Original Article

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Obstetrics and Gynaecology Section

Comparison of Pritchard and Dhaka Regimen in Outcome of Patients with Severe Preeclampsia and Eclampsia in Eastern Part of India: A Prospective Observational Study

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ABSTRACT

Introduction: Preeclampsia and eclampsia are one of the leading causes of maternal mortality. Magnesium sulphate is the drug of choice to prevent and avoid recurrences of convulsions. Pritchard is the standard regimen of Magnesium sulfate ($MgSO_4$). But keeping in view the small stature and low Body Mass Index (BMI) of Indian women low dose regimen of $MgSO_4$ (Dhaka regimen) is also effective.

Aim: To compare the efficacy of Pritchard and Dhaka regimen in control of convulsions in severe preeclampsia and eclampsia.

Materials and Methods: A prospective observational study was done at Institute Of Medical Sciences-Banaras Hindu University, Varanasi, Uttar Pradesh, India, in Department of Obstetrics and Gynaecology in collaboration with Department of Biochemistry from January 2019 to December 2020. Two groups were made. In group I standard Pritchard regimen (n=48) and in group II Dhaka regimen (n=36) was given. Outcome was measured in terms of recurrence of convulsions, $MgSO_4$ toxicity. Various parameters age, BMI, APGAR score, mode of delivery, birth weight were also measured. Student t-test was used to compare two groups.

Results: The mean age in group I was 26.48±4.677 years and in group II was 24.64±3.743 years. Incidence of preeclampsia and eclampsia was 8.92%. The maternal mortality due to preeclampsia and eclampsia was 30.05%. Recurrence of convulsion was seen in two cases in group II and one case in group I. Serum magnesium level was statistically significant at 30 minute and at 4 hours. Various parameters like age, (p-value=0.056) duration of stay in hospital, (p-value=0.110) BMI, (p-value=0.304) mode of delivery (p-value=0.186) was not statistically significant.

Conclusion: The low dose Dhaka is as effective as Standard Pritchard regimen. Magnesium sulphate toxicity was seen in three cases in Pritchard and not in single case in Dhaka regimen. It is a better choice for women of short stature of Asian women as it is less toxic.

Keywords: Body mass index, Recurrence of convulsions, Serum magnesium, Toxicity

INTRODUCTION

Preeclampsia and eclampsia are major cause of maternal morbidity and mortality [1,2]. It is seen that overall 10 to 15 % maternal deaths are associated with preeclampsia [3]. Previously preeclampsia is defined as hypertension after 20 weeks of gestation and proteinuria (>300 mg in 24 hrs). But according to recommendation of American College of Obstetricians and Gynaecologists (ACOG) and International society for the study of hypertension in pregnancy it is diagnosed if there is new onset of hypertension after 20 weeks and or proteinuria, liver involvement, renal problems, pulmonary oedema [4,5].

If preeclampsia is not treated in time it can progress to eclampsia. Eclampsia has so many complications like Cerebro-Vascular Accident (CVA), seizure, renal failure, pulmonary oedema, embolism, intrauterine death and can also cause maternal death [1,6]. The definitive management is delivery of foetus and placenta [7].

In 1955 Pritchard JA, used magnesium sulphate to control convulsions [8]. Magnesium sulphate is drug of choice in control of convulsions [9,10]. There are various regimen of magnesium sulfate depending on the dose and rout of administration. These are Pritchard, Zuspan and Dhaka. The rout of administration can be intramuscular or intravenous or both. The dose can vary from 44 gm in Pritchard to 25 gm in Dhaka regimen. The most commonly used is Pritchard Regimen. Indian women are small as compared to western women. Pritchard regimen was standardised for western women. But Indian women are also getting the same Pritchard regimen in same dose. Pritchard JA, had suggested that dose of Magnesium sulfate ($MgSO_4$) should be limited in women of smaller stature [11].

So interest in research increased whether low dose magnesium sulphate regimen (Dhaka) is effective for Indian women. This is also important because magnesium sulfate has narrow therapeutic window and can cause toxicity. Therapeutic level of magnesium sulphate is 4 to 7 meq/l [8]. The most common side-effects are loss of knee jerk and respiratory depression. Oliguria is because of the kidney pathology of eclampsia itself but if the urinary output is less than 30 mL/hr then magnesium sulfate should be discontinued. The most serious side-effect of magnesium sulphate is cardiac arrest. The safety and toxicity is reviewed by Smith JM et al., [12]. So very close monitoring of patient is required after giving magnesium sulphate. The antidote for magnesium sulfate toxicity is calcium gluconate.

The present study had aimed to compare the efficacy of standard dose Pritchard regimen with low dose Magnesium sulfate (Dhaka) regimen in Indian women of eastern part of India in controlling convulsions in severe preeclampsia and eclampsia patients. Authors conducted this study because maximum healthcare centres in India still use Pritchard regimen only. It will be easy to change their mindset when they see results in their own setup and it will add to existing data.

MATERIALS AND METHODS

This was a prospective and observational study done in Department of Obstetrics and Gynaecology in collaboration of Department of Biochemistry over a period of two years, from January 2019 to December 2020. Ethical Clearance was taken from Institutional

Ethical Committee (No. EC/2086). Informed written consent was taken from attendants/guardians of eclampsia patients because these patients were sick and not able to give consent themselves. Patients with severe preeclampsia when stable were able to give consent themselves in few cases.

Inclusion criteria: In the present study, pregnant patients having severe preeclampsia and eclampsia were included and patients of gestational age >30 weeks were included in the study.

Exclusion criteria: Patient with chronic hypertension, epilepsy, meningitis, encephalitis, doubtful history of convulsions, metabolic abnormalities, conditions in which magnesium sulphate is contraindicated like myasthenia gravis, chronic renal disease, when other medical disorders also present like heart disease, jaundice were excluded. The other conditions which were excluded were patient is in moribund conditions and intrauterine death.

Sample size calculation: For comparison of Dhaka and Pritchard regimen the sample size was calculated by the following formula for two independent sample proportions of important study parameters of a pilot study and 1:1.25 ratio for Dhaka vs Pritchard:

$n=2(Z_{1-\alpha/2}+Z_{1-\beta})^2\times(p_1q_1+p_2q_2)/(p_1-p_2)^2$

p_1=proportion of outcome variable in group I

p_2=proportion of outcome variable in group II

$q_1=1-p_1$

$q_2=1-p_2$

$Z_{1-\alpha/2}$=1.96 at 5% level of significance

$Z_{1-\beta}$=0.842 at 80% power

The maximum of the sample size calculated on study parameters was 36 for Dhaka Group (group II) and 48 for Pritchard Group (group I).

Total 97 patients were recruited initially (in Pritchard 50 and 47 in Dhaka). But after exclusion of Intrauterine death patients in final study there were 48 patient in Pritchard regimen and 36 patients in Dhaka regimen. It was difficult to convince for Dhaka regimen so sample size was less.

Procedure

Serum magnesium was measured in Department of Biochemistry. Serum magnesium sample was taken just before giving magnesium sulfate therapy and then after 30 minutes and 4 hours after giving magnesium sulfate.

The patient was divided in two groups. In first group Pritchard regimen was given and in second group Dhaka regimen was given.

Pritchard regimen: Pritchard regimen contains loading dose and maintainance dose. Loading dose is 14 gm. Out of 14 gm loading dose 4 gm is given intravenously and 10 gm is given intramuscularly (5 gm in each buttock). Maintenance dose is given 5 gm intramuscular in alternate buttocks every 4 hourly. Total dose in 24 hours is 44 gm [8].

Dhaka regimen: Dhaka regimen [13] consists of 10 gm loading dose. In loading dose 4 gm is given intravenously and 6 gm is given intramuscular (3 gm in each buttock). The maintainance dose is 2.5 gm every 4 hourly in alternate buttock. Total dose in 24 hours is 25 gm. These patients were taken irrespective of parity, booking status and age.

In all patients age, Body Mass Index (BMI), booking status, mode of delivery, residence were recorded. Neonatal outcomes in terms of live or dead, Appearance, Pulse, Grimace, Activity, and Respiration (APGAR) score and birth weight were recorded. The number of patients who develop magnesium sulphate toxicity and recurrence of convulsions were noted. Magnesium sulphate toxicity is there when there was loss of knee jerk respiration rate was less than 12/minute and urine output was less than 30 mL/hr [12].

STATISTICAL ANALYSIS

Data was entered in excel sheet and analysis was done using Statistical Package for the Social Sciences (SPSS) IBM 20. Chi-square test and student's t-test were used. Student's t-test was used for age, duration of hospital stay, birth weight, serum magnesium level at 0 hour, 30 minute and at 4 hours. Chi-square test was used for mode of delivery, sex of baby, recurrence of convulsions and magnesium sulphate toxicity.

RESULTS

Incidence of preeclamsia/eclampsia in the present study was 8.92% (245/2745×100). In this, 245 was total number of preeclampsia and eclampsia and 2745 was the total number of deliveries. Deaths due to preeclampsia/eclampsia was 30.50% (18/59×100). There were total 59 maternal deaths and deaths due to preeclampsia and eclampsia was 18. In the present study, various parmeters are compared between Pritchard and Dhaka regimen group.

Maximum patients were from rural background (79.16% in Pritchard regimen and 83.3% in Dhaka regimen and Most of the patients were un-booked in both the groups (88%) in Pritchard regimen and (91.7%) in Dhaka regimen [Table/Fig-1].

Variables	Group I n (%)	Group II n (%)	Comparison between the groups
Age (Mean±SD, years)	26.48±4.677	24.64±3.743	t=1.940, p=0.056
Residence			
Rural	38 (79.16%)	30 (83.33%)	χ^2=0.232, p=0.630
Urban	10 (20.83%)	6 (16.66%)	
Booking status			
Unbooked	42 (88%)	3 (8.33%)	χ^2=0.373, p=0.541
Booked	6 (12.5%)	33 (91.7%)	
Preeclampsia/eclampsia			
Preeclampsia	24 (50%)	17 (47.2%)	χ^2=0.064, p=0.801
Eclampsia	24 (50%)	19 (52.8%)	
Mode of delivery			
Spontaneous Vaginal Delivery (SVD)	7 (14.6%)	2 (5.6%)	χ^2=1.753, p=0.186
Lower Segment Caesarean Section (LSCS)	41 (85.4%)	34 (94.4%)	
Sex of baby			
Male	23 (47.9%)	18 (50%)	χ^2=0.036, p=0.850
Female	25 (52.1%)	18 (50%)	

[Table/Fig-1]: Socio-demographic and clinical parameter comparison.
p-value <0.05 was considered statistically significant

In [Table/Fig-2] while comparing two regimens the mean age in group I was 26.48 years while in group II it was 24.64 years. The mean hospital stay duration was 8.10 days in group I and 6.31 days in group II.

In Pritchard regimen total number of patients were (n=48). Out of this 24 (50%) patients were having preeclampsia and rest 24 (50%) were having eclampsia. In Dhaka regimen total number of patients were (n=36). Out of this 17 (47.2%) were having pre eclampsia and 19 (52.8%) were having eclampsia. In [Table/Fig-3] outcome parameters for efficacy and safety were compared. It was seen that recurrence of convulsions in Pritchard regimen is 2.1% and 5.6% in Dhaka regimen. Magnesium sulphate toxicity was seen in three cases in Pritchard and not in single case in Dhaka regimen. In Pritchard group there were 6.25% early neonatal deaths and in Dhaka regimen there were 5.55% early neonatal deaths as shown in [Table/Fig-3].

Parameters	Group I Mean±SD	Group II Mean±SD	Comparison between the groups
Duration of hospital stay (days)	8.10±6.110	6.31±3.078	t=1.617, p=0.110
Birth weight (gm)	2331.63±678.153	2305.19±707.091	t=1.74, p=0.863
APGAR score			
At 1 minute	6.9375±1.43521	6.9167±1.42177	t=0.066, p=0.947
At 5 minute	8.31±1.095	8.28±.974	t=0.151, p=0.881
Body mass index (kg/m^2)	23.9618±2.94998	23.2482±3.34841	t=1.035, p=0.304
Serum magnesium			
At 0 hr (mmol/L)	2.0875±.44546	1.8453±.24888	t=2.934, p=0.004
At 30 min (mmol/L)	5.0298±0.94985	4.2553±0.66686	t=4.193, p=0.001
At 4 hr (mmol/L)	4.3296±.91883	3.5467±.66686	t=4.326, p=0.001

[Table/Fig-2]: Comparison of group I and group II according to study parameters. p-value <0.05 is considered statistically significant; APGAR: Appearance, pulse, grimace, activity, and respiration score

Variables	Group I n (%)	Group II n (%)	Comparison between the groups
Recurrence of convulsions			
Present	1 (2.1%)	2 (5.6%)	χ^2=0.720 p=0.396
Absent	47 (97.9%)	34 (94.4%)	
Magnesium sulphate Toxicity			
Present	3 (6.25%)	0	χ^2=2.33 p=0.127
Absent	45 (93.8%)	36 (100%)	
Neonatal Deaths			
Early neonatal death	3 (6.25%)	2 (5.55%)	χ^2=0.017 p=0.894
Live	45 (93.8%)	34 (94.4%)	

[Table/Fig-3]: Comparison of outcome parameters.

DISCUSSION

In this study incidence of severe preeclampsia and eclampsia was 8.92%. According to Abalos E et al., the global incidence of preeclampsia and eclampsia is 2.16% and 0.28%, respectively [14]. Maternal mortality rate due to severe preeclampsia and eclampsia was 30.50%. According to Duley L there is variation in cause of mortality in Asia [15]. According to his study 10 to 15 % deaths are due to hypertensive disorders of pregnancy and 10% are due to eclampsia. Maximum patients were un-booked in both the groups 88% in Pritchard and 91.7% in Dhaka. A study done by Bhagat N et al., had also shown that 65% patient in Pritchard and 75% patients in Dhaka were unbooked [16]. The mode of delivery was mainly by lower segment caesarean section (85.4% in group 1 and 94.4% in group 2). A study by Nagaria T et al., (2017) [17] has also shown that there was no statistical significant difference in the caesarean section rate in both groups (36.9% vs 50.8%, p=0.112).

Mean age of presentation was 26.48 in Pritchard regimen group and 24.64 in Dhaka regimen group. In Bhagat N et al., study the mean age in Pritchard was 25.67±3.79 years and in low dose group was 24.90±4.02 years [16]. Recurrence of convulsion was seen in (2.1%) in Prichard and 5.6% in Dhaka regimen. Ranjana et al., had also shown the same result 5% in Dhaka and 2.5% in Pritchard [18]. Kedia V and Gehlot H had also shown that 2.22% recurrence in Dhaka and zero in Pritchard [19].

Magnesium sulfate toxicity was seen in three cases in Pritchard regimen and in Dhaka regimen no case shows toxicity. It was not statistically significant. The study done by Bhagat N et al., also had shown the same results [16]. A Study by Sahu L et al., also found no case of magnesium sulphate toxicity in Dhaka regimen [20]. The present study study shows that low dose Dhaka regimen is as effective and more safe as standard Pritchard regimen. A study by Begum R et al., in also shows that low dose magnesium sulfate is as effective as standard Pritchard [13]. Similar statements are also made by Bera P et al., [21]. So, our study has also added to the existing facts that Dhaka regimen is as good as Pritchard. So many studies had shown similar results as shown in table below [Table/Fig-4] [13,16-18,20,22-26].

All the above studies shown in table conclude that low dose magnesium sulphate therapy (Dhaka) regimen is equally effective in controlling convulsions in preeclampsia and eclampsia patients. The toxicity of magnesium sulphate is less with Dhaka regimen in Indian women.

Name of study	Results of previous study	Results of present study
Sardesai SP et al., (2000) [25]	Used low dose $MgSO_4$ in Indian women and found safe and effective Convulsion control was 97.5% in Group 1 (Dhaka) and 100% in Group 2 (Pritchard) with comparable results (χ^2=1.013; p=0.314).	Low dose $MgSO_4$ (Dhaka) is safe and effective 94.4% convulsions were controlled with Dhaka regimen and 97.9% with Pritchard regimen (χ^2=0.720; p=0.396).
Begum R et al., (2001) [13]	98% convulsions controlled with Dhaka regimen.	94.4% Convulsions were controlled with Dhaka regimen.
Bhagat N et al., [16]	Convulsions controlled 97.5% with Dhaka regimen and 100% with Pritchard regimen. $MgSO_4$ toxicity was seen in 10% cases in Dhaka regimen and 32.5% cases in Pritchard.	94,4% convulsion controlled with Dhaka regimen and 97.9% with Pritchard regimen. In Dhaka regimen group no case of magnesium sulphate toxicity and in Pritchard regimen 6.25% cases $MgSO_4$ toxicity seen.
Abdul MA et al., (2013) [23]	Overall 4.2% recurrence of convulsions were recorded.	5.6% recurrence of convulsions were recrded in Dhaka regimen.
Sahu L et al., (2014) [20]	96% cases control of convulsion in low dose group. In this study 92% of low dose and 84% of standard dose group were unbooked cases. Mean Systolic Blood Pressure (SBP) 159±17.2 (mmHg) in Dhaka and164±14.14 (mmHg) in pritchard.	94.4% control of convulsion in Dhaka regimen group. 91.7% patient was unbooked in Pritchard regimen and 88% were unbooked in Dhaka regimen. Mean SBP in Dhaka regimen group was 159±18.07 (mmHg) and in Pritchard regimen 147±13.95 (mmHg).
Ranjana et al., (2017) [18]	Convulsion control 95% with Dhaka regimen and 97.5% with Pritchard regimen.	Convulsion control 94.4% with Dhaka regimen and 97.9% with Pritchard regimen.
Nagaria T et al., (2017) [17]	Control of convulsion was 97.6% in low dose group. The mean serum Mg^{2+} levels were significantly lower in the low dose regimen at 30 minutes as well as at four hours of therapy.	Control of convulsion was 94.4% in low dose (Dhaka) regimen. Serum magnesium level were significantly lower than Pritchard regimen at 30 minute and at 4 hour.
Kansa VM et al., (2019) [24]	Neonatal deaths were 5% in low dose group and 6.7% in Pritchard group.	Neonatal death 5.55% in Dhaka regimen group and 6.25% in Pritchard regimen.
Bangal V et al., (2009) [26]	90% cases were unbooked.	91.7% patient were unbooked in Pritchard regimen and 88% were unbooked in Dhaka.
Jana N et al., (2013) [22]	Mean body mass index 19.3±2.1 kg/m^2.	Mean body mass index 23.96±2.94 kg/m^2.

[Table/Fig-4]: Table for studies on low dose magnesium sulphate therapy [13,16-18,20,22-26].

Limitation(s)

Larger sample size should have been considered and it needs multicentric trial. It was challenging to take serum magnesium sample three times (0 hr, 30 min, and 4 hrs) and then transport it to Biochemistry Department. Patients of eclampsia were so sick then sometime authors forget to take serum magnesium before starting magnesium sulfate. Because of this problem we take only those patients in which all the three values were taken. It further reduced the sample size. There was no funding for this project.

Maximum doctors still use Pritchard regimen and was difficult to convince them for Dhaka regimen. So sample size was less inspite of large number of patients. Inspite of so many studies available that Dhaka is equally effective as Pritchard regimen in Asian women which has low BMI as compare to western women, but still maximum doctors in this area (Uttar Pradesh) give Pritchard only.

CONCLUSION(S)

Severe preeclmapsia and eclampsia are still major cause of maternal mortality. This study concluded that low dose Dhaka regimen was quite effective in control of convulsion like Pritchard. The chances of Magnesium sulfate toxicity are less in low dose regimen for women of low body weight. But still more studies with larger sample size and at multicentres are required to make final statement.

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