Glyceryl Trinitrate Patch in Management of Preterm Labour

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Summary

A total 100 patients of preterm labour were recruited in this prospective study undertaken to assess the efficacy of glyceryl trinitrate patch as a tocolytic. The success rate was 95%. Incidence of PROM was 4% and incidence of recurrent preterm labour was 4%. On the whole, the patch was found to be well tolerated though 12% complained of headache, 7% complained of itching at the site of patch application and 2% had dizziness though Glyceryl trinitrate, a nitric oxide donors, is an efficacious tocolytic convenient to use.

Introduction

In the era of modern obstetrics, where there has been a rapid advancement in all specialities, preterm labour remains an enigma for the obstetrician of today. The incidence of preterm delivery is 7-10% and about 70-80% of perinatal deaths occur in preterm infants.

Recent reports indicate that the nitric oxide released from L arginine is central to the inhibition of uterine activity during gestation. Taking this fact into consideration, it was thought that perinatal salvage can be dramatically improved by preventing preterm labour and glyceryl trinitrate sustained release preparation was used in the form of a transdermal patch as a tocolytic agent in management of preterm labour.

Material and Methods

In this study, 100 patients of preterm labour with gestational age between 28-37 weeks, uterine contractions of more than 3 in 10 min, cervical dilation of upto 3cm and effacement less than 50% were included.

The enrolled cases were given bed rest and hydrated with two units of Ringer lactate over a period of two-three hours, after which a 10mg glyceryl trinitrate patch was applied over the abdomen. The patch was removed every 24 hours and a fresh patch was applied till uterine contractions had completely subsided for 24 hours. If the uterine contractions did not subside by two hours, another patch was applied. Not more than two patches were applied per 24 hours for the same patient. Inj. Betamethasone 12 mg intramuscular 12 hourly was given to the patient.

The treatment was discontinued, if there was maternal tachycardia greater than 100 / minute, blood pressure less than 90/60mm Hg, fever more than 100 F or premature rupture of membranes. Side effects like headache, tachycardia, hypotension, dizziness, weakness, skin irritation were noted. The treatment was considered successful if uterine contractions subsided and tocolysis was achieved for more than 48 hours. This minimum time interval was chosen because it is considered sufficient for the steroids administered to decrease respiratory complications in the premature

neonate and for transfer to well equipped centre for further management of preterm neonates.

Observations

Table I shows that the maximum number of patients i.e. 47% belonged to the age group of 21-25 years; 33% belonged to the age group of <20 years and 20% belonged to the age group of more than 26 years. The mean age of the patients was 22.35 years.

Table I: Age Distribution

S. No.	Age	% of Patients
1.	<20	33%
2.	21-25	47%
3.	>26	20%
Total		**100%**

Figure 1 shows that the maximum number of patients enrolled had a gestational age of 31-32 weeks. The mean gestational age was 31.59 weeks. Figure 2 shows the distribution of patients according to the cervical dilatation at the time of intervention. Twenty three patients had an undilated cervix, 56 had a dilatation of 1 cm and 21 had a dilatation of 2 cm. The mean cervical dilatation was 0.98 cm.

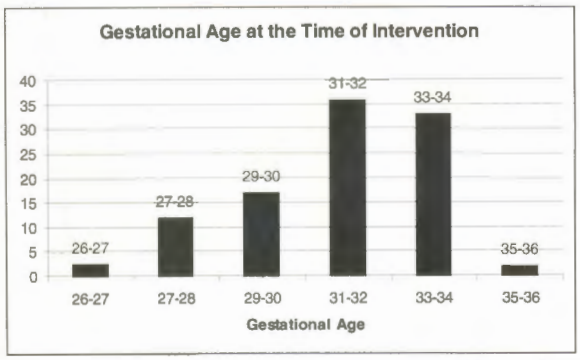

Fig 1

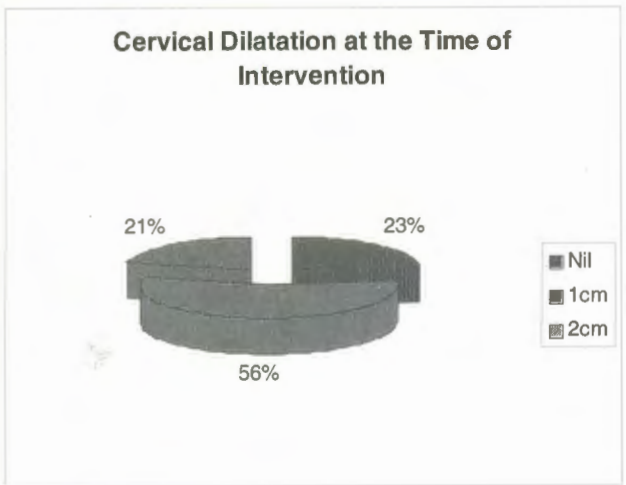

Fig 2

A delay of delivery for 48 hours was observed in 95% patients while 90% patients required only one patch and 10% required 2 patches in 24 hours.

As seen in Table II headache was observed in 12% of patients. It was treated by aspirin or paracetamol.In 2 patients, patch had to be removed due to severe headache. Skin rash and itching at the site of patch application was observed in 7% of patients. Skin irritation was the cause of patch removal in one patient. Tachycardia maternal or foetal, and hypotension were observed in none of the patients. As shown in Table III, premature rupture of membranes and recurrence of labour pains were observed in 4%.

Table – II
Maternal & Fetal Side Effects

Side Effects	No. of Patients and Percentage
Headache	12%
Maternal Tachycardia	-
Hypotension	-
Dizziness	2%
Skin Rash / Itching	7%
Fetal Tachycardia	-

Table - III
PROM and Recurrence of Labour

No. of Cases	PROM	Recurrence of Labour
100	4%	4%

The success rate was found to be 95% as shown in fig 3.

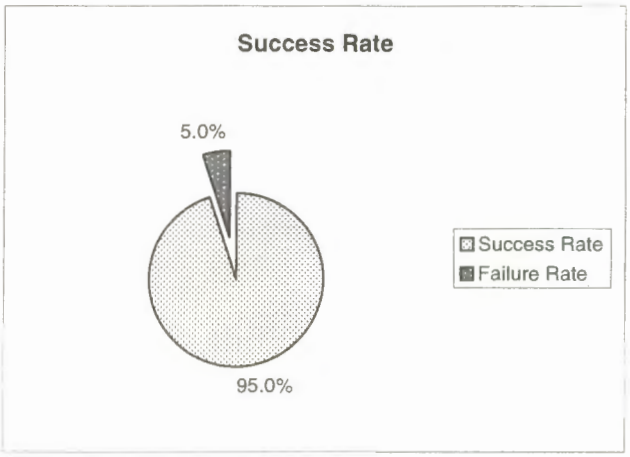

Fig 3

Discussion

In our study, the gestational age was between 26-37 weeks. In a study by Lees (1994) it was 22-33 weeks. In the cases studied by Krishna (1996) the duration of pregnancy varied from 18 to 34 weeks whereas Rowlands (1996) in his study recruited patients at a gestational age of 16-32 weeks.

In our study, the cervical dilatation was in the range of 0-3 cm, whereas in the study by Rowlands (1996) ranged between 2-8 cm. Rowlands (1996) used a 50 mg patch whereas Lees (1994), Krishna (1996) and we used a 10 mg patch.

The success rate was 100% in the study reported by Krishna et al (1996). Lees (1994) and Rowlands (1996) reported a success rate of 92.3% and 90% respectively. In our study, the success rate was found to be 95%.

Conclusion

The glyceryl trinitrate patch has the advantage that it avoids hepatic first pass metabolism, maintains constant blood levels for 24 hours, improves bioavailability, and has minimal side effects. It is an efficacious tocolytic and is a convenient therapy for administration. It is well tolerated and is safe for the mother and fetus. The monitoring with the therapy is simple and does not require use of any sophisticated equipment or highly qualified staff.

References

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2. Krishna U, Damle S, Obs Gynae Today, 1: 305, 1996.
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