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# Title: Real-world data on the efficacy and safety of oral di-hydralazine in pregnancy-induced hypertension in Indian patients.

## Introduction

The physiological changes occurring during pregnancy can significantly affect the pharmacokinetics of drugs[1]. Labetolol, hydralazine, and nifedipine are recommended as first-line agents for severe/urgent and non-severe/non-urgent pregnancy-induced hypertension (PIH) by international guidelines[2]

## Objectives

Few studies have evaluated the safety and efficacy of hydralazine in patients with PIH. We prospectively investigated the effect of oral di-hydralazine in Indian women with PIH at 2 centers in Mumbai.

## Materials and Methods

Patients newly diagnosed with PIH were prescribed hydralazine monotherapy while those with uncontrolled PIH despite ongoing therapy received di-hydralazine as add-on therapy. Nifedipine was added if the BP remained uncontrolled despite a maximum dose of hydralazine.

## Results

92 women with a mean gestational age of 31.7 weeks were included. Of these, 14 were newly diagnosed with PIH while 79 were already on treatment for PIH for a median of 10 days (5-196 days). The baseline treatment is shown in Fig 1. Most patients required oral di-hydralazine 50 or 75 mg (Fig 2). More than 70% of treatment-naïve women required a dose of 75 mg. The median duration of oral di-hydralazine treatment was 21 (3-112) days.

Fig 1. Distribution of anti-hypertensive treatment at baseline

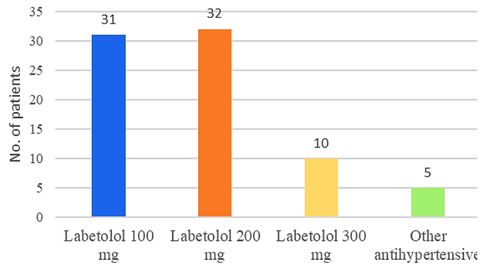


Fig 2. Dose of oral di-hydralazine required per day

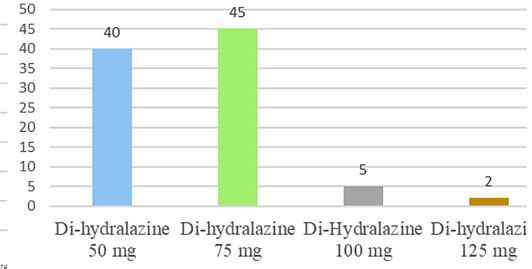


Fig 3. Change in BP after oral di-hydralazine treatment

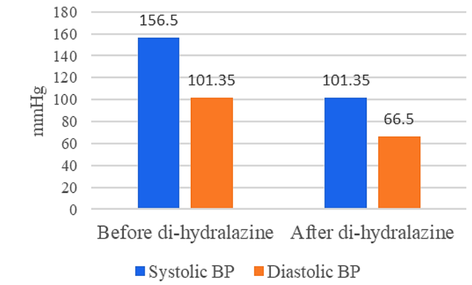


**Table 1. Obstetric outcomes**

| | |
|---|---|
| Mean gestational age at delivery | 36 weeks |
| Mean 1-min Apgar score | 7.2 |
| Mean fetal birth weight | 2.6 kg |
| Mean cord blood platelet count (n=40) | 2,51,000/µL |

## Discussion

The change in BP after initiating di-hydralazine is shown in Fig 3. The obstetric outcomes are shown in Table 1. Six patients required the addition of nifedipine and one developed pre eclampsia. There were no fetal abnormalities or deaths. One patient required Cesarean section, one had intrauterine growth retardation, and two cases had fetal thrombocytopenia.

## Conclusion

Oral di-dydralazine is safe and effective in the management of treatment-naïve PIH as well as PIH not responding to previous treatment.

## References

1. Ahizechukwu C, et al. The Journal of Clinical Pharmacology. 2023, 63(S1) S34–S50.
2. Braunthal S, et al. SAGE Open Medicine. 2019;7.

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