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ORIGINAL ARTICLE

Efficacy of Dhaka Regimen in Comparison to Zuspan Regimen in Prevention of Eclampsia: A Randomized Control Trial

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Abstract

Introduction: Severe preeclampsia leads to significant maternal and neonatal morbidity and mortality if not treated in time. Existing treatment with MgSO4 using high dose Zuspan regimen can lead to toxicity associated with high dose of Mg. Our study compares low dose (Dhaka) with High dose (Zuspan) in efficacy of management of Severe preeclampsia. **Methodology:** It's a pilot RCT with 30 cases in each arm. Group A received MgSO4 as per Dhaka Regimen and Group B received as per Zuspan regimen. Various maternal (Age, PoG, Proteinuria, Serum Mg levels, Eclampsia) and neonatal parameters (APGAR and NICU admission) were assessed. **Results:** In the present study average age in both the groups was 27 yrs with range between 20-39 years with no statistical difference. Commonest gestational age at presentation was between late preterm (34 wks – 36 wks) or early term (37-38 wks). Average BMI in low dose group (Group A) was 25.81 kg/m^2 and that for high dose (Group B) was 24.39 kg/m^2. Most of the maternal parameters in both the groups were comparable as the difference between them was statistically insignificant. There was no statistically significant difference in Fetal parameters. Results elaborated before show that the level of magnesium at 12th and 18th hour is less in Group A (Dhaka) in comparison to Group B (Zuspan). This reduced levels are statistically significant and also show that even with low dose $MgSO_4$ there was no occurrence of eclampsia. **Conclusion:** It may be formulated that low dose Dhaka regime may be a safer than High dose Zuspan regime. Trial registration: CTRI/2019/05/018950.

Keywords: Zuspan, Preeclampsia, Dhaka

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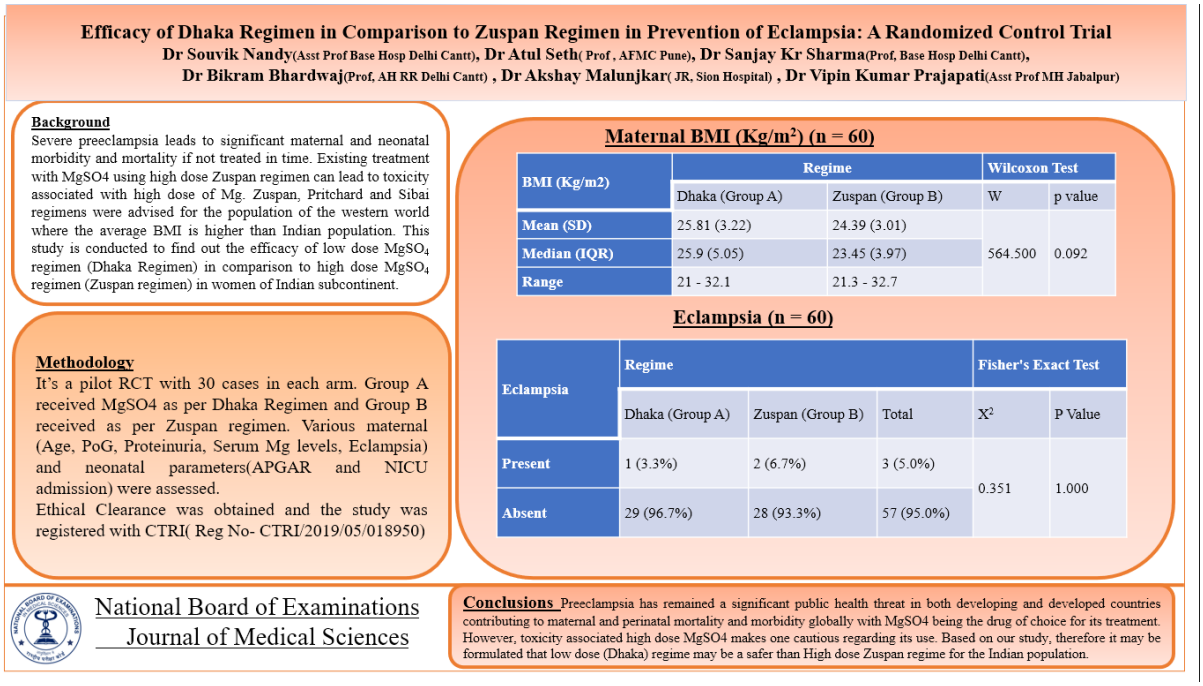
Graphical Abstract



Introduction

Hypertensive disorders are one of the most significant and intriguing unsolved problem in obstetrics. They complicate 5 to 10 percent 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.

Maternal complications of severe pre eclampsia include abruptio placentae, thrombocytopenia, hepatic haemorrhage and rupture, eclampsia, disseminated intravascular coagulation (DIC), intracerebral haemorrhage, acute respiratory distress syndrome (ARDS), acute renal failure and HELLP (Haemolysis-Low platelet- Elevated liver enzymes) syndrome.

The World Health Organization (WHO) states that 16% of maternal deaths in developed world and 9% in Asian population was attributed to hypertensive disorders [1]. In the United States from 2011 to 2013, 7.4 percent of 2009 pregnancy-related maternal deaths were caused by preeclampsia or eclampsia [2]. A similar rate was 10 percent in Europe from 2006 through 2018 [2]. Importantly, more than half of these hypertension-related deaths were deemed preventable [3].

Eclampsia is defined as the occurrence of generalized tonic-clonic convulsion in women with pre-eclampsia. It is one of the most common obstetrical emergencies in developing countries causing significant maternal and perinatal morbidity and mortality.

Incidence of eclampsia is 1.4% and that of pre eclampsia is 4.6 % worldwide [4]. In India, the incidence of eclampsia is 1.5% -2.2% [5].

The principle management for eclampsia is control of convulsions along with supportive life measures and termination of pregnancy. Various $MgSO_4$ regimens are followed for management of eclampsia such as Zuspan [6], Pritchard [7], Sibai [8], Sardesai [9] and Dhaka [9] regimen. The efficacy of MgSO4 in severe preeclampsia and eclampsia is time tested in several studies. The Collaborative Eclampsia Trial randomized a large number

of women to receive Diazepam or Magnesium sulphate and showed greater efficacy of $MgSO_4$ in terms of seizure control [10].

Zuspan, Pritchard and Sibai regimens were advised for the population of the western world where the average BMI (Body Mass Index) is higher than Indian population.

However, because of its narrow therapeutic index, toxic side-effects are the major area of concern in clinical use. Potential complications of MgSo4 treatment include maternal hypotension, respiratory depression, respiratory arrest and although rare, cardiac arrest.

Apprehension regarding these toxicities lead to the limited use of this drug in many developing countries. Reduction of MgSo4 toxicity without compromising efficacy (such as control of seizures and fatality rate) re-mains a major challenge.

Several studies have been carried out, particularly in developing countries, to determine the lowest effective dose of MgSO4, which would potentially offer lower toxicity than the standard regimens. Dhaka regimen is a low dose regimen used in management of Eclampsia.

A low dose regimen may ensure greater safety and in developing countries like India [11].

This study is conducted to find out the efficacy of low dose $MgSO_4$ regimen (Dhaka Regimen) in comparison to high dose $MgSO_4$ regimen (Zuspan regimen) in women of Indian subcontinent.

Aims & objectives

To assess the efficacy of Dhaka regimen for prevention of eclampsia in cases of severe pre eclampsia and compare maternal and fetal outcomes in Dhaka versus Zuspan regimen.

Methodology

Study Population

Ante natal cases with diagnosis of Severe preeclampsia

Place of Study

Tertiary care hospital in western Maharashtra

Inclusion Criteria

All Ante natal cases diagnosed with Severe preeclampsia

Exclusion Criteria

Ante natal cases with pre-existing deranged Renal Function Test, coagulation profile, Seizure disorder.

Study Design

Pilot Randomized Control trial

Sample Size

Since this being a pilot randomized control study, 30 patients in each arm was taken on advise of epidemiologist.

Period of Study

18 months

Methodology

30 patients in each group with severe preeclampsia were started on Dhaka regimen (Group A) and Zuspan regimen (Group B) for prevention of eclampsia.

Group A (Dhaka Regimen)

- **Loading Dose**- Inj MgSO4 4gm IV over 10 mins and followed by MgSO4 3 gm IM in each buttock

- **Maintenance Dose**: Inj MgSO4 2.5 gm in alternate buttock every 4 hours till 24 hours after the last episode of seizure or after delivery whichever was later.

Total dose of MgSO4 was calculated to be 25 gms over 24 hrs.

Group B (Zuspan Regimen)

- **Loading Dose** Inj MgSO4 4gm IV over 10 mins
- **Maintenance Dose**: Continuous infusion of Inj MgSO4 @ 1gm/hr till 24 hours after the last episode of seizure or after delivery whichever was later

Total dose of MgSO4 was calculated to be 28 gms over 24 hrs.

This study was analysed on the basis of following parameters:

Results

Table 1a. Age (n = 60)

Age (Years)	Regime		t-test	
	Dhaka (Group A)	Zuspan (Group B)	T	p value
Mean (SD)	27.90 (4.88)	27.37 (3.96)	0.465	0.644
Median (IQR)	27 (7)	27 (5)		
Range	20 - 39	20 – 34		

Table 1b. Gestational Age (n = 60)

Period Of Gestation (Weeks) (PoG)	Regime		Wilcoxon Test	
	Dhaka (Group A)	Zuspan (Group B)	W	p value
Mean (SD)	36.26 (1.60)	36.13 (2.48)	408.000	0.539
Median (IQR)	36.36 (2.39)	37 (1.86)		
Range	33.29 - 39.29	28.57 - 39.57		

Table 1c. Maternal BMI (Kg/m^2) (n = 60)

BMI (Kg/m2)	Regime		Wilcoxon Test	
	Dhaka (Group A)	Zuspan (Group B)	W	p value
Mean (SD)	25.81 (3.22)	24.39 (3.01)	564.500	0.092
Median (IQR)	25.9 (5.05)	23.45 (3.97)		
Range	21 - 32.1	21.3 - 32.7		

Table 1d. BP (mmHg) (n = 60)

	Regime		Wilcoxon Test	
	Dhaka (Group A)	**Zuspan (Group B)**	**W**	**p value**
Systolic BP (mmHg)				
Mean (SD)	162.67 (20.80)	162.60 (14.93)	422.500	0.684
Median (IQR)	160 (20)	160 (16)		
Range	120 - 220	136 – 204		
Diastolic BP (mmHg)				
Mean (SD)	108.47 (23.57)	105.20 (9.89)	422.000	0.675
Median (IQR)	106 (10)	107 (11.5)		
Range	82 – 226	76 - 120		

Table 1e. Proteinuria (n = 60)

Proteinuria	**Regime**			**Fisher's Exact Test**	
	Dhaka (Group A)	**Zuspan (Group B)**	**Total**	**X^2**	**P Value**
Nil	1 (3.3%)	5 (16.7%)	6 (10.0%)	8.068	0.054
1+	3 (10.0%)	7 (23.3%)	10 (16.7%)		
2+	16 (53.3%)	15 (50.0%)	31 (51.7%)		
3+	10 (33.3%)	3 (10.0%)	13 (21.7%)		

Table 1f. Eclampsia (n = 60)

Eclampsia	**Regime**			**Fisher's Exact Test**	
	Dhaka (Group A)	**Zuspan (Group B)**	**Total**	**X^2**	**P Value**
Present	1 (3.3%)	2 (6.7%)	3 (5.0%)	0.351	1.000
Absent	29 (96.7%)	28 (93.3%)	57 (95.0%)		

Table 1g. Mode of Delivery (n = 60)

Mode of Delivery	**Regime**			**Chi-Square Test**	
	Dhaka (Group A)	**Zuspan (Group B)**	**Total**	**X^2**	**P Value**
Vaginal	16 (53.3%)	15 (50.0%)	31 (51.7%)	0.067	0.796
LSCS	14 (46.7%)	15 (50.0%)	29 (48.3%)		

Table 1h. Parity (n = 60)

Parity	Regime			Chi-Square Test	
	Dhaka (Group A)	Zuspan (Group B)	Total	X^2	P Value
Primigravida	23 (76.7%)	25 (83.3%)	48 (80.0%)	0.417	0.519
Multigravida	7 (23.3%)	5 (16.7%)	12 (20.0%)		

Table 1j. Premonitory Signs (n = 60)

Premonitory Signs	Regime			Chi-Square Test	
	Dhaka (Group A)	Zuspan (Group B)	Total	X^2	P Value
Present	21 (70.0%)	10 (33.3%)	31 (51.7%)	8.076	0.004
Absent	9 (30.0%)	20 (66.7%)	29 (48.3%)		

Table 1k. Respiratory Rate (n = 60)

Respiratory Rate	Regime		Wilcoxon Test	
	Dhaka (Group A)	Zuspan (Group B)	W	p value
Mean (SD)	17.03 (1.69)	15.97 (1.79)	614.000	0.010
Median (IQR)	18 (2)	16 (4)		
Range	12 – 19	14 – 20		

Table 1m. Urine Output (ml/Day) (n = 60)

Urine Output (ml/Day)	Regime		Wilcoxon Test	
	Dhaka (Group A)	Zuspan (Group B)	W	p value
Mean (SD)	1556.17 (292.23)	1399.67 (418.35)	610.500	0.018
Median (IQR)	1550 (487.5)	1355 (375)		
Range	1000 – 2100	950 – 3000		

Table 1n. Magnesium Level at 6 Hours after starting MgSO4 (n = 60)

Magnesium Level (6 Hours)	Regime		Wilcoxon Test	
	Dhaka (Group A)	Zuspan (Group B)	W	p value
Mean (SD)	4.55 (0.78)	4.71 (1.18)	395.500	0.424
Median (IQR)	4.5 (0.95)	4.75 (1.33)		
Range	3.1 - 6.6	2 - 8.5		

Table 1p: Magnesium Level at 12 Hours after starting MgSO4 (n = 60)

Magnesium Level (12 Hours)	Regime		t-test	
	Dhaka (Group A)	Zuspan (Group B)	T	p value
Mean (SD)	4.32 (0.74)	4.77 (1.05)	-1.919	0.060
Median (IQR)	4.25 (0.92)	4.85 (1.22)		
Range	3 – 6	2.2 - 6.8		

Table 1q. Magnesium Level at 18 Hours after starting MgSO4 (n = 60)

Magnesium Level (18 Hours)	Regime		t-test	
	Dhaka (Group A)	Zuspan (Group B)	t	p value
Mean (SD)	4.20 (0.78)	5.14 (1.40)	-3.222	0.002
Median (IQR)	4.25 (1.05)	5.65 (1.95)		
Range	2.7 – 6	1.8 - 7.4		

Table 1r. Change in Magnesium Level over time (n = 60)

Magnesium Level	Regime		P value (@each of the timepoints) (Wilcoxon Test)
	Dhaka (Group A)	Zuspan (Group B)	
	Mean (SD)	Mean (SD)	
6 Hours	4.55 (0.78)	4.71 (1.18)	0.424
12 Hours	4.32 (0.74)	4.77 (1.05)	0.031
18 Hours	4.20 (0.78)	5.14 (1.40)	0.002
P Value (@ over time within each group)	0.002	0.522	
Overall P Value	0.016		

This eclampsia had occurred prior to the start of therapy in either regimen.

3.3% of the patients in the group A had Eclampsia.

6.7% of the patients in the group B had Eclampsia

There was **no significant difference** between the various groups in terms of distribution of Eclampsia (p = 1.000).

Table 2. Neonatal Parameters

Timepoint Comparison	Change in Magnesium Level from 6 Hours to Follow-up Timepoints			
	Group A		Group B	
	Mean (SD) of Absolute Change	P Value of Change Within Group	Mean (SD) of Absolute Change	P Value of Change Within Group
12 Hours - 6 Hours	-0.23 (0.59)	0.032	0.06 (1.01)	0.991
18 Hours - 6 Hours	-0.35 (0.65)	0.003	0.43 (1.44)	0.638

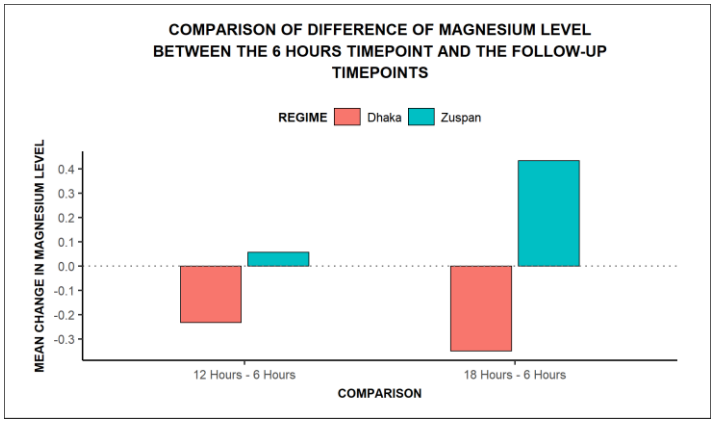


Figure 1. Bar diagram depicting the difference of Magnesium Level between the 6 Hours timepoint and the follow-up timepoints in both the groups

In Group A the fall in magnesium levels at 18th hour and at 12th hour respectively from 6th hour was statistically significant.

It is important to note that even at this low levels of serum magnesium (Group A) there was no occurrence of eclampsia.

Fetal parameters

Table 2a. APGAR @ 1 minute after birth (n = 65)

APGAR (@1 minute)	Regime		Wilcoxon Test	
	Dhaka (Group A)	Zuspan (Group B)	W	p value
Mean (SD)	6.27 (0.87)	6.53 (0.78)	374.000	0.198
Median (IQR)	7 (1.75)	7 (1)		
Range	5 - 7	5 - 7		

Table 2b. APGAR @5 minutes after birth (n = 65)

APGAR (@5 minutes)	Regime		Wilcoxon Test	
	Dhaka (Group A)	Zuspan(Group B)	W	p value
Mean (SD)	9.00 (0.00)	8.93 (0.37)	465.000	0.334
Median (IQR)	9 (0)	9 (0)		
Range	9 - 9	7 – 9		

Table 2c. NICU Admission (n = 65)

NICU Admission	Regime		Chi-SquareTest	
	Dhaka (Group A)	Zuspan (Group B)	X^2	P Value
Present	33.3%	36.7%	0.073	0.787
Absent	66.7%	63.3%		

Discussion

Since the introduction of Zuspan and Pritchard regime of magnesium sulphate there has been a constant discussion regarding the dose of Magnesium sulphate and therapeutic serum Magnesium levels.

Winit Phuapradit et al. [14] and Andrea Witlin [15] thought that Magnesium sulphate dosing should vary according to the patients' weights or body mass index. Based on these observations various low dose regimens have been introduced in Asian countries.

The present study conducted at our centre is a comparison between low dose $MgSO_4$ (Group A- Dhaka regimen) and high dose $MgSO_4$ (Group B- Zuspan regimen) in terms of efficacy in preventing eclampsia in patients with severe preeclampsia. Below mentioned are some comparisons amongst our study and other studies.

The mean gestational age at presentation in Group A was 36 wks 2 days. The mean gestational age at presentation in Group B was 36 wks 1 day. Similar distribution of mean gestational age was observed in the comparison groups in the study conducted by Shikha Seth et al. [16] where mean gestational age was 34 wks 1 day in low dose group and 34 wks 5 days in high dose group.

There was no neonatal mortality noted in this study. All of the babies in both groups had a good Apgar score at 1 minute and 5 minutes.

Results elaborated before show that the level of magnesium at 12^{th} and 18^{th} hour is less in Group A (Dhaka) in comparison to Group B (Zuspan). This reduced levels are statistically significant and also show that even with low dose $MgSO_4$ there was no occurrence of eclampsia.

Conclusion

Preeclampsia has remained a significant public health threat in both developing and developed countries contributing to maternal and perinatal mortality and morbidity globally [17] with MgSO4 being the drug of choice for its treatment. However, toxicity associated high dose MgSO4 makes one cautious regarding its use. Based on our study, therefore it may be formulated that low dose (Dhaka) regime may be a safer than High dose Zuspan regime for the Indian

population. More elaborate studies with higher sample size can be formulated to further authenticate our findings [18].

Conflicts of interest

The authors declare that they do not have conflict of interest.

Ethical Approval

Approval has been taken before initiation the study (IEC/OCT/2018, dt 23rd Oct 2018)

Human and animal rights

This article does not contain any studies with human participants or animals performed by any of the authors.

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