

A COMPARATIVE STUDY OF PRITCHARDS REGIMES WITH ZUSPAN'S REGIMEN IN THE MANAGEMENT OF ECLAMPSIA AND PRE-ECLAMPSIA

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Abstract

Aim: In the present study, intravenous magnesium sulfate (Zuspan's regimen) compared with the standard Pritchards regimen.

Methodology: The present study is conducted in District Head quarter Hospital, Apollo Institute of Medical Sciences and Research, The Apollo Medical College, Chittoor from September 2021 to August 2023 for a period of 24 months. It is a tertiary care center with a high number of referral cases of preeclampsia and eclampsia from surrounding rural areas.

Results: In the present study, the maximum number of cases is from a rural background, with low socioeconomic status and were unbooked cases. The majority are primigravidae with a mean age of 25.02 years. In the present study, 74% of cases from both groups are primigravida. In terms of efficacy in preventing recurrence of convulsions, 6% of cases in the Pritchards group, and 4% of cases in the Zuspan's group had recurrences. Hence recurrence is more common with Pritchards regimen. 4% cases reported loss of knee jerks in Pritchards regimen, 2% reported in Zuspan's regimen. With standard Pritchards regimen, toxicity is high compared to the Zuspan's regimen. Zuspan's regimen is as effective as Pritchard in preventing eclamptic convulsions in severe preeclampsia cases. It is our policy to give Magnesium sulfate prophylaxis to all patients of severe preeclampsia cases. The common mode of delivery is by vaginal route. 64% and 62% vaginal delivery rate is recorded in the Pritchards and Zuspan's group, respectively. Maternal complications are comparable in both groups and may be due to pathological implications of disease per se and not directly due to MgSO₄. No maternal deaths were reported in the study.

Conclusion: we may conclude that the awareness regarding antenatal checkups among the poor population is still deficient, resulting in poor maternal and fetal outcomes. Eclampsia could be predicted and effectively prevented if there is proper antenatal booking, and clinical obstetrics and biochemical assessment of pregnant women who are unaware of prenatal care and its importance. Early identification of risk factors for pre-eclampsia is also essential.

Keywords: Eclampsia, MgSO₄, Zuspan's regimen, Pritchard regimen,

Introduction

Eclampsia is one of the principal causes of mortality and morbidity during pregnancy, childbirth & puerperium. Eclampsia is a type of hypertensive encephalopathy with generalized seizures or coma.

The incidence of Eclampsia in India is 0.43%, and pre-eclampsia is 1.97%, and the global incidence of eclampsia and pre-eclampsia is 0.28% and 2.16% respectively¹. Eclampsia alone accounts for fifty thousand maternal deaths per year worldwide².

The maternal mortality rate is 1.8%, and 35% of eclamptic will have one major complication. The perinatal mortality rate in developed countries is less than 10/1000 births to as high as 80 (or) more/1000 deliveries in economically developing countries. The incidence of PMR in eclampsia ranges from 224 to 307/1000 in the study done by the Collaborative Eclampsia Trial³.

The women, Pritchard studied were obese and well-nourished and are from developed countries; the same dosage may not apply to the lean and malnourished Indian women. Though magnesium sulfate is known for its effective therapeutic control of convulsions, there is a dangerously narrow margin between therapeutic and toxic serum levels. Monitoring the serum magnesium levels to assess the toxicity is an uphill task in our hospitals because of infrastructure constraints. So by using continuous intravenous infusion dose of magnesium sulfate, early detection of toxicity can be identified and adequately managed.

The standard Pritchard regimen practiced at our institution. Various reasons for hindrance in accepting the IV regimen are; lack of trained staff for monitoring, lack of types of equipment, lack of infusion sets, and no familiarity with the IV dosing regimen.

In the present study, intravenous magnesium sulfate (Zuspan's regimen) compared with the standard Pritchards regimen.

AIMS AND OBJECTIVES

To compare both groups i.e Pritchards regimen and Zuspan's regimen in terms of prevention of convulsions in severe preeclampsia & recurrence of convulsions in case of eclampsia.

To compare and prevent maternal complications, which include intracranial hemorrhage, acute pulmonary edema, antepartum hemorrhage, acute renal failure, HELLP syndrome, aspiration pneumonia in eclampsia, and preeclampsia cases.

To compare perinatal outcome, which includes APGAR score, perinatal mortality, and incidence of neonatal ICU admissions in eclampsia and preeclampsia cases.

To compare signs of magnesium toxicity, which includes loss of patellar reflex, decreased urine output, and respiratory depression.

METHODOLOGY

It is a prospective study conducted in the District Head quarter Hospital, Apollo Institute of Medical Sciences and Research, The Apollo Medical College, Chittoor. After taking a detailed history, obstetrical examination, and BISHOP scoring done. Consent for the magnesium sulfate regimen was taken.

Laboratory investigations blood grouping, hemogram, platelet count, liver function test, kidney function test, serum electrolytes, coagulation tests, fundus examination, and urine for proteinuria done- the data will be collected.

In the Pritchards Regimen, a loading dose of 4 gms of MgSO₄, 20%(w/v) solution is given slow intravenous over 5-10 min, followed by ten(10) gms of MgSO₄, 50%(w/v) given intramuscularly (5 gms in each buttock). Subsequently, five(5) gms of MgSO₄ is given intramuscularly in alternate buttocks every 4th hourly.

In the Zuspan's regimen, a loading dose consists of an initial intravenous dose of 4 gms of MgSO₄, 20%(w/v) solution slowly over 5-10 min followed by a maintenance dose of 1 gram per hour given by an infusion pump or a gravity-fed infusion.

MgSO₄ will be administered till 24 h after delivery or after the last fit (whichever comes last).

The occurrence of convulsions in case of severe preeclampsia and recurrence of convulsions in the case of eclampsia are documented.

Maternal complications, which include intracranial hemorrhage, acute pulmonary edema, antepartum hemorrhage, acute renal failure, HELLP syndrome, aspiration pneumonia in eclampsia, and preeclampsia cases are documented.

The perinatal outcome, which includes APGARscore, perinatal mortality, and incidence of neonatal ICU admissions in eclampsia and preeclampsia cases, are documented.

Magnesium toxicity, which includes loss of patellar reflex, decreased urine output, and respiratory rate < 16/min, are documented.

Table-2. Gestational age

Gestational age	Pritchard regimen	Zuspan regimen	Chi -square	P value	Inference
<24 yrs	27 (54%)	26 (52%)	0.4431	0.801272	Not significant
25-32 yrs	21 (42%)	23 (46%)			
33-36yrs	2 (4%)	1 (2%)			
> 36yrs	0	0			
Mean age	24.86	25.22			

Inclusion Criteria

1. Women with severe preeclampsia:

preeclampsia was diagnosed in cases with hypertension ($\geq 160/110$ mmHg) with proteinuria of at least 1+ assessed by semi-quantitative dipstick method or proteinuria greater than or equal to 300mg/dl or protein/creatinine ratio greater than or equal to 0.3.

2. Women with eclampsia

Eclampsia was diagnosed in cases with a history of generalized tonic-clonic convulsions with the elevated blood pressure and proteinuria (by dipstick method) in the absence of any underlying seizure disorders after 20 weeks of gestational age.

3. All cases of antepartum, intrapartum, and postpartum eclampsia, presenting in an obstetric emergency (labor room), were included in the study.

Exclusion Criteria

1. Patients with severe preeclampsia or eclampsia having received magnesium sulfate and/or other anticonvulsants before coming to our hospital

2. Patients with severe preeclampsia or eclampsia who had prior renal failure, acute pulmonary edema with respiratory failure, or hydatiform mole, diabetes mellitus, thyrotoxicosis, epilepsy, cerebrovascular accident and Disseminated Intravascular Coagulation (DIC) were excluded from the study

RESULTS

CASE DISTRIBUTION

As shown in table-1, A total number of 100 cases with Preeclampsia and eclampsia were selected and randomized into two groups Pritchards group and Zuspan's group. Fifty cases received the Pritchards regimen, and 50 cases received the Zuspan's regimen.

Table -1. Case distribution

Regimen	Number	%
Pritchards	50	50.00%
Zupan's	50	50.00%
Total	100	100.00%

AGE DISTRIBUTION

Twenty-seven cases in patients receiving the Pritchards regimen and 26 cases in patients receiving Zuspan's regimen were less than 24 years. Twenty-one cases in patients receiving the Pritchards regimen and 23 cases in patients receiving the Zuspan's regimen belong to the 25-32 age group. Two cases treated with the Pritchards regimen and 1 case treated with Zuspan's regimen belongs to the 33-36yrs age group.

The mean age in the patients treated with the Pritchards regimen was 24.86, and the mean age in the patients treated with the Zuspan's regimen was 25.22. Results were comparable and statistically insignificant.

BMI

Out of 100 cases registered 41 from Pritchards group and 28 from the Zuspan's group had a BMI of 18.5-24.9, 8 patients from Pritchards group, and 21 from the Zuspan's group had BMI of 25-29.9, and one from each group had BMI above 30.

Table- 3. BMI

BMI	Pritchards regimen	Zuspan's Regimen	Chi Square	P value	Inference
>18.5	0	0	8.2769	0.15948	Significant
18.5-24.9	41	28			
25-29.9	8	21			
>30	1	1			

DISTRIBUTION OF CASES

In Pritchard regimen group, out of 50 cases, 30 had severe preeclampsia and 20 had eclampsia. In Zuspan regimen group out of 50 cases, 25 had severe preeclampsia and Twenty-five had eclampsia. Results were comparable and not significant.

Table 4. Types of Eclampsia

Type of Eclampsia	Pritchard Regimen	Zuspan regimen	Chi Square	P value	Inference
Severe preeclampsia	30 (60%)	25 (50%)	1.0101	0.314	Not significant
Eclampsia	20 (40%)	25 (50%)			

PARITY

Out of 50 in the Pritchards group, 32 cases were primi, and eight were G2,10 were G3& above. Out of 50 in the Zuspan's group, 28 cases were primi, 14 were G2, 9 were G3 & above. Distribution of patients was similar hence considered for statistical analysis.

Table -5. Parity

	Pritchard Regimen	Zuspan Regimen	Chi square	P value	Inference
Primi	32 (64%)	28 (56%)	2.1253	0.345547	Not Significant
G2	8 (16%)	14 (28%)			
G3 & above	10 (20%)	8 (16%)			

Blood pressure

6, 29 and 15 patients had Systolic B.P between 130-149,150-169,170-190 respectively in patients who were treated with Pritchards regimen, and 5,30,15 had systolic B.P between 130-149,150-169,170-190 respectively in patients who were treated with Zuspan's regimen.

Table 5. Blood pressure

	Pritchard regimen	Zuspan regimen	Chi square	P value	Inference
< 130	0	0	0.1079	0.947499	Not significant
130-149	6 (12%)	5 (10%)			
150-169	29 (58%)	30 (60%)			
170-190	15 (30%)	15 (30%)			

11,8 and 31 patients had diastolic B.P between 90-99,100-109,110-120 respectively in patients who were treated with Pritchards regimen .8,4 and 38 patients had diastolic B.P between 90-99,100-109 and 110-120 in Zuspan regimen group. Mean systolic B. P was 161mm hg and 161.36 mm hg in the patients receiving Pritchardsand Zuspan's regimen, respectively. Mean diastolic B.P was 106.4 mm hg and 108.4 mm hg in the Pritchards group and Zuspan's group, respectively.

Table-6. Systolic Blood pressure

Mean B.P	Pritchards regimen	Zuspan's regimen
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Systolic B.P	161	161.36
Diastolic B.P	106.4	108.4

TREATMENT

In the study, among patients treated with the Pritchard regimen, one patient with severe preeclampsia had a convulsion, and two patients with eclampsia had a recurrence of convulsion. Among patients treated with Zuspan regimen, one with severe preeclampsia had a convulsion, and one with eclampsia had a recurrence of convulsion, Both groups are comparable, and results were not significant(p<0.005).

MATERNAL COMPLICATIONS**Table -7. Complications**

	Complication	PRITCHARDS REGIMEN	ZUSPAN REGIMEN	Chi-square`	P VALUE	Inference
1	Convulsionsin preeclampsia	1 (2%)	1 (2%)	0.1389	0.709388	Not significant
2	Recurrenceof convulsion in eclampsia	2 (4%)	1 (2%)			

The table shows maternal complications. Forty-five cases of the Pritchard regimen and 49 cases of Zuspan regimen had no complications. One patient treated with the Pritchard regimen had an antepartum hemorrhage, and another patient on the Pritchard regimen had an acute renal failure while patients in the zuspan regimen group had neither antepartum hemorrhage nor acute renal failure. Two patients in Pritchards group and one in Zuspans group had pulmonary edema. Though the number of complications is more in Pritchard's regimen statistically it was not significant (p <0.05)

Table -8. Maternal Complications

	Complication	PRITCHARDS REGIMEN	ZUSPAN REGIMEN	Chi-square	P VALUE	Inference
1	Intra cranial haemorrhage	0	0	1.20	0.75304	Not significant
2	Pulmonary edema	2 (4%)	1 (2%)			
3	Ante partum haemorrhage	1 (2%)	0			
4	Acute renal failure	1 (2%)	0			
5	HELLP syndrome	0	0			
6	Aspiration pneumonia	1(2%)	0			

MATERNAL MORTALITY**Table-9. Maternal Mortality**

	Pritchard regimen	Zuspan regimen
Maternal mortality	0	0

Maternal deaths were zero in both regimens. Complications were adequately managed, and all cases recovered.

MAGNESIUM TOXICITY

Two cases had DTR loss, and one patient had decreased urine output in Pritchards group, while one patient had DTR loss, and one case had decreased urine output in the Zuspans group.

Table-10. Magnesium Toxicity

	Toxicity symptom	Pritchards regimen	Zuspan regimen	P-value	Inference
1	Loss of DTR	2 (4%)	1 (2%)	0.5552	Not significant
2	Respiratory depression	0	0		
3	Decreased urine output	1 (2%)	1 (2%)	1	Not significant

MODE OF DELIVERY

Thirty-two cases of Pritchards regimen group and 31 cases of the Zuspan regimen group were delivered by vaginal delivery, and 18 cases of the Pritchards group and 19 cases of the Zuspans group were delivered by LSCS.

Table-11. Mode of delivery

Mode of delivery	Pritchard regimen	Zuspan regimen	Chi-square	P value
Vaginal delivery	32 (64%)	31 (62%)	0.0429	0.835914
LSCS	18 (36%)	19 (38%)		

FETAL OUT COME

The live birth rate was 92% in both groups. 4(8%) IUDs were reported in the Pritchards group, and 3(6%) IUDs and 1(2%) stillbirth were reported in the Pritchards group. 4(8%) IUDs were noted in the Zuspans group. Fetal outcome in the IM group and IV group was statistically insignificant (p< 0.005)

Table-12. Fatal Outcome

Neonatal outcome	Pritchard regimen	Zuspan regimen	Chi-square	P-value
ALIVE	46 (92%)	46 (92%)	1.142857	0.564718
Stillbirth	1(2%)	0		
Intrauterine death	3 (6%)	4 (8%)		

NICU ADMISSION

Four babies out of 46 live-born in the Pritchard group and three babies out of 46 live-born in the Zuspans group required NICU admission due to perinatal depression.

Table-13. NICU Admission

Term live newborn outcome	Pritchard regimen	Zuspan regimen	Chi-square	P value
Requiring NICU admission	4 (8%)	3 (6%)	0.1546	0.694157

DISCUSSION

Prevention of convulsions in preeclampsia and recurrence of convulsions in eclampsia is associated with the reduction of adverse outcomes. Magnesium sulfate is an ideal drug, with rapid onset of action, a non-sedative effect on mother and baby, a fairly wide safety margin and a readily available antidote in the form of calcium gluconate.⁵

The routine use of seizure prophylaxis in women with mild preeclampsia has never been supported by evidence. It has been found that the routine use of magnesium sulfate therapy is not without complications. Maternal morbidity and mortality can occur because of magnesium overdose and toxicity, which can be prevented by giving magnesium sulfate at a controlled rate and by close monitoring of the patient, and this can be accomplished by IV continuous MgSO₄ regimens.

While most of the health centres in world administer MgSO₄ by continuous infusion since the IV route for MgSO₄ administration has many advantages over IM MgSO₄ but, in India most medical centers prefer IM route of administration as described by Pritchards because most of the healthcare centers have poor resources and giving IV magnesium sulfate is not practical due to non-availability of infusion sets, too busy nursing staff.

In this study, both the route for MgSO₄ administration were compared in terms of magnesium sulfate efficacy and toxicity and maternal and perinatal outcome. Toxicity was monitored by clinical parameters.

In the present study, 29 (58%) in the Pritchards group and 31 (62 %) in the Zuspan's group belongs to the rural background. Most of the cases of eclampsia (79.41%) and severe preeclampsia (87.5%) belonged to the rural environment in Kanti et al. study.⁶

There were 18 (36.00%) booked cases in the Pritchards group, while 21 (42.00%) in the Zuspan's group. There were 32(64.00%)unbooked cases in the Pritchards group and 29 (58.00%) in the Zuspan's group. These women didn't seek antenatal care previously in our institute. The majority of women in both groups were unbooked. Lack of antenatal care is a risk factor for preeclampsia and eclampsia. The percentage of unbooked cases reported decreased when compared to previous studies. Unbooked cases were reported by Agarwal⁷ (1983) in range of 92%, Sahu L⁸ (2012) in range of 92%-84%, Kanti v et al.⁶(2015) in a range of 85.3%.

The maximum number of cases 26/50 (52%) in the Pritchards group and 28/50(56%) of cases in the Zuspan's group belong to body weight ranging from 55 -64 kgs and body weight is within the normal range. In the present study, 41 cases of Pritchards group and 28 cases of study group belong to BMI 20-24 kgs/m², which is normal.

In the present study, 32 (64.00%) in the Pritchards group and 28 (56.00%)in the Zuspan's group were nulliparous. The difference was not statistically significant (P = 0.345). Though it is not statistically significant, primigravidae are at more risk of developing preeclampsia and eclampsia due to exposure of chorionic villous for the first time and lack blocking antibodies to placental antigenic sites because they are not exposed to pregnancy previously. In Kanti et al. study, the majority of the cases of eclampsia (64.70%) and severe preeclampsia (58.33%) were nulliparous. Rashmi et al⁹, in her study, reported 45 in the IM group and 46 in IV Group as nulliparous. Ekel¹⁰ (2005)

reported it to be 89%, while Seth et al.¹¹(2010) found the incidence of eclampsia in primigravida to be 74.2%.

In our study, the mean systolic blood pressure was 161mm of Hg in the IM group while in the IV group, it was 161.36 mm of Hg. Similarly, mean diastolic blood pressure was 106.4 and 108.4 mm of Hg in the IM and IV group, respectively. Coetzee EJ et al.¹² found mean systolic blood pressure of 173 mmHg and diastolic blood pressure of 116 mmHg, respectively.

In the present study, 1/50 (2%) cases from each group had convulsions in patients with pre-eclampsia after initiation of treatment and 2/50 (4%) in Pritchard's group and 1/50 (2%) in Zuspan's group had a recurrence of convulsions in patients with eclampsia. The difference between the two groups was statistically insignificant (P=0.70938). Kanti et al.⁶ had 5.88% of recurrence in each group. Pritchard⁴ and Sibai¹³ have reported recurrence rates of 11% and 16%, respectively. The recurrence rate reported in the collaborative eclampsia trial study using Pritchard's regimen ranged between 5.7 and 13.2%. There was no occurrence of convulsion in any subject with severe preeclampsia. Coetzee et al¹⁴. Found occurrence of convulsion rate of 0.3% in the eclampsia group after receiving IV magnesium sulfate.

The most common mode of delivery in the present study is by vaginal route. 64% of patients in the Pritchards group (32/50) were delivered by vaginal delivery. In the Zuspan's group, 62% (31/50) were delivered by vaginal delivery. Overall cesarean section rate is 36% (18/50) in the IM group and 38% (19/50) in the IV group. In Kanti et al. study, the mode of delivery in most of the cases was by vaginal route. 68.29% in the IV group and 75.60% in the IM group delivered vaginally. In eclampsia patients, the more common mode of delivery was by the vaginal route, i.e., 70.58%; LSCS was done in 29.41% women. Also, among severe preeclampsia common route of delivery was vaginal route 72.91 %. Cesarean section rate in collaborative eclampsia trial study 10 was 66 to 72% using standard Pritchard's regimen. In the study of Chissell S¹⁵, the cesarean section rate was 4/8 in the IV group and 3/9 in the IM group. Present study results are similar in comparison with other studies.

No maternal death was reported in this study. There is a wide variation in the reporting of maternal mortality from different parts of the world. In the developed world, no maternal death was reported in the studies of Sibai et al., Lee E. et al¹⁶, and DJ Tuffnel, et al¹⁷. whereas A. Pal, et al¹⁸ has reported maternal mortality as high as 27.85%. In Kanti et al.⁶ study, one case of eclampsia in the IM group was shifted to ICU, expired of respiratory depression. In sipra et al. study, maternal mortality was 24% in the IM group and 20% in the IV group. As the MgSO₄ is the best drug for the prevention and treatment of eclampsia, further areas of research shall include knowing the minimum effective dose of

MgSO₄ under the surveillance of serum magnesium levels, which should be cost-effective and readily available. There is a need to conduct large randomized multicenter trials on these topics in various aspects to prevent preeclampsia and morbidity of eclampsia in mother and fetus and long term sequelae of eclampsia like posterior reversible encephalopathy syndrome and further research work to be done for early detection of preeclampsia even at the domiciliary level.

CONCLUSION

From the above study, we may conclude that the awareness regarding antenatal checkups among the poor population is still deficient, resulting in poor maternal and fetal outcomes. Eclampsia could be predicted and effectively prevented if there is proper antenatal booking, and clinical obstetrics and biochemical assessment of pregnant women who are unaware of prenatal care and its importance. Early identification of risk factors for pre-eclampsia is also essential.

Conflict of Interest: None

Funding Support: Nil

Acknowledgment

The author is thankful to Department of OBG for providing all the facilities to conduct this study.

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