence of convulsion in above group , although side effects were insignificant in both groups[11]. Our study predicting the low dose of Magnesium sulfate to have maximum effects with least toxicity. Our primary objective is to reduce the incidence of eclampsia while dealing with least drug toxicity , with improved neonatal outcome as a secondary benefit. Because of easy intramuscular administration over intravascular access even a paramedical staff sitting in a primary health care centre may give the low dose before referring a woman with severe pre eclampsia to a tertiary care centre . The drawback of present study is the small sample size and further large RCT are still needed to prove its efficacy.

CONCLUSION -

10gm intramuscuar Magnesium sulfate may be considered as an effective alternative for eclampsia prophylaxis specially in low resource peripheral settings . With minimal monitoring it can help to reduce maternal morbidity & mortality with improved neonatal outcome.

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