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## Comparison of isoxsuprine 10 mg and 40 mg for the management of preterm mothers: A prospective study

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### Abstract

**Background:** The preterm labor causes 30% of all preterm births. The preterm birth occurs in about 11% of all pregnancies. It accounts for major neonatal mortality and morbidity. WHO defined the preterm labor, as the onset of labor prior to the completion of 37 weeks of gestation, in a pregnancy beyond 20 weeks of gestation.

This Research Article is an attempt to study the efficacy of Tablet Isoxsuprine as a tocolytic agent in the treatment of preterm labor 10mg versus 40mg regarding beneficial effect of prolonging pregnancy, neonatal outcome, the incidence of neonatal mortality and adverse effects.

**Aim:** The purpose of this study is to compare the effectiveness in the use of tablet Isoxsuprine hydrochloride as a tocolytic agent in the treatment of preterm labor 40mg vs. 10mg oral route and thereby evaluate its beneficial effect regarding

1. Prolonging the pregnancy
2. Neonatal outcome
3. Perinatal mortality and morbidity.
4. Maternal adverse effects.

### Materials & Methods

**Study design:** It is a prospective comparative study. The study was conducted in Institute of social obstetrics ISO Government Kasturba Gandhi hospital for women and children-Triplicane from Dec 2011 to Dec 2012. The study population comprised of patients who were admitted either through casualty or OPD, who comes with complaints of preterm labour. Two groups of patients were selected randomly of which one group of patients were treated with 10mg of Tablet Isoxsuprine twice a day.

The next group of patients were treated with 40mg of Tablet Isoxsuprine as once a day. All patients were closely monitored for the adverse reactions of the drug and Foetal surveillance by biophysical profile. All the patients who were in the study received intramuscular dose of betamethasone for lung maturity and to prevent other neonatal complications like, respiratory distress syndrome, necrotizing enterocolitis. Written informed consent was obtained from all the patients under the study.

**Results:** There was no age related significant difference, in patients with preterm labour. The mean age is 25. P value < 0.393 which indicates no significant difference.

In primi 50% received 10mg Tablet Isoxsuprine and another 50% received 40mg. Among the multi gravida 66.7% received 10 mg and 33.3% received 40mg. P-value is -0.061 (>0.05) which indicate no statistically significant difference. There is no significant risk factors noted.

Adverse effects were very minimum and can be reversed by withdrawing the drug. No significant different in adverse effects noted between 10mg and 40mg of Tablet Isoxsuprine.

**Conclusion:** The maternal side effects like headache more common in 40mg of Tablet Isoxsuprine and nausea and vomiting more common in 10mg of Tablet Isoxsuprine.

The incidence of Foetal mortality, morbidity was due to complications of prematurity of baby and not by the Tablet Isoxsuprine and its dosage.

However, early identification of risk factors, better antenatal care, treat the correctable causes, improving the socio-economic standards, early detection and intervention reduce the incidence of preterm labour.

**Keywords:** Preterm, isoxsuprine

### Introduction

The preterm labor causes 30% of all preterm births. The preterm birth occurs in about 11% of all pregnancies. It accounts for major neonatal mortality and morbidity. WHO defined the preterm labor, as the onset of labor prior to the completion of 37 weeks of gestation, in a pregnancy beyond 20 weeks of gestation. There are various reasons behind the increased incidence of preterm birth, particularly usage of fertility drugs, assisted reproduction, increase in the number of pregnancies and higher order births. Goldenberg (1) studied in a three part series on preterm births under, Spontaneous labor with intact membranes.

PPROM (Preterm premature ruptured of membranes). Labor induction (or) cesarean section delivery for Foetal and maternal indications (indicated preterm).

Black women compared to white, have twice the risk of giving preterm birth. This is explained by various factors, like race, medical disorders, socio economic status, genetic predisposition are behind the occurrence of preterm birth.

Various tocolytic agents are used for treatment of preterm labor in women at risk of pregnancy. Tocolytic agents inhibit the uterine contraction thereby prolonging the pregnancy and the neonate get the benefit of corticosteroid for their lung maturity.

More than 1 million death occur due to preterm labor in low income countries. Steroid therapy may be very effective in the prevention of neonatal mortality, morbidity.

The efficacy of tocolytic agents were studied in various analysis. The end point of the studies on tocolytic agents is that it acts in the cessation of uterine contraction for 24 hours, 48 hours and 7 days etc. At the same time there is no proven benefit of maintenance therapy after complete relaxation of uterus. Tocolytic drug is used in early preterm labor, when the cervical dilatation is >1cm with 80% effacement.

This Research Article is an attempt to study the efficacy of Tablet Isoxsuprine as a tocolytic agent in the treatment of preterm labor 10mg versus 40mg regarding beneficial effect of prolonging pregnancy, neonatal outcome, the incidence of neonatal mortality and adverse effects.

#### AIM

The purpose of this study is to compare the effectiveness in the use of tablet Isoxsuprine hydrochloride as a tocolytic agent in the treatment of preterm labor 40mg vs. 10mg oral route and thereby evaluate its beneficial effect regarding

1. Prolonging the pregnancy
2. Neonatal outcome
3. Perinatal mortality and morbidity.
4. Maternal adverse effects.

#### Methodology

##### Study design

It is a prospective comparative study. The study was conducted in Institute of social obstetrics ISO Government Kasturba Gandhi hospital for women and children-Triplicane from Dec 2011 to Dec 2012. The study population comprised of patients who were admitted either through casualty or OPD, who comes with complaints of preterm labour. Two groups of patients were selected randomly of which one group of patients were treated with 10mg of Tablet Isoxsuprine twice a day.

The next group of patients were treated with 40mg of Tablet Isoxsuprine as once a day. All patients were closely monitored for the adverse reactions of the drug and Foetal surveillance by biophysical profile. All the patients who were in the study received intramuscular dose of betamethasone for lung maturity and to prevent other neonatal complications like, respiratory distress syndrome, necrotizing enterocolitis. Written informed consent was obtained from all the patients under the study.

##### Inclusion Criteria

1. Patients with Gestational age between 30 to 36 weeks, as determined by clinical Examination, menstrual History, USG Finding, dating scan if available.
  2. By examination, the patients with preterm labor showed the following findings.
- Progressive uterine contractions 4/20mins or 8/60 minits

lasting for 40 seconds,

- Effacement of cervix upto 80%,
- Dilatation of cervix 1-3cm with intact membrane,
- USG showing cervical length-less than 2.5 cm.

##### Exclusion Criteria

1. Rupture membrane
2. Presence of infection
3. Cervical dilatation more than 3cm.
4. Antepartum Hemorrhage.
5. Heart disease.
6. Anemia.
7. Hypertension, Preeclampsia.
8. Diabetic, Gestational diabetes mellitus.
9. Glaucoma.
10. Liver disorder.

##### Foetal Factors

1. Twins
2. Foetal distress/Foetal death
3. IUGR
4. Oligohydramnios/polyhydramnios
5. Congenital anomalies.

##### Investigations

1. Hb %, PCV
2. Urine analysis.
3. Vaginal swab.
4. ECG
5. Foetal assessment by USG with modified Bio- physical profile.

##### Study

Patients were selected randomly, not based on age, parity and risk factors.

All studied patients were admitted and were on bed rest in left lateral position with monitoring of vital parameters such as PR, HR, Temperature. CVS, RS examined. Two doses of Betamethasone 12mg, 12 hourly given intramuscularly in all admitted patients.

Group A patient received 10mg of Tablet Isoxsuprine twice a day orally and group B patient received 40mg once a day orally. After administration of the drug, patients were closely monitored for the adverse effects, any progression of labour, and Foetal compromise, by observing the increase in Foetal heart rate (non-reactive NST). Analysis was done between the 2 doses of Tablet Isoxsuprine in view of its efficacy and effectiveness by the following.

- Prolonging the pregnancy towards term.
- Perinatal outcome by observing the APGAR and weight of the baby.
- Maternal side effects
- Reduction in the incidence of perinatal mortality and morbidity.

Tablet Isoxsuprine was given orally. The onset of action is 1 hour after the administration. The half-life of Tablet Isoxsuprine is 1.25 hours. It is eliminated primarily through urine as conjugates and small amount through feces. It can cross the placenta.

When the uterine contractions did not stop within 1½ hours of administration and there was presence of progression of labour, it was considered as failure.

If the uterine contraction stopped and non-progression of cervical dilatation and postponement of labor for varying period of 48 hr, 4 days, and 7 days and term, was as considered positive result.

Pregnancy outcome and efficacy of 10mg and 40mg of Tablet Isoxsuprine was analysed.

In this study, how long the preterm labor is prolonged to term by using 10mg and 40mg of Tablet Isoxsuprine was studied. The efficacy of 40mg compared to 10mg of Tablet Isoxsuprine was done.

When the patient, delivered within 2 days after administration of the drug and gave a preterm birth, that dosage was considered as not effective. When the dosage of drug prolongs the pregnancy to term and give good perinatal outcome, it was considered to have high efficacy. The drugs are also compared by other factors such as maternal side effects and mode of delivery.

**Results and Discussion**

**Table 1:** Age Related To Preterm

Dose	N	Mean (Age)	Std. Deviation	P value
10mg	72	25.63	3.54	0.393
40mg	51	25.06	3.70	

Out of 72 patients who received 10mg of Tablet Isoxsuprine and 51 patients who received 40mg of Tablet Isoxsuprine, the mean age of patients receiving both the doses of Tablet Isoxsuprine was 25 years.

The P value is > 0.05 and hence not statistically significant ie, the maternal age in our study is not an important factor for the efficacy of Tablet Isoxsuprine in prolonging the pregnancy.

**Table 2:** Parity

Parity	Tablet Isoxsuprine 10mg	Tablet Isoxsuprine 40mg	P Value
Primi	30 (41.7%)	30 (58.8%)	0.061
Multi	42 (58.5%)	21 (41.5%)	
Total	72	51	

- Out of 72 patients who received 10mg of Tablet Isoxsuprine 41.7% were primi and 58.5% were multipara.
- Out of 51 patients who received 40mg of Tablet Isoxsuprine 58.8% were primi and 41.5% were multipara.

P value- >0.061- not statistically significant. There is no parity related difference in the action of 40mg vs 10mg Tablet Isoxsuprine, since P value is > 0.05.

**Table 3:** Estational Age

Dose	N	Mean (gestational age)	Std deviation	P value
10mg	72	33.82	1.7	0.055
40mg	51	34.35	1	

Among 72 patients who received 10mg Tablet Isoxsuprine were in the mean GA of 33.8 weeks and 51 patients who received 40mg of Tablet Isoxsuprine in the mean GA of 34.3 weeks with a standard deviation of 1.7 weeks and 1 week respectively showed,

P value of >0.05 with both doses. So it is not a significant factor.

**Table 4:** Risk Factors

Risk Factors	Tablet Isoxsuprine 10mg	Tablet Isoxsuprine 40mg
BOH	3 (4.2%)	2 (3.9%)
Breech	0 (0%)	1 (2%)
H/o Preterm	0 (0%)	1 (2%)
Hypothyroidism	2 (2.8%)	2 (3.9%)
IUI treated	0 (0%)	1 (2%)
Previous LSCS	3 (4.2%)	5 (9.8%)
Nil	63 (87.5%)	39 (76.5%)
Total No of cases	72	51

Out of 72 patients getting 10mg of Tablet Isoxsuprine had risk factors such as BOH 4.2%, Hypothyroidism 2.8%, Previous LSCS 4.2%.

Out of 51 patients getting 40mg of Tablet Isoxsuprine had risk factors, of BOH 3.9%, Breech 2%, H/o Preterm 2%, Hypothyroidism 3.9%, IUI treated 2%, Previous LSCS 9.8%.

The P value is > 0.443, so not significant. In our study these risk factors are not related to efficacy of 10mg and 40mg doses.

**Table 5:** Maternal Adverse Effects

Maternal Adverse effect	Tablet Isoxsuprine 10mg	Tablet Isoxsuprine 40mg
↑ HR	8 (25%)	0 (0%)
Nausea	2 (6.3%)	1 (7.7%)
Nausea Vomiting	20 (62.5%)	8 (61.5%)
Headache	2 (6.3%)	4 (30.8%)
Total	32	13

Out of 72 patients getting 10mg of Tablet Isoxsuprine, adverse effects were noted in 32 patients. ↑ HR 25%, Nausea 6.3%, Nausea, Vomiting 62.5%, Headache 6.3%.

Out of 51 patients getting 40mg of Tablet Isoxsuprine adverse effects were noted in 13 cases. No tachycardia, Nausea 7.7%. Nausea Vomiting 61.5%, Headache 30.8%. P value is > 0.059 which indicate that there is no significant difference in causing side effect in comparison between 40mg, 10mg of Tablet Isoxsuprine.

**Table 6:** Mode of Delivery

Mode of delivery	Tablet Isoxsuprine 10mg	Tablet Isoxsuprine 40mg	P Value
Normal	50 (69.4%)	37 (72.5%)	0.709
LSCS	22 (30.6%)	14 (27.5%)	
Total	72	51	

In 10mg Tablet Isoxsuprine group 69.4% had normal vaginal delivery and 30.6% had LSCS. In 40mg group 72.5% had normal vaginal delivery, 27.5% had LSCS.

P value is > 0.709 - not statistically significant. The doses do not influence the mode of delivery.

**Table 7:** Neonatal Morbidity and Mortality

S. No	Cause	T. Isox 10mg	T. Isox 40mg
1	Birth Asphyxia	2 (16.7%)	1 (25%)
2	RDS	5 (41.5%)	1 (25%)
3	IVH	2 (16.7%)	0 (0%)
4	Foetal tachycardia	2 (16.7%)	2 (50%)
5	Septicemia	1 (8.3%)	0 (0%)
	Total	12	4

The conditions observed in 10mg group were Birth asphyxia

(16.7%), ARDS (41.7%), IVH (16.7%), Foetal tachycardia (16.7%) and septicemia (8.3%) in our study. In 40mg of group these were Birth asphyxia (25%), RDS (25%), IVH (0%), Foetal tachycardia (50%) and Septicemia (0%). Foetal mortality and morbidity were due to prematurity of lung and other organs.

**Table 8:** Duration of Prolongtion

Dose	No	Mean in days	Std Deviation	Std error mean	P Value
T. Isox 10mg	72	4.3	3.4	0.4	0.001**
T. Isox 40mg	51	15	10.8	1.5	

Prolongation of the duration of pregnancy towards term, compared in two different doses of Tablet Isoxsuprine 10mg Vs 40mg.

The mean duration of prolongation of pregnancy in 10mg group was 4 days and in 40mg group was 15 days.

P value < 0.001\*\* it indicate significant different at 1% level.

Tablet Isoxsuprine 40mg dose effectively prolonged the pregnancy than 10mg Tablet Isoxsuprine.

**Table 9:** Weight of Babies at Birth

Weight	Tablet Isoxsuprine 10mg	Tablet Isoxsuprine 40mg	P Value
< 2 kg	11 (15.3%)	2 (3.9%)	<0.001**
2-2.5 kg	51 (70.8%)	20 (39.2%)	
> 2.5 kg	10 (13.9%)	29 (56.9%)	
Total	72	51	

Out of 72 babies born in 10mg group, the birth weight shows < 2kg- 15.3%, between 2 to 2.5kg -70.8%, > 2.5kg -13.9%.

Out of 51 babies born in 40mg group, the birth weight shows < 2kg - 3.9%, between 2 to 2.5kg -39.2%, > 2.5kg- 56.9%.

P Value < 0.001\*\*, hence significant at 1% level. The Birth weight more than 2.5kg mostly occurred in 40mg than 10mg.

**Table 10:** Apgar score

Apgar value	Tablet Isoxsuprine 10mg	Tablet Isoxsuprine 40mg
4	1 (1.4%)	0 (0%)
5	25 (34.7%)	8 (15.7%)
6	41 (56.9%)	28 (54.9%)
7	5 (6.9%)	15 (29.4%)

APGAR score of the newborn baby was compared with 10mg and 40mg of Tablet Isoxsuprine. The APGAR is found to be increased in 40mg, compared to 10mg of Tablet Isoxsuprine.

- In Apgar value of 4 is found in 1.4% in 10mg Tablet Isoxsuprine and 0% in 40mg of Tablet Isoxsuprine.
- Apgar value of 5 is found in 34.7% in 10 mg Tablet Isoxsuprine and 15.7% in 40mg of Tablet Isoxsuprine.
- Apgar value of 6 is found in 56.9% in 10mg Tablet Isoxsuprine and 54.9% in 40mg of Tablet Isoxsuprine.
- Apgar value of 7 is fond in 6.9% in 10mg Tablet Isoxsuprine and 29.4% in 40mg of Tablet Isoxsuprine.

P value is < 0.05 hence the P value is significant at 5% level.

There was no age related significant difference, in patients with preterm labour. The mean age is 25. P value < 0.393 which indicates no significant difference.

In primi 50% received 10mg Tablet Isoxsuprine and another

50% received 40mg. Among the muti gravida 66.7% received 10 mg and 33.3% received 40mg. P-value is -0.061 (>0.05) which indicate no statistically significant difference. There is no significant risk factors noted.

Adverse effects were very minimum and can be reversed by withdrawing the drug. No significant different in adverse effects noted between 10mg and 40mg of Tablet Isoxsuprine.

The mode of delivery by normal vaginal and LSCS in two doses of Tablet Isoxsuprine was analysed. The P value is <0.709, so no statistically significant difference. The doses do not influence the mode of delivery.

The APGAR and birth weight was found increased with 40mg Tablet Isoxsuprine compared to 10 mg. Because of the prolongation of pregnancy with 40mg Tablet Isoxsuprine is better than 10mg the APGAR and birth weight is markedly improved with P value of <0.001 which is highly significant.

In prolongation of pregnancy with 10mg of Tablet Isoxsuprine – mean value of prolongation of duration is 4 days and 15 days in 40mg of Tablet Isoxsuprine. The P< 0.001 with standard error of mean of 1.5 days. Hence it is statistically significant in our study.

The 40mg oral tablet had good patient compliance. Prolongation of pregnancy and perinatal outcome were better with 40mg Tablet Isoxsuprine compared to 10 mg Tablet Isoxsuprine in the treatment of preterm labour.

**Summary**

The preterm labor is the main cause of perinatal morbidity and mortality in both developed and developing countries. The incidence of preterm labor is quite more in our country (23%) compared to developed country (11%). About 10 million of babies born prematurely per year, of which 1 million die per year. It accounts for one in eight live births.

In order to minimise the perinatal mortality and morbidity, various methods and studies tried for prolonging the pregnancy towards term and allowing the time for steroid to work in fetus to mature.

The main aim of tocolytic agent is to prevent the uterine contraction and not to treat the predisposing factors of preterm labor. Various tocolytic agents were used for treating preterm labour. In our study Tablet Isoxsuprine was taken. The two doses of Tablet Isoxsuprine 10mg and 40mg were compared for their efficacy, and its effectiveness in treating the preterm labour. Tablet Isoxsuprine 10mg twice a day and 40mg once a day were given.

In olden days it was used for treating cerebrovascular disorder. It can be given by both oral and parenteral route. It has better absorption by oral route. It is eliminated through urine. Adverse reactions are due to the activation of the beta receptors in other sites like blood vessels, cardiac muscle, SA node and CNS. The adverse effects are very negligible, sometime may need immediate attention and intensive care.

After excluding the exclusion criteria, patients with complaints of preterm labor were grouped into two. First group of patients getting 10mg of Tablet Isoxsuprine oral twice a day and the second group of patients getting 40mg of Tablet Isoxsuprine once a day.

The patient selection was done randomly not related to age, parity, and risk factors. The results were observed. The patients were closely monitored for the adverse reactions, like increased pulse rate, hypotension, nausea, vomiting, headache, fascia flushing, and some rare complications which need medical attention like pulmonary oedema.

In our study only minor side effects happened. All adverse

effects disappeared after delivery. During this study, the Foetal condition was also monitored by modified biophysical profile. The result of the study analysed by the beneficial effects of the 2 different doses of Tablet Isoxsuprine were compared by the following factors.

- Prolonging the pregnancy towards term.
- Comparing the adverse effects.
- Perinatal outcome by observing the apgar and weight of the baby.
- Reduction in the incidence of perinatal mortality and morbidity.

There were no significant differences between the two groups patients with regard to age, parity, gestational age, mode of delivery and risk factors.

Prolonging the duration of pregnancy in 40mg Tablet Isoxsuprine was 15 days, compared to 4 days in 10mg Tablet Isoxsuprine. So both doses provided, minimum of 48 hours, to allow the steroid to work, for Foetal lung maturity. Steroids also decreases the incidence of other neonatal complications like intraventricular hemorrhage, necrotising enterocolitis, and PDA. Two cases of Birth Asphyxia noted in 10mg and 1 case in 40mg Tablet Isoxsuprine. 5 cases of Respiratory distress noted in 10mg, 1 case in 40mg. 2 cases of IVH noted in 10mg, nil cases in 40mg. 1 case of Septicaemia noted in 10mg, nil case in 40mg. 4 cases Foetal tachycardia noted 2 in 10mg, 2 in 40mg of Tablet Isoxsuprine.

Foetal complications were due to prematurity and not by Tablet Isoxsuprine and its dosage. Drug and Dosage did not altered the mode of delivery.

### Conclusion

A tocolytic agents make the uterus refractory to stimuli for a short time to days. The tocolytic agents provide enough time for exogenous corticosteroid to act on the Foetal lung. In our clinical trial, there was good response to 40mg oral Tablet Isoxsuprine therapy than 10 mg oral dose. The beneficial results observed were,

- The mean prolongation of pregnancy was 15 days in 40mg compared to 4 days in 10mg of Tablet Isoxsuprine.
- Good perinatal outcome in 40mg of Tablet Isoxsuprine evidenced by good Apgar score of 7 and birth weight >2.5 kg. Compared to Apgar of 5 and Birth weight between < 2.5kg in 10mg of Tablet Isoxsuprine.
- Regarding the Foetal mortality and morbidity, RDS 5 cases observed in 10mg compared to 1 case in 40mg of Tablet Isoxsuprine.
- The maternal side effects like headache more common in 40mg of Tablet Isoxsuprine and nausea and vomiting more common in 10mg of Tablet Isoxsuprine.

The incidence of Foetal mortality, morbidity was due to complications of prematurity of baby and not by the Tablet Isoxsuprine and its dosage.

However, early identification of risk factors, better antenatal care, treat the correctable causes, improving the socio-economic standards, early detection and intervention reduce the incidence of preterm labour.

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