

Ethnic Differences in Antihypertensive Medication Response among Pregnant and Postpartum Patients

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Protocol

Patients were randomized to first receive IV labetalol or oral nifedipine and the number of doses of each medication that was given was recorded. The protocol used for medication administration was the same as the ACOG protocol for treatment of acute hypertension in pregnancy (See medication specific protocol below). Blood pressure for all women in the study was taken in the right arm with an automated blood pressure cuff while the patient was resting in bed in the semi-recumbent position. The systolic blood pressure and diastolic blood pressure was recorded before and after administration of each medication. A short survey to assess patient-reported side effects were provided prior to and post medication administration.

IV Labetalol protocol

Labetalol 20mg IV was given over 2 minutes and the systolic and diastolic blood pressures were recorded 10 minutes after the medication was given. If SBP was ≥ 160 mmHg or DBP was ≥ 110 mmHg, labetalol 40mg IV was given over 2 minutes and the systolic and diastolic blood pressures were recorded 10 minutes after the medication was given. If SBP was ≥ 160 mmHg or DBP was ≥ 110 mmHg, labetalol 80mg IV was given over 2 minutes and the systolic and diastolic blood pressures were recorded 10 minutes after the medication was given. If SBP was ≥ 160 mmHg or DBP was ≥ 110 mmHg, then another medication was chosen based on institution specific protocol. (ACOG Safe Motherhood Initiative)

Oral nifedipine protocol

Nifedipine 10mg oral was given and the systolic and diastolic blood pressures were recorded 20 minutes after the medication was given. If SBP was ≥ 160 mmHg or DBP was ≥ 110 mmHg,

nifedipine 20mg oral was given and the systolic and diastolic blood pressures were recorded 20 minutes after medication was given. If SBP is ≥ 160 mmHg or DBP is ≥ 110 mmHg, nifedipine 20mg oral was given and the systolic and diastolic blood pressures were recorded 20 minutes after medication was given. If SBP was ≥ 160 mmHg or DBP was ≥ 110 mmHg, then another medication was chosen based on institution specific protocol. (ACOG Safe Motherhood Initiative)

Statistical Analysis

In the following sample size calculation, our primary aim is to detect an interaction effect between race and hypertensive treatment on time to reach goal blood pressure. We assume that the race distribution would be 20% for African Americans and 80% for Caucasians or Asians entering the clinic during the trial enrollment period. Randomization will be stratified by race at a 1:1 ratio to Nifedipine or Labetalol.

We assume the minimally clinical difference for African American patients on Labetalol is expected to take 30 minutes longer compared to patients on Nifedipine to reach their goal blood pressure. For Caucasian or Asian patients, those on Labetalol are expected to take 20 minutes longer compared to those on Nifedipine to reach their goal blood pressure. We expect residuals to be normally distributed with a mean of 0 and standard error of 8. We assume that time to goal blood pressure is normally distributed and power to detect an interaction by a linear regression is at least 85% with an alpha of 0.05.

Based on the above, we used a simulation approach to estimate that we would need a total of 146 patients to provide at least 85% power to detect an interaction effect between race and hypertensive treatment.

Power	Assumed Effect Size for African Americans	Assumed Effect Size for Caucasians or Asians	Assume Proportion of African Americans	Minimal Number of African Americans	Minimal Number of Caucasians or Asians	Total N
0.85	30 min	20 min	40%	40	58	98
0.90	30 min	20 min	40%	46	68	114