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Original Research Article

Effectiveness and safety of isoxsuprine hydrochloride as tocolytic agent in women with preterm labor in India: A prospective, observational study

Shrinivas N Gadappa[1]*, Mary Snigdha[2], Arun N Nayak[3], Pragya Pandey[4]

[1]Dept. of Obstetrics and Gynecology, Government Medical College, Aurangabad, Maharashtra, India
[2]Dept. of Obstetrics and Gynecology, AC Subba Reddy, Government Medical College and Hospital, Nellore, Andhra Pradesh, India
[3]Dept. of Obstetrics and Gynecology, Lokmanya Tilak Municipal Medical College, Mumbai, Maharashtra, India
[4]Dept. of Obstetrics and Gynecology, Shubham Sadbhavna Hospital, Varanasi, Uttar Pradesh, India

Abstract

Background: Preterm labor (PTL), defined as labor occurring between 20 to 37 weeks of gestation, is one of the primary etiological factors for neonatal disease burden and fatality. This study assessed the effectiveness and safety of isoxsuprine, a tocolytic agent, in women experiencing PTL.
Materials and Methods: Pregnant women (n=170) were treated at onset of PTL with isoxsuprine hydrochloride intravenous infusion (four 2-mL ampoules diluted in 500 mL of 5% w/v dextrose/Ringer lactate; drip rate of 8 drops per minute, increased by 8 drops per minute every 15 minutes), until uterine quiescence was achieved. This was followed by oral isoxsuprine therapy (40 mg twice daily) for up to 48 hours.
Results: Successful tocolysis was achieved in 166 (97.6%) women at 24 hours and in 165 (97.1%) women at 48 hours, after the start of therapy (primary endpoint). Ten adverse drug reactions (ADRs) were reported in 10 (5.9%) women; four were classified as serious (fetal distress syndrome [n=2], stillbirths [n=2]); all were considered unlikely to be related to the study drug. No action was taken with the study medication in response to any of the ADRs. No clinically significant abnormalities like tachycardia or hypotension were reported during vital sign monitoring every 4 hours from baseline to 48 hours. Delivery outcomes data were available for 146 (85.9%) women. All of them had delivered healthy babies with no congenital abnormalities (mean ± standard deviation birth weight: 2.7±0.43 kg).
Conclusion: Isoxsuprine was effective and well-tolerated in the treatment of PTL, with acceptable maternal and perinatal outcomes.
Clinical Trial Registration Number: CTRI/2020/01/022643, registered at www.ctri.nic.in.

Keywords: Effectiveness, Isoxsuprine hydrochloride, Observational study, Preterm labor, Prospective, Safety, Tocolysis.

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1. Introduction

Preterm births (PTBs) are a leading cause of neonatal mortality, accounting for nearly one million deaths.[1] In 2020, the global PTB rate was 9.9%; the rates were highest in India (13.0%).[2] Spontaneous preterm labor (PTL) is said to account for nearly two-thirds of PTBs.[3] Amongst the developing countries, India has a very high incidence of PTL (23.3%).[4]

Efforts to mitigate the impact of PTB primarily focus on prevention and care. Tocolytic treatment with beta-adrenergic agonist is recommended in guidelines for short-term prolongation of pregnancy.[5] Tocolytics are one among the ten elements of care recommended by World Health Organization for improved PTB outcomes.[6] Tocolytics help delay labor (by up to 48 hours) by inhibiting uterine contractions and promoting relaxation of the uterine myometrium, thereby providing the crucial window for administering antenatal corticosteroids.[7,8]

Isoxsuprine hydrochloride is a beta-agonist that causes vascular smooth muscle relaxation and peripheral vascular

*Corresponding author: Shrinivas N Gadappa
Email: gadappashrinivas@gmail.com

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dilation.[9] It is approved in India as a tocolytic agent, and has been widely used for over six decades.[10] A systematic review of data from double-blind studies as well as studies containing individual or general patient data showed an approximately 89% efficacy rate with isoxsuprine in the management of PTL.[11] A retrospective analysis of practice patterns in the management of PTL indicated isoxsuprine to be the most frequently used tocolytic agent, and to more successfully prolong delivery for at least 48 hours compared with nifedipine (57.76% versus 34.78%, respectively).[12] The mean latency period, birthweight and APGAR score at 5 minutes were also higher with isoxsuprine versus nifedipine, both in women with mean gestational age <32 weeks as well as in those with mean gestational age >32 weeks.[12] In a prospective, open-label study, successful tocolysis was achieved in all 50 women studied at 24 hours post-isoxsuprine administration (intravenous followed by intramuscular), as well as in the subsequent 24 hours with isoxsuprine oral therapy.[13] The gestation period was found to be considerably prolonged with usage of isoxsuprine in maintenance therapy. Results from the study presented evidence that use of isoxsuprine, intravenous followed by oral therapy, leads to overall improvement in neonatal outcomes in terms of birth weight and APGAR score.[13] Isoxsuprine is considered by experts in the field to be the first-line tocolytic agent,[10] and it is part of the treatment algorithm recommended by the Federation of Obstetrics and Gynecological Societies of India (FOGSI) for PTL management.[4]

In this study, the effectiveness and safety of isoxsuprine in acute management and as maintenance therapy for PTL were assessed prospectively in an Indian multicenter setting.

2. Materials and Methods

This prospective, open-label, single-arm, observational study was conducted from February 2020 to May 2023 across 4 centres in India (1 each in Aurangabad, Mumbai, Nellore and Varanasi).

Enrolled women were administered an intravenous infusion of isoxsuprine hydrochloride (Duvadilan™, Abbott India Ltd.) at the onset of PTL. The infusion constituted of four 2-mL ampoules of isoxsuprine hydrochloride injection (each mL containing isoxsuprine hydrochloride 5 mg) diluted in 500 mL of 5% w/v dextrose/Ringer lactate. The drip rate was set at 8 drops per minute (0.04 mg/min) and was increased by 8 drops per minute every 15 minutes until uterine quiescence was achieved. The maximum dose given was up to 40 drops per minute. In cases where uterine quiescence was not achieved, rescue medications were prescribed. Blood pressure was monitored frequently to ensure that no clinically significant hypotension developed. The infusion continued for 12 hours after the arrest of PTL. This was followed by oral administration of isoxsuprine hydrochloride sustained-release capsules (40 mg twice daily) for 48 hours. If signs of PTL recurred, intravenous therapy as detailed above was restarted. In case of failure of tocolysis, treatment was administered as per the standard practice of the hospital.

The study was conducted in compliance with the principles of the Declaration of Helsinki, International Council for Harmonization - Good Clinical Practice (GCP) guidelines and applicable national regulations (Indian Council of Medical Research and Indian GCP guidelines). The study protocol and all study-related documents were approved by an institutional review board/independent ethics committee at each study site. All participants provided written informed consent.

2.1. Selection criteria

Women ≥18 years of age, with singleton or twin pregnancy of 24 to 37 weeks, having ≥ 1 contraction per 10 minutes, each lasting for 20 seconds with or without cervical dilatation ≤ 4 cm, for whom the physician had prescribed isoxsuprine during routine practice, were enrolled for the study.

Women with premature rupture of membranes or with cervical dilatation > 4 cm and /or ≥ 4 contractions per 10 minutes were excluded. Additional exclusion criteria were: history of hypersensitivity to tocolysis, high-risk pregnancy (history of recent cerebral hemorrhage, antepartum hemorrhage, intrauterine fetal death, lethal fetal anomalies, chorioamnionitis, hydramnios, cervical trauma including surgery like previous cone knife or laser, large loop excision of the transformation zone, radical diathermy), short cervix (< 25 mm), systolic blood pressure < 100 mmHg and /or pulse rate > 100 beats per minute, heart disease, pre-existing hypotension, and diabetes mellitus.

2.2. Assessments of effectiveness

The study involved a total of 3 scheduled assessments (after 12 hours, 24 hours, and 48 hours of initiation of treatment) and a telephonic follow-up.

The following assessments were carried out at baseline and at 24 and 48 hours post- treatment: transvaginal CL measurement; amniotic fluid index measurement; clinical examination at the time of enrolment (recording of pulse, blood pressure, respiratory rate, and temperature) and every 4 hours until 48 hours (as per available records); the number of uterine contractions, measurement of cervical dilation, and cervical effacement; checking for signs and symptoms such as pelvic pressure, lower abdominal cramping, lower back pain, vaginal loss (mucus, blood, fluid), genital tract infections, urinary tract infections; and recording results of hemogram, bleeding time, clotting time, ABO Rh grouping, urine examination, vaginal swab, and urine for culture and sensitivity. Telephonic follow-up was done with all enrolled women near their expected date of delivery in order to collect the perinatal outcome data.

In addition, changes in treatment for PTL, if any, and pregnancy outcome, if any, were recorded at 24 hours and 48 hours follow-up.

2.3. Safety

Adverse drug reactions (ADRs) were recorded from the initiation of the study. ADRs were collected, recorded and presented by system organ class and preferred term, corresponding severity per Common Terminology Criteria for Adverse Events (CTCAE) version 5.0, and relationship to isoxsuprine.

2.4. Study endpoints

The primary endpoints of the study included the number and percentage of women achieving successful tocolysis (total suppression of labor, i.e., no contractions) at 24 hours and 48 hours after the start of therapy with isoxsuprine.

Secondary endpoints included: 1) the number and percentage of women with failure of tocolysis (defined as no reduction in contractions) requiring a shift of tocolytic agent; 2) the number and percentage of women having a reduction in the number of contractions at 12 hours after start of therapy with isoxsuprine; 3) number and percentage of women with ADRs and 4) number and percentage of women with ADRs leading to treatment discontinuation.

Exploratory endpoints included the number and percentage of women who delivered normal babies (no congenital abnormalities) after usage of isoxsuprine and the birth weight of these babies.

2.5. Statistical analysis

The sample size calculation was based on the results obtained from a systematic review[11] which indicated a beneficial effect of isoxsuprine treatment in 89% of women at risk of premature delivery. To achieve an expected event rate of 89% with a precision of 5%, 151 women having PTL were required to be included. Factoring in an anticipated dropout and withdrawal rate of 11.6%, a total of 171 women were planned to be enrolled. All participants who were enrolled were included in all analyses.

Continuous variables were summarized using descriptive statistics and categorical data were summarized as numbers and percentages and corresponding 95% confidence interval (CI) of the percentage values by using the Clopper Pearson method.[14] The efficacy analysis was carried out as two-sided at a 5% level of significance. Missing data was not imputed. Data was analyzed using SAS system version 9.4.

3. Results

A total of 170 women experiencing PTL were screened and enrolled in the study, of whom 146 (85.9%) completed the study. Of the 24 women who did not complete the study, 17 (10.0%) were lost to follow-up, 2 (1.2%) had ADRs, and 5 (2.9%) were withdrawn from the study due to lack of efficacy (**Figure 1**). The mean (standard deviation [SD]) age of study participants was 24.7 (4.57) years, and the mean body mass index was 25.1 (3.28) kg/m^2. The mean (SD) gravidity was 2.1 (1.19), and the median (min: max) parity was 1.0 (0.0:3.0). Of the 170 enrolled women, 7 (4.1%) had a history of preterm birth, 28 (16.5%) had a history of abortion (**Table 1**). None of the participants had a significant medical or surgical history. Concomitant medications taken by ≥ 5% of women during the study were corticosteroids for systemic use (10.0% [n=17]), anti-anaemic preparations (9.4% [n=16]), mineral supplements (9.4% [n=16]), and drugs for acid-related disorders (8.8% [n=15]).

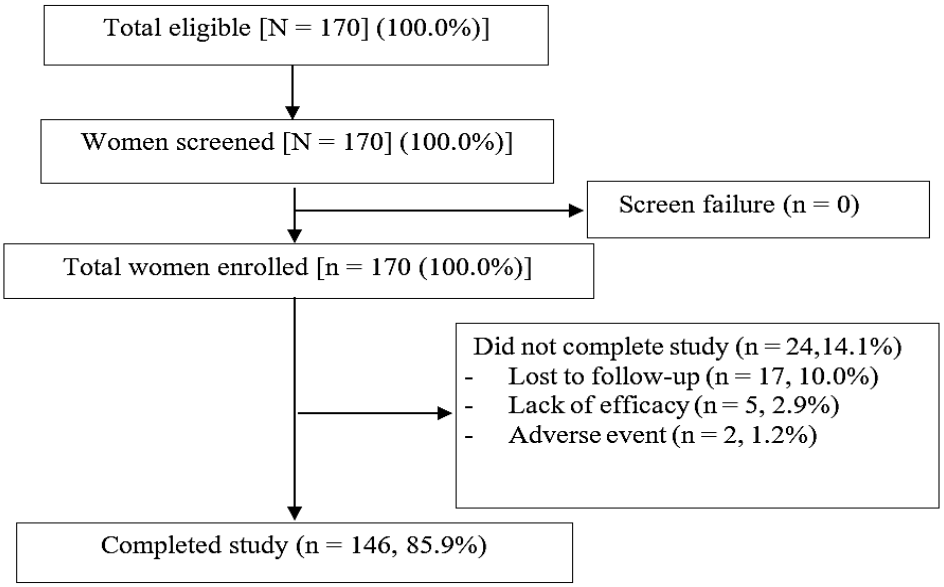

Figure 1: Study disposition

Table 1: Summary of baseline demographics and clinical characteristics

Parameter /Response, n (%)	All Enrolled (N=170)
Age (years)	
- Mean (SD)	24.7 (4.57)
- Median (Min: Max)	24.0 (18.0:38.0)
BMI (kg/m^2)	
- Mean (SD)	25.1 (3.28)
- Median (Min: Max)	24.9 (18.2:39.1)
Occupation of head of family, n (%)	
- Unemployed	4 (2.4)
- Elementary occupation	27 (15.9)
- Plant and machine operators and assemblers	11 (6.5)
- Craft and related trade workers	34 (20.0)
- Skilled agricultural and fishery workers	27 (15.9)
- Skilled workers and shop and market sales workers	41 (24.1)
- Clerks	11 (6.5)
- Technicians and associate professionals	6 (3.5)
- Professionals	9 (5.3)
- Legislators, senior officials, and managers	0 (0.0)
Education of head of family, n (%)	
- Illiterate	1 (0.6)
- Primary school certificate	17 (10.0)
- Middle school certificate	53 (31.2)
- High school certificate	50 (29.4)
- Intermediate or post-high school diploma	19 (11.2)
- Graduate	24 (14.1)
- Profession or honor	6 (3.5)
Monthly family income (Rs.), n (%)	
- ≤3,907	3 (1.8)
- 3,908–11,707	27 (15.9)
- 11,708–19,515	48 (28.2)
- 19,516–29,199	70 (41.2)
- 29,200–39,032	19 (11.2)
- 39,033–78,062	3 (1.8)
- ≥78,063	0 (0.0)
Gravidity	
- Mean (SD)	2.1 (1.19)
- Median (Min: Max)	2.0 (1.0:8.0)
Parity	
- Mean (SD)	0.8 (0.87)
- Median (Min: Max)	1.0 (0.0:3.0)
Preterm births	
- Yes	7 (4.1%)
- No	163 (95.9%)
Abortion	
- Yes	28 (16.5%)
- No	142 (83.5%)
Newborn birthweight (Kg)	
- Mean (SD)	2.0 (0.53)
- Median (Min: Max)	1.9 (1.5:2.8)

3.1. Effectiveness of isoxsuprine

1. Primary endpoint: Successful tocolysis after receiving isoxsuprine therapy was achieved in 166 women (97.6%, 95% CI [94.09:99.36]) at 24 hours and in 165 women (97.1%, 95% CI [93.27:99.04]) at 48 hours after the start of therapy.
2. Secondary endpoint(s): Tocolysis achieved at 24 hours was maintained for up to 48 hours in all but one of the women. More than half of the enrolled women (n=99, [58.2%, 95% CI: 50.44:65.74]) showed a reduction in uterine contraction at 12 hours after initiation of isoxsuprine.

Tocolysis failure was seen in 4 (2.4%, 95% CI [0.64:5.91]) patients at 24 hours and 5 (2.9%, 95% CI [0.96:6.73]) patients at 48 hours after start of therapy with isoxsuprine hydrochloride.

Exploratory endpoint: Telephonic follow-up was completed for 146 (85.9%) women and all of them delivered normal babies without any congenital abnormalities. The mean (SD) birth weight of these babies was 2.7 (0.43) kg.

3.2. Safety of isoxsuprine

Overall, 10 ADRs were reported in 10 (5.9%) patients (**Table 2**). Of the 10 ADRs, 9 were of grade 3 and 1 was of grade 1. The causal relationship was considered by the investigator as unlikely to be related to study treatment for 5 (2.9%) ADRs (fetal distress=2, stillbirth=2, drug ineffective=1, **Table 3**), as conditional/unclassified for 3 (1.8%) ADRs (drug ineffective, n=3) and as possibly related to study treatment for 2 (1.2%) ADRs (drug ineffective n=1, scar pain n=1). No action was taken with the study medication in response to any of the ADRs.

Seven (4.1%) ADRs/OPRIs led to study discontinuation.

Four (2.4%) serious ADRs were reported - 2 [1.2%] fetal distress syndrome and 2 [1.2%] stillbirths). The fetal distress syndrome resolved without any action and without any concomitant medication, while the stillbirths were fatal pregnancy outcomes. All serious ADRs were considered by the investigator as unlikely to be related to the study treatment. No action was taken for any of the serious ADRs. No deaths were reported.

During the study period, no clinically significant abnormalities like tachycardia or hypotension were reported during vital sign monitoring every 4 hours from baseline to 48 hours. Moreover, no clinically significant abnormality in any of the organ systems as well as in any hematological parameters was reported.

Table 2: Summary of ADRs by Severity- all enrolled (N = 170)

Preferred Term	Severity	Number of Events	Number of Women	% of Women
Total		10	10	5.9%
─ Drug Ineffective	All Grade 3	5	5	2.9%
─ Fetal Distress Syndrome	All Grade 3	2	2	1.2%
─ Stillbirth	All Grade 3	2	2	1.2%
─ Scar Pain	Grade 1	1	1	0.6%

Table 3: Summary of ADRs by Preferred term (PT) by Relationship with drug - all enrolled (N= 170)

Preferred Term	Relationship With Drug	N of Events	N of Women	% of Women
Drug Ineffective		5	5	2.9
	- Possible	1	1	0.6
	- Unlikely	1	1	0.6
	- Conditional/Unclassified	3	3	1.8
Fetal Distress Syndrome		2	2	1.2
	- Unlikely	2	2	1.2
Stillbirth		2	2	1.2
	- Unlikely	2	2	1.2
Scar Pain		1	1	0.6
	- Possible	1	1	0.6

4. Discussion

Preterm birth represents the single largest cause of mortality and morbidity for newborns. Treatment with tocolytics has been associated with successful pregnancy prolongation for 48 hours, permitting the administration of antenatal corticosteroids, and reducing neonatal morbidity and mortality.[13]

Results from this prospective, observational study reaffirmed the effectiveness of isoxsuprine (intravenous followed by oral administration) as a tocolytic agent in arresting PTL. Successful tocolysis was achieved in >97% of women having PTL at 24 and 48 hours after the start of therapy with isoxsuprine. Moreover, the tocolytic effect of isoxsuprine was observed as early as 12 hours after the start of therapy in more than half of the treated women. In a prospective pilot study, women with PTL achieved a tocolysis success rate of 100% at 48 hours.[13] Similarly, our study demonstrated a success rate of >97%, showing that our results were highly consistent with prior findings. This prolongation of pregnancy observed in the current study suggests that isoxsuprine hydrochloride therapy provided the 48-hour delay required for corticosteroids to act.

During the study, 10 ADRs were reported in 10 patients, most of which belonged to the system organ class “General Disorders and Administration Site Conditions”. Lack of drug efficacy was the most common ADR reported in 5 patients. No action was taken with the study medication in response to any of the ADRs. No clinically significant abnormality in any of the body systems as well as in any vital or hematological parameter was reported. The safety findings from this study are consistent with previous studies which have shown isoxsuprine treatment (intravenous and oral) acceptable safety profile and well-tolerated tocolytic agent in Indian women experiencing PTL.[14-19]

The data from the current study revealed an acceptable effect with the use of isoxsuprine on the fetus. Follow-up of treated women indicated that their newborns were healthy with no congenital anomalies. The mean (±SD) birth weight of the babies in our study was 2.7 (± 0.43) kg, which was comparable to the birth weight of 2.7 kg and 2.8 kg reported previously by Jaju *et al*[13] and Roy *et al*[15] respectively.

The findings derived from the present study suggest a beneficial effect conferred by isoxsuprine treatment in patients at risk of preterm delivery. In addition, good tolerability was observed, in that few ADRs were reported. Together, these observations reaffirm the use of isoxsuprine as a tocolytic agent. This study adds significant value, as to our knowledge, it is the first study conducted in India to evaluate a large population of women with PTL under real-life conditions, which serves as a major strength of the research. Moreover, this study contributes significantly to the existing body of research on isoxsuprine, especially considering there remains a significant paucity of data on the role of isoxsuprine in preterm labor management.

One of the limitations of the study is that considering it is an observational study, no comparator analysis was performed. Additionally, this study could not comprehensively measure the impact of isoxsuprine on neonatal outcomes. Future studies should be planned to measure neonatal outcomes.

5. Conclusion

Isoxsuprine intravenous infusion followed by oral treatment was found to be an effective and well-tolerated tocolytic agent in women at risk of preterm delivery and resulted in acceptable maternal and perinatal outcomes.

6. Clinical Significance

This study provides prospective, real-world evidence for the effectiveness and safety of isoxsuprine treatment in women experiencing preterm labor.

7. Authorship Criteria

All authors have made substantial contributions to the conception or design of the work, to the acquisition, analysis, or interpretation of the data and to drafting the work and substantively revising it. All authors have read and approved the manuscript for submission. All authors meet the ICMJE's requirements for authorship. The paper represents their honest efforts, and all authors independently validate the accuracy of the data presented.

8. Source of Funding

This study was funded by Abbott India Ltd.

9. Conflict of Interest

The authors declare no conflicts of interest.

10. Data Availability Statement

All data generated or analyzed during this study are included in this published article.

11. Acknowledgment

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