OBSTETRICS

Hydralazine vs nifedipine for acute hypertensive emergency in pregnancy: a randomized controlled trial

Chanderdeep Sharma, MD (OBG), DNB (OBG); Anjali Soni, MD (OBG); Amit Gupta, MD (OBG); Ashok Verma, MD (OBG); Suresh Verma, MD (OBG)

OBJECTIVE: We sought to compare the efficacy of intravenously administered hydralazine and oral nifedipine for acute blood pressure control in acute hypertensive emergency of pregnancy.

STUDY DESIGN: In this double-blind, randomized, controlled trial, pregnant women (≥24 weeks POG) with sustained increase in systolic blood pressure of ≥160 mm Hg or diastolic blood pressure of ≥110 mm Hg were randomized to receive intravenous hydralazine injection in doses of 5, 10, 10, and 10 mg and a placebo tablet or oral nifedipine (10 mg tablet up to 4 doses) and intravenous saline injection every 20 minutes until the target blood pressure of 150 mm Hg systolic and ≤100 mm Hg diastolic was achieved. Crossover treatment was administered if the initial treatment failed. The primary outcome of the study was time necessary to achieve target blood pressure. The secondary outcomes were the number of dosages required, adverse maternal and neonatal effects, and perinatal outcome.

RESULTS: From December 2014 through September 2015, we enrolled 60 patients. The median time to achieve target blood pressure was 40 minutes in both groups (intravenous hydralazine and oral nifedipine) (interquartile interval 5 and 40 minutes, respectively, *P* value .809). The median dose requirement in both groups was 2 (intravenous hydralazine and oral nifedipine) (interquartile range 1 and 2 doses, respectively, *P* value .625). Intravenous hydralazine was associated with statistically significantly higher occurrence of vomiting (9/30 vs 2/30, respectively, *P* value .042). No serious adverse maternal or perinatal side effects were witnessed in either group.

CONCLUSION: Both intravenous hydralazine and oral nifedipine are equally effective in lowering of blood pressure in acute hypertensive emergency of pregnancy.

Key words: acute hypertensive emergency of pregnancy, blood pressure, critical care, double blind, hypertension, intravenous hydralazine, maternal morbidity, maternal mortality, oral nifedipine, preeclampsia

Introduction

Hypertension is one of the most common medical disorders during pregnancy.[1] Hypertensive disorders of pregnancy constitute one of the major causes of maternal and fetal morbidity and mortality worldwide.[2] The American Congress of Obstetricians and Gynecologists (ACOG) defines systolic blood pressure (BP) ≥160 mm Hg or diastolic BP ≥110 mm Hg as one of the severe features of preeclampsia. BP readings should preferably be taken on 2 occasions with an interval of at least 4 hours between them. Nonetheless, diagnosis can be confirmed within a shorter interval (even minutes) to facilitate timely antihypertensive therapy.

Increased BP is associated with increased risk of morbidity and mortality in preeclamptic women.[2] ACOG Task Force recommends use of antihypertensive therapy to lower severe hypertension in preeclamptic women during pregnancy.[2] Cochrane meta-analysis on drugs for the treatment of very high BP during pregnancy states that until better evidence is available, the choice of antihypertensive should depend on clinician experience and women's preferences.[3] Commonly used agents for acute lowering of BP in preeclamptic women with severe hypertension in pregnancy are intravenous hydralazine, intravenous labetalol, and oral nifedipine.[3,4]

However, there is limited evidence with respect to nature of drug to be used. Cochrane meta-analysis found no significant difference regarding efficacy between various agents (hydralazine, labetalol, or nifedipine). Recently there was concern regarding use of hydralazine for acute BP control in preeclamptic women with severe hypertension.[1,4] Use of intravenous hydralazine for acute BP control in pregnant women with severe sustained hypertension has been implicated with increased risk of cesarean delivery, placental abruption, maternal overshoot hypotension, and low Apgar scores in neonates.[4-6]

Additionally, on detailed evaluation of available evidence[7-13] comparing hydralazine with nifedipine for acute BP control in women with severe hypertension during pregnancy, it is observed that the majority of these studies actually used short-acting sublingual nifedipine,[7,8,11,13] which was withdrawn because of concerns of excessive cardiovascular morbidity and mortality.[4] From 1995 through 2013 a PubMed database search for trials comparing hydralazine and nifedipine BP control in pregnant preeclamptic women with severe hypertension using key words "severe hypertension," "pregnancy," "nifedipine," and "hydralazine" revealed only 1 randomized controlled trial[10] that had compared nifedipine and intravenous hydralazine for the lowering of BP during hypertensive emergency in pregnancy.

Hence, in the present era of evidence-based medicine there is a paucity of good-quality evidence on the better option between 2 commonly used agents, ie, intravenous hydralazine and oral nifedipine, for the control of acute BP control in women with severe preeclampsia during pregnancy.

Cite this article as: Sharma C, Soni A, Gupta A, et al. Hydralazine vs nifedipine for acute hypertensive emergency in pregnancy: a randomized controlled trial. Am J Obstet Gynecol 2017;volume:x.ex-x.ex.

0002-9378/$36.00
© 2017 Elsevier Inc. All rights reserved.
http://dx.doi.org/10.1016/j.ajog.2017.08.018

UNCORRECTED PROOF

FLA 5.5.0 DTD ■ YMOB11812_proof ■ 8 September 2017 ■ 1:07 pm ■ ce

With this objective in mind, we conducted this double-blind randomized controlled trial to evaluate which of the 2 drugs—intravenous hydralazine or oral nifedipine—has better efficacy in controlling acute severe hypertension in pregnant women with preeclampsia.

Materials and Methods

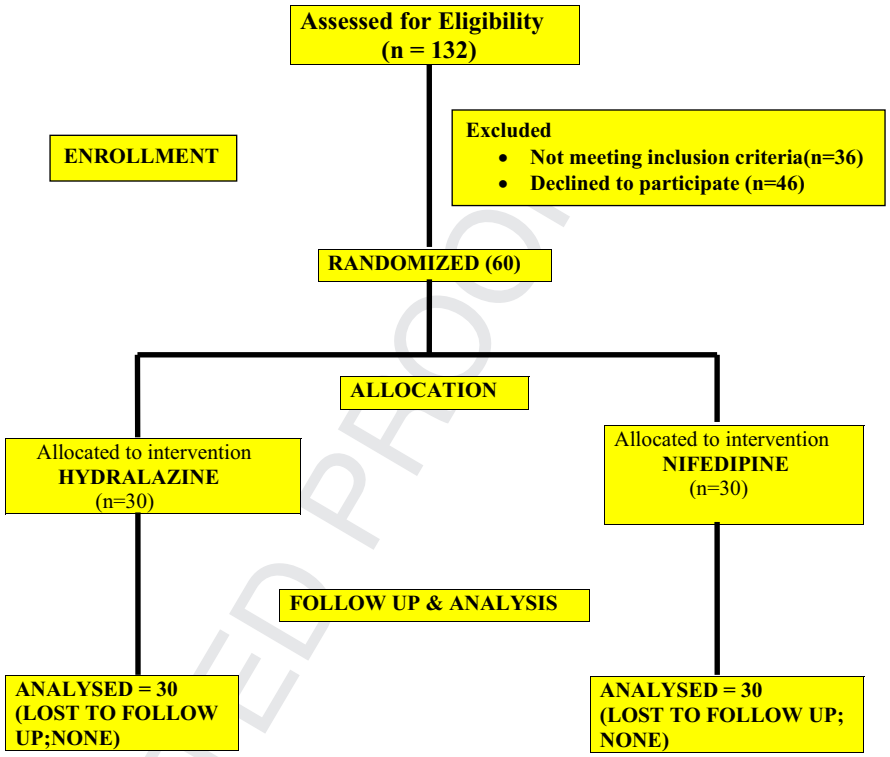
We conducted this randomized, double-blind, controlled trial for acute lowering of BP during hypertensive emergency of pregnancy. The trial was conducted in the labor ward of the Department of Obstetrics and Gynecology of Dr Rajendra Prasad Government Medical College and Hospital, Tanda, India, a tertiary care teaching and referral hospital. The recruitment took place from December 2014 through September 2015 after obtaining approval from the institutional ethics committee. The trial was also registered with the Trial Registry of India (vide no. CTRI/2014/12/005285).

All pregnant women with sustained severe hypertension (defined as systolic BP ≥160 mm Hg or diastolic BP ≥110 mm Hg on 2 separate occasions, at least 30 minutes apart) were approached for enrollment. Women were eligible for inclusion if they were between 18-45 years of age, they were at ≥24 weeks of gestation, their heart rate was between ≥60 and <120 beat/min, and they had a reassuring fetal heart rate (120-160 beat/min, with no abnormality detected on admission cardiotocography).

The exclusion criteria were a known atrial-ventricular heart block or history of heart failure, moderate to severe bronchial asthma provoked by either drug under study, exposure to any antihypertensive medication within the past 24 hours, and nonpregnancy-related hypertension (diagnosed cases of chronic or secondary hypertension). Consolidated Standards of Reporting Trials (CONSORT) guidelines were strictly followed throughout the trial.

Written informed consent was obtained from the participating women. The randomization sequence was computer-generated in blocks of 4 or 8. Study medications were placed in sequentially numbered sealed envelopes.

FIGURE 1



Consolidated Standards of Reporting Trials (CONSORT) flow chart of participants.

Sharma et al. Hypertensive emergency: hydralazine vs nifedipine. Am J Obstet Gynecol 2017.

Each envelope contained 2 packages. One was labeled as package A and the other was labeled as package B.

Package A contained either intravenous hydralazine vials (total 10 mL as hydralazine, 5 mg/mL) (Dralgeen; Bharat Serums and Vaccines Ltd) and 4 placebo tablets or intravenous saline (10 mL as 0.9%) and 4 10-mg nifedipine tablets (Zydus Cadila).

Package B contained the opposite regimen if treatment crossover was required. These envelopes were opened by an investigator, and package A was administered first to the participant. Oral nifedipine and placebo tablets were identical in appearance. Each tablet contained 10 mg nifedipine or placebo. Colorless intravenous study solution (hydralazine or saline) was placed into a 10-mL syringe by the investigator and was labeled as "A," then given to the physician (resident doctor) for intravenous administration, along with 4 tablets (nifedipine or placebo) from package A.

Intravenous study solution was administered through an intravenous line secured as soon as the women were enrolled in the trial. In case of crossover to regimen B, the contents of package B were prepared in a manner similar as described for regimen A, and the syringe was labeled "B." Thus, the physician and the participant were blinded regarding the treatment administered. The women rested in bed in the semirecumbent position. The physicians were instructed to administer 1 tablet to be swallowed from package A and to administer 1 mL intravenously from syringe A over 1 minute as the initial treatment (ie, 5 mg of intravenous hydralazine or 1 mL saline). After 20 minutes, if the systolic BP was >150 mm Hg or if the diastolic BP was >100 mm Hg, the second tablet was administered and 2 mL intravenous solution from syringe A was administered over 1 minute (ie, 10 mg of intravenous hydralazine or 2 mL of saline). If the target BP was not achieved even after

print & web 4C/FPO

UNCORRECTED PROOF

Download English Version:

https://daneshyari.com/en/article/8752941

Download Persian Version:

https://daneshyari.com/article/8752941

Daneshyari.com