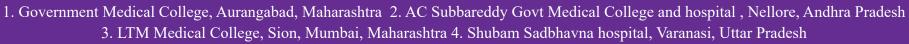


Effectiveness and Safety of Isoxsuprine Hydrochloride as Tocolytic Agent in Women with Preterm Labor in India - A Prospective, Observational Study

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Introduction & Objectives

Preterm labor (PTL) is defined as labor occurring between 20 to 37 gestation weeks. Amongst the developing countries, India has a very high incidence of PTL (23.3%). PTL management utilizes tocolytic therapy to extend gestation which allows usage of corticosteroids and MgSO4.

Although β-agonists are extensively used for tocolysis, various studies have reported undesirable safety profiles. Among β-agonists, Isoxsuprine is being used in India for last six decades and approved by CDSCO for the management of PTL. Although, Isoxsuprine is known to be effective, safe and well tolerated tocolytic agent, there is a lack of recent evidence supporting efficacy and safety of molecule. The current study re-assessed the effectiveness and safety of isoxsuprine in managment of preterm labor in an Indian Multicenter setting.

Materials & Methods

N=170 Women with diagnosis of PTL were treated at onset of PTL with an intravenous infusion of Isoxsuprine hydrochloride followed by oral isoxsuprine therapy (40 mg bd-daily) Assessment done at 12, 24 & 48 hours of initiation of therapy & telephonic follow-up for delivery outcome.

4 investigators from 4 centres across India participated in study.

- 1. Dr. Shrinivas N Gadappa (Aurangabad) 3. Dr Arun Nayak (Mumbai)

2. Dr Mary Snigdha (Nellore)

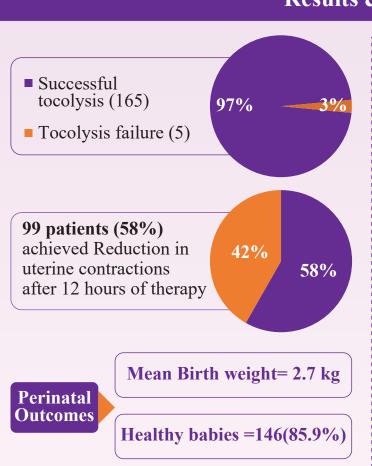
4. Dr Pragya Pandey (Varanasi)

Primary Endpoint: Percentage of women achieving Successful tocolysis at 24 and 48 hours after start of therapy

Secondary Endpoints: Percentage of women with (1) ADRs, (2) ADRs leading to discontinuation of isoxsuprine (3) Failure of tocolysis (4) Reduction in number of contractions at 12 hours

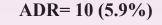
Exploratory Endpoints: (1) Percentage of women with healthy babies (2) Mean Birth Weight

Results & Discussion



Successful tocolysis rate (97.1%)

indicate that isoxsuprine provided sufficient time for corticosteroids minimizing incidence of neonatal complications.



Lack of efficacy: 5 (2.9%) Still birth: 2(1.2%) Fetal Distress: 2 (1.2%) Scar pain: 1(0.6%)

In response to AEs, no action was taken with use of Isoxsuprine therapy. No clinically significant abnormality like tachycardia or hypotension were reported

Isoxsuprine when used in management of preterm labor resulted in favorable outcomes in terms of birth weight and healthy babies (no congenital abnormalities)

Conclusion: Isoxsuprine was found to be an effective & well tolerated tocolytic agent in patients at risk of preterm delievery resulting in favorable maternal & perinatal outcomes

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Abbreviations: PTL: Preterm Labor; ADR: Adverse Drug Reaction; AE: Adverse Event