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Demographic Characteristics and Severity of Hypertension in Women Randomly Assigned to Receive Phenytoin or Magnesium Sulphate

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Original Research Article

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Abstract: Magnesium sulfate is used widely to prevent eclamptic seizures in pregnant women with hypertension, but few studies have compared the efficacy of magnesium sulfate with that of other drugs. The aim of this study is to Associate Demographic Characteristics and Severity of Hypertension in Women randomly. It is therefore inferred that MgSO4 therapy has proved superior to Sodium Phenytoin therapy because of minimal CNS depressant action, minimum fits recurrence, better levels of consciousness and improving uterine blood flow. All the above factors collectively help in reducing maternal mortality, morbidity and fetal salvage.
Keywords: Severity Hypertension, Phenytoin, Magnesium & Sulphate.

INTRODUCTION

Magnesium Sulphate, a known laxative, still commonly used in India was first used in treatment of puerperal eclampsia in 1925. It is widely used in the prevention and management of eclampsia in North America and many other parts of the world [1]; Pritchard *et al*. [2]. However, the popular and universal use of drug in preeclampsia and eclampsia is credited to the efforts of Pritchard and Zuspan.

Sodium phenytoin was first used anticonvulsant in 1978 and its pharmacological action is well described [3] sodium phenytoin is well recognized as a specific drug for the prevention and control of epileptic seizures and recent studies [4, 5] have advocated its use in the management of eclampsia and severe gestational proteinuric hypertension (Pre-eclampsia).

A review of the obstetric literature in the United States during the past 60 years indicate that magnesium sulphate satisfies all the criteria of an ideal anticonvulsant in eclampsia. Its efficacy and safety have been well documented during the past 60 years. Recently sodium phenytoin has been recommended as an alternative for magnesium sulphate, however, comprehensive data regarding its safety and efficacy are lacking.

MATERIAL & METHODS

The present study was carried out on all cases of eclampsia (antepartum, intrapartum, postpartum) admitted in Department of Obstetrics and Genecology, of Tertiary Care Centres of Central India for treatment during January 2004 to December 2004.

Study design

This is a prospective study of 50 eclamptic patients. They were randomly divided into two groups of 25 patients each.

Group I (Magnesium Sulphate Group): 25 patients having no renal and respiratory disorder.

Group II (sodium phenytoin Group): 25 patients having no cardiac disorder.

Inclusion criteria

- Women with clinical diagnosis of eclampsia with no other seizure disorder
- Antenatal, intranatal and postnatal cases
- Patients having no renal and respiratory disorder will be included in Magnesium sulphate study group.
- Patients having no cardiac disorder will be included in sodium phenytoin Study group

Methods

After taking a detailed obstetric, family and personal history, performing clinical examination, sending routine and special investigations as written in the forma attached herewith, the patients were divided in 3 groups:

- Antepartum eclampsia
- Intrapartum eclampsia
- Postpartum eclampsia

The patients were treated on the basis of:

- MgSO4 regime - Pritchard regime
- Sodium phenytoin regime

MgSO4 DOSAGE SCHEDULE FOR ECLAMPSIA

- Give 4 g of Magnesium Sulphate (MgSO4.7H2O USP) as a 20% solution at a rate not to exceed 1 gm/min.
- Follow promptly with 10 gm of 50% Magnesium, one half (5 g) injected deeply in the upper outer quadrant of both buttocks through a 3 inch long 20 gauge needle. (Addition of 1 ml of 2% Lidocaine minimizes discomfort). If convulsions persist after 15 minutes, give upto 2 gm more iv as 20% solution at a rate not to exceed 1 gm/min. If the woman is large, upto 4 gm may be given slowly of a 50% solution of magnesium
- Every 4 hrs thereafter give 5 gm sulphate injected deeply in the upper quadrant of alternate buttocks, but only
  After assuring that:

- The patellar reflex is present
- Respiration is not depressed
- Urine output in the previous 4 hrs exceeded 100 ml.
- Magnesium sulphate is discontinued 24 hrs after delivery

Renal function is estimated by measuring plasma creatinine and whenever it is 1-3 mg/dl or higher, we give only half of the maintenance magnesium sulphate i.e. routine loading dose to be followed by 2.5 gm in every 4 hrs.

Antepartum cases were induced by oxytocin drip and artificial rupture of membrane if bishop score was favorable and prostaglandin E2 (PGE2) gel if bishop score was unfavorable. If the fits were controlled and signs of toxemia were not worsening, then patients were allowed for vaginal delivery. In some patients when fits were not controlled or for some obstetrical reasons caesarean section was done. The mother was monitored for her general condition, BP, edema, proteinuria, urinary output or any febrile episode during and after delivery. Mother was also monitored for any adverse reaction to MgSO4.

If respiratory depression occurred, calcium gluconate was given iv slowly as antidote (1 gm of 10 ml 10% solution over 3 min).

SODIUM PHENYTOIN REGIME

An initial loading dose of 500 mg of sodium phenytoin diluted in 200 ml of normal saline was administered over 20 min at an infusion rate of <50 mg/ min. This was followed immediately by 500 mg diluted in 200 ml Normal saline administered over the next 4 hrs. A final dose of 500 mg administered over 4 hrs was given 12 hrs after initiating therapy. BP and pulse were recorded every 2 min during infusion and every 15 min thereafter. Continuous monitoring of Vitals was done during infusion only. A maintenance dose of 200 mg/ 8 hr was given intravenously during the intrapartum period and orally in the postpartum period for 24 hrs and was then discontinued. The occurrence of side effects such nausea, vomiting, nystagmus, incoordination, dysarthria and arrhythmia are noted, the aim was to achieve therapeutic blood level of 10-25 mg/L.

In case of mortality, the cause of death was also determined. The general condition of baby was recorded at the time of birth along with sex, weight Apgar scores and any congenital malformations.

The baby was monitored in nursery by pediatrician for any complication that occurred. In case of fetal death, the cause of death was also evaluated.

RESULTS & OBSERVATIONS

Table-01: characteristics of Patients in MgSO4 and Sodium Phenytoin Regime (Clinical and Laboratory)

	MgSO4 regime		Sodium Phenytoin regime	
	No.	%	No.	%
Number patients	25	100	25	100
Age in years				
< 20 years	06	24	06	24
21-25 years	14	56	14	56
26-30 years	05	20	02	08
> 30 years			03	12
Gestational age (weeks)				
<34 weeks				
34-37 weeks	13	52	09	36
> 37 weeks	09	36	09	36
	03	12	07	28
Mean arterial pressure (MAP) mm Hg	122.8	-	121.7	-
Proteinuria (albustix)				
1+				
2+	01	04	03	12
3+	04	16	06	24
4+	06	24	06	24
	14	56	10	40
Unbooked	25	100	25	100
Rural	17	68	18	72
Type of eclampsia				
APE	13	52	13	52
IPE	09	36	06	24
PPE	03	12	06	24
Mean Birth weight (gm)	2000	-	2000	-
Average length of hospital stay (days)	08	-	10	-

There was no comparable difference between the patients given magnesium sulphate regime and sodium phenytoin as far as the age, parity, gestational age in weeks and mean arterial pressure was concerned. Most of the patients in both the groups belonged to rural habitat having no antenatal checkup with albuminuria (3+ or more) in urine. There was no difference between the mean birth weight of newborn babies given magnesium sulphate and sodium phenytoin regime. Average length of hospital stay of patients in sodium phenytoin regime was slightly longer than magnesium sulphate regime.

Table-02: Control of fits in MgSO4 and Sodium Phenytoin Regime

Hours of therapy	MgSO4 N 25		Phenytoin N-25	
	Controlled		Uncontrolled	
	Case (n)	%	Case (n)	%
00-04	24	96	18	72
04-08	-	-	05	20
08-12	01	04	02	08
12-24	-	-	-	-

Seizures were controlled within 4 hours in 96% patients given magnesium sulphate regime as compared to 7.2% in sodium phenytoin regime. Thus magnesium sulphate is superior to sodium phenytoin in controlling the fits immediately.

DISCUSSION

Table No. 01

There was Comparable difference between the patients given magnesium sodium phenytoin as far as the age, parity, gestational age sulphate regime a in weeks and mean arterial pressure was concerned. Most of the patients in both belonged to rural habitat having no antenatal checkup with albuminuria (3+ or more) in urine. There was minimal difference between the mean birth weight of newborn babies given magnesium sulphate and sodium regime. Average length of hospital stay of patients in sodium phenytoin regime was slightly longer than magnesium sulphate regime[7].

In our study the number of days of hospital stay was found to be significant P<005) and also birth weight was also found to be highly significant (P<0.005).

Table No. 02

Seizures were controlled within 4 hours in 96% patients given magnesium sulphate regime as compared to 7.2% in sodium phenytoin regime. Thus magnesium sulphate is superior to sodium phenytoin in controlling the fits immediately.

This is due to the fact that CSF Mg++ ion is independent of and significantly higher (2.4 mEq/L or 2.2-2.8 mg/dL) than plasma concentration. 4 gm IV injection causes an immediate elevation of plasma level 7-9 mEq/L which returns to 4-5 mEq/L one hour after injection. Only a small amount of Mg++ crosses the blood brain barrier after at least 1 1/2 hours of therapy. This small crement in CSF Mg++ concentration (2.9-3.2 mg/dL) reduces the electric large frequency in cortical neurons. It acts as a calcium channel blocker and causes vasodilation in vascular beds leading to reduction of cerebral ischemia, which improves perfusion and prevention of cerebral edema and convulsions [8].

CONLCUSION

It is therefore inferred that MgSO4 therapy has proved superior to sodium phenytoin therapy because of minimal CNS depressant action, minimum fits recurrence, better levels of consciousness and improving uterine blood flow. All the above factors collectively help in reducing maternal mortality, morbidity and fetal salvage.

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