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A COMPARATIVE STUDY OF THE EFFICACY AND SIDE EFFECTS OF ISOXSUPRINE AND MAGNESIUM SULPHATE IN THE MANAGEMENT OF PRETERM LABOUR

Gynaecology

Deepthy G

Bindu Menon

Lola Ramachandran*

*Corresponding Author

ABSTRACT

Preterm labour, the most important single determinant of adverse infant outcome in terms of both survival and quality of life, is problematic because of the several neonatal complications and the long term sequelae. Preterm birth affects 12 – 18% of all births in India. Tocolytic therapy is the most commonly used strategy to arrest preterm labour. Isoxsuprine, a ß sympathomimetic agent is a drug that is currently used as a tocolytic but is associated with serious side effects. Magnesium sulphate is another Tocolytic which has also been the focus of recent research for its neuroprotective effects on preterm babies. We have compared the two in this study.

Objectives: To compare the efficacy of Isoxsuprine with magnesium sulphate with respect to

1. Cessation of labour pains and prolongation of gestational age
2. Drug related side effects
3. The perinatal outcome

Methodology : 50 patients who came to Jubilee Mission Medical College hospital with preterm labour from November 2012 to April 2014 were randomised into two groups of 25 each. Group I was given Isoxsuprine 90mg intravenously in 1000ml Ringer lactate solution at the rate of 0.05 – 0.20 mg/min. Group M was given magnesium sulphate, loading dose of 4gm diluted in 100ml normal saline intravenously, followed by a continuous infusion of 2gm/hr for at least 12 hours. The vitals, urine output and patellar reflex of the patients were monitored.

Results : The mean number of days gained in utero in group I and group M were 30.88 ±21.24 and 27.26±18.79 days respectively. The percentage of NICU admissions in group I was 28% and group M was 28%. Maternal side effects were noted in 32% in group I and 20% in group M.

Conclusion: Magnesium sulphate is comparable to Isoxsuprine in its efficacy in managing preterm labour with less maternal and neonatal side effects.

KEYWORDS

Preterm Labour, Isoxuprine, Magnesium Sulphate, Tocolytics

INTRODUCTION

Preterm labour, defined as birth at less than 37+0 weeks of gestation is the most important single determinant of adverse infant outcome in terms of both survival and quality of life. Preterm deliveries are problematic because of the severe neonatal complications and the long term sequelae which includes cerebral palsy, developmental delay, chronic lung diseases, visual as well as hearing impairment. Preterm birth affects 12 – 18% of all births in India. About 40% of preterm births follow idiopathic preterm labour, 35% follow preterm premature of membranes and the remainder are iatrogenic because of maternal or fetal indications. It is also a serious economic burden for the country in terms of the neonatal intensive care given to these babies.

Tocolytic therapy is the most commonly used strategy to arrest preterm labour.Tocolytics when they succeed in abolishing uterine contractions, provide time for administration of corticosteroids and also to transfer the patient to a centre with better neonatal facilities if so required. Isoxsuprine, a ß sympathomimetic agent is a drug that is currently used as a tocolytic but is associated with serious side effects. Magnesium sulphate is another Tocolytic which has also been the focus of recent research for its neuroprotective effects on preterm babies. We have compared the two in this study. The choice of the first line tocolytic is controversial because of inconclusive evidence that any one is better than the other. Relative safety is the main reason for choosing one over the other.

AIMS AND OBJECTIVES

To compare the efficacy of Magnesium sulphate with Isoxsuprine with respect to period of prolongation of pregnancy, adverse drug reactions and the perinatal outcome.

MATERIALS AND METHODS

This study was conducted in the labour room of jubilee mission medical college from November 2012 to April 2014.During this period 50 women who came to the labour room and satisfied the inclusion criteria and did not come under the exclusion criteria with the clinical diagnosis of preterm labour were included in the study. 28 and 34 weeks. These 50 women were randomised into two groups of 25 each alternatively. The first group was given Isoxsuprine, one of the routine tocolytics used in our hospital. The second group was given Magnesium Sulphate.

The inclusion criteria were women with singleton pregnancy >28 weeks and <34+6 weeks of gestational age with any of the following

1. Contractions of 4 in 20 minutes or 8 in 60 minutes.
2. Cervical dilatation >1cm
3. Cervical effacement 80% or more

The exclusion criteria were

1. Gestational hypertension
2. Gestational Diabetes Mellitus
3. Cardiac disease
4. Intrauterine fetal demise
5. Renal disease
6. Premature rupture of membranes
7. Cervix >4cm dilated
8. Fetal anomalies
9. Fetal distress
10. Placental Abruption

Grouping – Study Design: Bivariate
Materials and Methods: Type of Data: Nominal

After taking written informed consent, a detailed history was taken regarding period of amenorrhoea and the last menstrual period, symptoms that the patient has presented with as well as her obstetric, menstrual and medical history. Then the patients were examined. A general physical examination was done to rule out any medical illness. An obstetric examination was done to ascertain the gestational age and fetal well being. A pelvic examination was also done to assess the Bishop's Score and to rule out premature rupture of membranes. The patients were subjected to basic investigations like haemoglobin, urine routine and obstetric ultrasonography. After that the patients were randomised into group I and group M alternatively. Group I received Isoxsuprine and Group M received Magnesium Sulphate (MgSO4). All the patients received antibiotics as infection is supposed to be a

major cause for preterm labour[1]. Injection betamethasone 12 mg IM was given as a stat dose and the same was repeated after 24 hours for fetal lung maturity[2].

The drugs were administered according to the following regimes. 90 mg Isoxsuprine was added to 1000ml Ringer lactate solution and this was infused at the rate of 0.05 – 0.2 mg/min to the patients who were randomised to group I[3]. Group M was given a loading dose of 6G diluted in 100ml Normal Saline intravenously, followed by a continuous infusion of 2gm/hr for at least 12hrs[4].

Group I was monitored by measuring their vital parameters every 15 minutes, especially pulse and respiratory rate. Fetal heart was monitored every 15 mins. Group M was monitored by checking their patellar reflex every 15 minutes for the first 2 hours, and then hourly. If patellar reflex was absent, the infusion was stopped and blood was collected fot serum Magnesium levels. The respiratory rate in Group M was monitored every 15 min during the first 2 hours and then hourly. If respiratory rate was less than 12/min, the infusion was stopped. Airway was maintained and oxygen was administered at 6 – 8 L/min. 10 ml of 10% calcium gluconate was given intravenously slowly. The blood was also collected for serum magnesium levels. The urine output was measured and recorded hourly. It should be >30ml/hr. Blood pressure was checked every 30 mins and the fetal heart monitored every 15 mins.

The patients were then analysed for the number of days gained in utero, adverse drug reactions noted and the perinatal outcome with regard to the NICU admissions needed. The observations were processed and statistically analysed.

RESULTS

Majority of the patients were in the age group 21 to 30 yrs. 72% in isoxuprine & 64% in magnesium sulphate group belonged to this group. Most of the patients who presented with preterm labour belonged to lower socio economic strata followed by middle class. Majority of the women in the study were housewives – 605 from Isoxuprine and 64% from magsulph group. 92% of the patients from the Isoxuprine group and 96% from the magsulph group were literate and educated which helped them in noting the warning signs and report to hospital early.

76% from each group were primigravidas. 56% from I group and 60% from M group presented at 32 – 34 weeks of gestation with symptoms suggestive of preterm labour Most of the patients had a normal body mass index between 18 and 23. More than half the patients in each group seeked treatment within 5 hours of onset of symptoms. 52% of women from I group and 44% from M group had only mild contractions as estimated by clinical palpation. 60% in I and 56% in M group had unfavourable cervix as evidenced by their Bishop's score on admission though they were symptomatic.

From both tocolytic limb 24% gained upto 10 days in utero. Another 24% in I group gained between 21 to 30 days and 20% from magsulph group gained 32 – 40 days. 56% of patients given Isoxuprine and 48% given magnesium sulphate delivered at term that is after 37 completed weeks. 68% from I gp and 76% from magnesium sulphate group delivered vaginally. 68% from I gp & 80% from M gp did not have any side effects. The Isoxuprine group had more side effects mostly tachy cardia. A feeling of warmth was the commonest side effect experienced by the magnesium sulphate group. More than 90% of the babies in both groups had APGAR more than or equal to 8. Only 7 babies from each group required NICU admission.

So to conclude both Isoxuprine and magnesium sulphate have comparable efficacy and side effects when used as tocolytics. Isoxuprine had a little more side effect but not satistically significant.

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