



INTRAMUSCULAR PHENYLEPHRINE DOSE COMPARISON FOR PREVENTION OF SPINAL ANESTHESIA INDUCED HYPOTENSION DURING CESAREAN SECTION: A PROSPECTIVE RANDOMIZED DOUBLE BLIND STUDY

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ABSTRACT

OBJECTIVE: To determine the more effective dose of intramuscular (IM) Phenylephrine in preventing hypotension due to spinal anesthesia (SA) administered for cesarean section.

METHODS: The study was conducted from January 1, 2020 to July 31, 2020, at Rehman Medical Institute, Peshawar, Pakistan. Sixty participants of American Society of Anesthesiologists (ASA) physical status I and 2, scheduled for elective cesarean section (CS) under SA were enrolled in this prospective double-blind study and randomized into two equal groups, P4-group and P8-group. P4-group received IM Phenylephrine 04 mg and P8-group received IM Phenylephrine 08 mg before SA. The incidence and intensity of hypotension, rescue doses of Phenylephrine and any adverse event, were recorded. Data collected was analyzed using Epi Info™ version 7.2.5.

RESULTS: Mean age of patients from P4-Group and P8-Group was 28.10 ± 4.39 years and 28.33 ± 4.95 years respectively. There were no statistically significant differences in the two groups with respect to demographic and clinical characteristics. Hypotension occurred in 33.3% (n=20/60) of participants. The incidence of hypotension in P4-group and P8-group were 46.7% (n=14/30) and 20% (n=6/30) respectively. In P8-group, risk of hypotension was 1.5 times less common compared with P4-group with 95% confidence interval of 1.02–2.19 (p=0.02). There was also no statistically significant difference between the onset of hypotension in the two groups. Those who developed hypotension had consumed a lesser amount of rescue Phenylephrine in P8-group compared with P4-group (p-value <0.01).

CONCLUSION: Phenylephrine 08 mg IM preemptively controlled SA induced hypotension in a sustained way in the fit parturients.

Clinical Trial Registration Number: NCT05348980

KEYWORDS: Phenylephrine (MeSH); Anesthesia (MeSH); Anesthesia, Spinal (MeSH); Intraoperative Complications (MeSH); Injections (MeSH); Blood Pressure (MeSH); Hypotension (MeSH); Cesarean Section (MeSH); Anesthesia, Obstetrical (MeSH); Randomized Controlled Trial (MeSH).

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INTRODUCTION

To cope with the mortality and morbidity associated with pregnancy and delivery is a significant global challenge. The global maternal mortality ratio (MMR) was 287

and 195 per 100 thousand live births in 2000 and 2015 respectively. In Pakistan, it was as high as 498 maternal deaths per hundred thousand live births in the year 2000, but it dropped to 348 in 2015.¹ The reduction in mortality and morbidity in high income countries is attributed to

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access of pregnant women to better health care facilities. According to 1990-91 and 2017-18 Pakistan Demographic and Health Survey data, the rate of CS has raised from 3.2% to 19.6%.² Cesarean section can be proceeded under cover of general anesthesia, spinal or epidural anesthesia. Spinal anesthesia (SA) is the commonly used anesthetic technique, believed to be the safest, though severe complications may occur.³⁻⁵ Hypotension and bradycardia are the most common side effects of SA.⁶⁻⁹ SA induced hypotension, a substantial clinical challenge, is caused by pharmacological sympathectomy.^{10,11} The incidence of hypotension in SA during CS is reported to be around 80%.^{4,5} Duration and severity of hypotension is responsible for maternal ill effects like nausea/vomiting initially, and later culminating to dyspnea, apnea and circulatory arrest, if poorly managed. Additionally there will be poor APGAR score or even fetal demise depending upon the severity.^{7,12} Hypotension occurs despite the recommended fluid preload, left lateral uterine displacement, left lateral table tilt and inotropic usage.^{5,13} Energetic use of strong vasopressors has been suggested to avoid or treat SA induced hypotension.¹² Phenylephrine, an α -1 adrenergic agonist is considered to be the vasopressor of choice in parturients. due to its propensity to cause less fetal acidosis.¹⁴ It can be administered by intravenous (IV) and intramuscular (IM)

routes.^{3,15,16} Its onset and duration of action are 1-3 minutes and 5-20 minutes respectively, when given intravenously; and 10-20 minutes and an hour respectively when given intramuscularly.¹¹ Intravenous infusion of Phenylephrine is studied intraoperatively to prevent hypotension but it needs continuous monitoring and is difficult to manage. IM Phenylephrine shortly before administering SA, though less studied, has shown promising results to prevent hypotension and provide longer hemodynamic stability and is easy to administer but its more effective dose is yet to be ascertained.

The primary objective of the study was to determine more effective dose of IM Phenylephrine using two different doses in preventing hypotension due to SA administered for CS in fit participants. Secondary objectives were to determine the need for total rescue doses of Phenylephrine, measure drop in systolic blood pressure (SBP) in the two trial groups and observe any side effects associated with IM injection of Phenylephrine.

METHODS

This double blind randomized controlled trial was conducted from January 01, 2020 to July 31, 2020 at Rehman Medical Institute, a tertiary care hospital in the private setup in Peshawar, Pakistan. This trial was registered with [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT05348980) (clinical trial registration ID NCT05348980). Study was approved by Institutional Research Ethical Committee (REC) of Rehman Medical Institute (approval number RMI/RMI-REC/Approval/57).

The sample size was calculated by using the World Health Organization (WHO) formula. Using probability of type I error (α) = 0.05, probability of type 2 error (β) = .10, power of the study (1 - beta) = .90, 09 % drop out rate, a total of 60 participants were needed to get significant results.

All pregnant ladies of ASA physical status I and 2 with singleton and full term pregnancy admitted for elective CS were included in the study. All those patients having systemic blood pressure $\geq 140/90$ mm of Hg, ASA physical status ≥ 3 , having any contraindications for SA, parturients of fetal anomalies, having abnormal placental attachment and un-consenting, were excluded from the study.

A total of 87 participants admitted for elective CS were assessed. Among these, 27 (31%) were excluded from the study as they were either not fulfilling the inclusion criteria (n=16) or refused to participate (n=11). The remaining 60 (69%) participated in the study (Figure 1). Written informed consent was obtained from all participants. Participants were distributed through simple random computer generated technique into two groups (P4-group and P8-group) with allocation ratio of 1:1. P4-group received IM Phenylephrine 04 mg and P8-group received IM Phenylephrine 08 mg before SA.

Upon arrival at the operating room (OR) on the day of surgery, IV cannulae were checked for patency and participants were preloaded with Lactated Ringer's solution at the rate of 08-10 mL/kg body weight. Before SA, basic monitoring parameters i.e. noninvasive systemic blood pressure, electrocardiography, and pulse oximetry were measured and base line values recorded in all participants. The participants were randomized using computer-generated numbers into two groups of 30 each.

P4-group received Phenylephrine 04 mg IM whereas P8-group received Phenylephrine 08 mg IM in the lateral aspect of the thigh in the Vastus lateralis muscle 05 to 06 minutes before SA. The study drug, i.e., Phenylephrine 04 and 08 mg was prepared upto 02 ml with addition of 0.9 % saline by a pharmacist not involved in the direct care of the participants and was handed over to anesthetist in color coded sealed envelopes bearing confidential written in red. Only the pharmacist knew the identity of the participants group. The other healthcare providers or data collectors were unaware of the group of the study participants. The drug was administered by an anesthetist not involved in the collection of data.

All The participants received a standard dose of 12.5 mg of 0.5% Bupivacaine heavy administered in the subarachnoid space (L3-L4 or L2-L3) using a 25 or 27G pencil point spinal needle with introducer (Pencan® B I BRAUN). Sensory block up to thoracic dermatome 4 (T4) was achieved and confirmed with loss of cold sensations to methyl alcohol swab applied. Intraoperatively hemodynamic parameters were recorded periodically in preformed structured pro-forma at three minutes' intervals. IV Phenylephrine 100

microgram was given as needed to participants who developed systemic hypotension (≤ 20 % of baseline SBP) as rescue dose. Bradycardia (heart rate < 60 beats per minute) was treated with IV Atropine Sulphate 0.6 mg.

The primary outcome was to find the incidence of hypotension in the two groups i.e. P4-group and P8-group; whereas secondary outcomes were to find the rescue dose (or doses) of IV Phenylephrine and onset of hypotension in the two groups (taking start time 0 minute when intrathecal hyperbaric Bupivacaine was administered).

Statistical software Epi Info™ v.7.2.5.0 by CDC and IBM SPSS version 20 was used for analysis of variables like age, hypotension, SBR, mean arterial pressure. Mean, median, mode, standard deviation, relative risk, risk difference, confidence interval and frequency distributions were calculated. For nominal variables, like group, gender, Phenylephrine requirement, hypotension occurrence frequency (percentage), tables and bar chart were used. For ordinal variables, like decrease in SBP from baseline in % (0-20, 21-40, >40) frequency (percentage) and column chart were used. For interval/ratio variables, like age, weight, duration of surgery, baseline heart rate, SBR, mean arterial pressure, rescue doses used and time to use first rescue Phenylephrine; mean, median, interquartile range (IQR), standard deviation (SD) and line charts were used. The Kruskal-Wallis Test used to compare the means of two groups with a p-value < 0.05 was considered significant.

RESULTS

Mean age of patients from P4-group and P8-group was 28.10 ± 4.39 years and 28.33 ± 4.95 years respectively. Mean weight of patients from P4-group and P8-group was 78.50 ± 12.89 kg and 77.86 ± 12.07 kg respectively ($p=0.72$). There were no statistically significant differences in the two groups with respect to demographic characteristics like age, gender and weight, indications for CS, base line SBP, mean arterial blood pressure (MAP), heart rate and duration of surgery (Table I).

Hypotension was recorded in 33.3% (n=20) of all participants. The incidence of hypotension in P4-group and P8-group were 46.7% (n=14/30) and 20% (n=6/30) respectively. Eleven (36.7%)

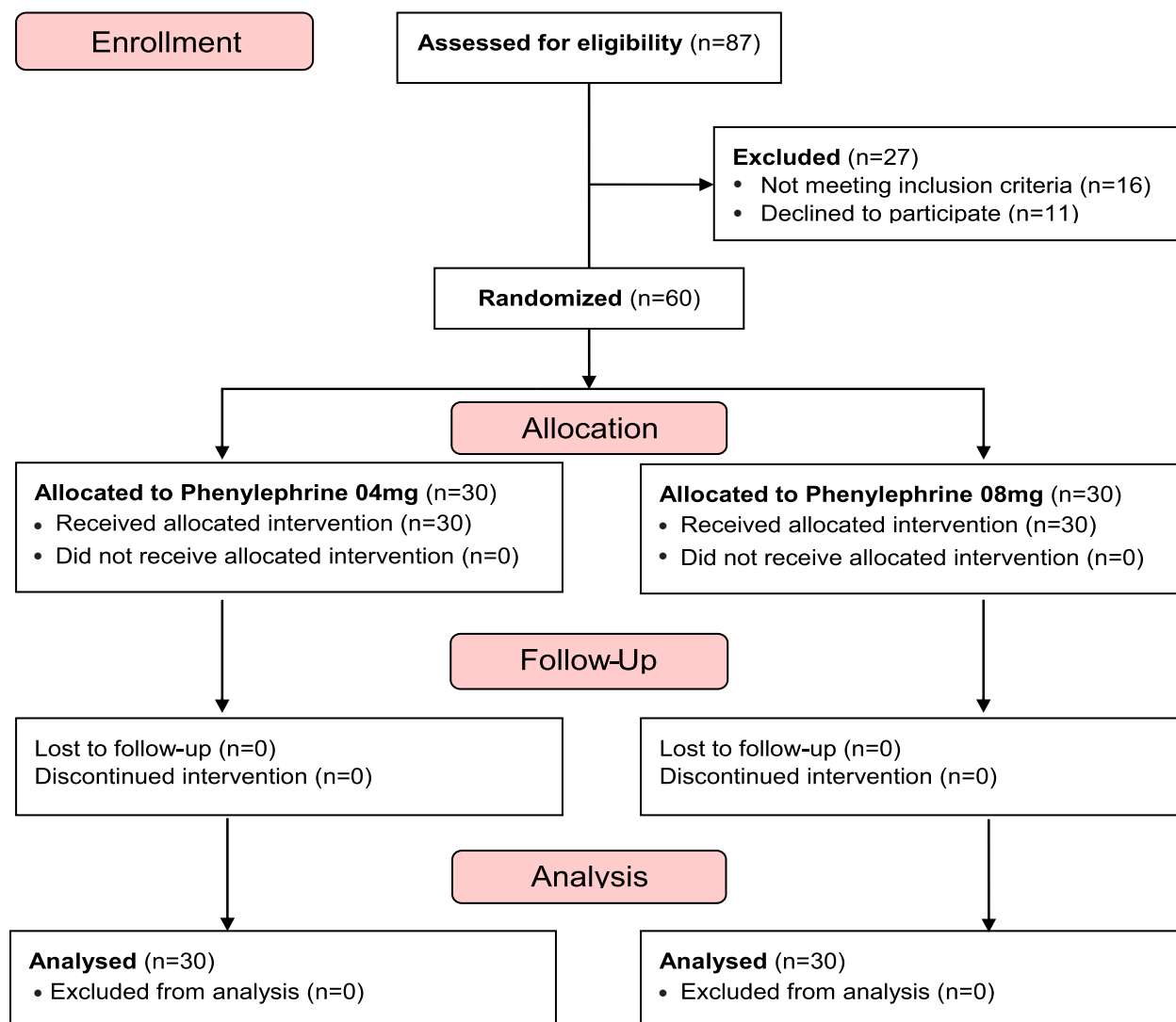


Figure 1: Methodology Flow Diagram

participants in P4-group and seven (23.3%) participants in P8-group dropped SBP from 21 to 40%, while nine (30%) participants in P4-group and five (16.7%) participants in P8-group dropped SBP more than 40 %. Sixteen (53.3%) participants in P4-group and twenty-four (80%) participants in P8-group did not develop hypotension. In P8-group, risk of hypotension was 1.5 times less common compared to P4-group with 95% confidence interval (CI) of 1.02–2.19 and p-value of 0.02 (Fisher exact 1-tailed) while in P4-group, the risk of developing hypotension was 2.33 times higher than in P8-group with 95% CI of 1.03–5.25 and p-value of 0.02 (Fisher exact 1-tailed) with a risk difference of 26.67 (95% CI: 3.78 -

49.54). There was no statistically significant difference between the onset of hypotension in the two groups ($p=0.96$). Those who developed hypotension had consumed a lesser amount of Phenylephrine in P8-group compared with P4-group (47 mcg vs 143 mcg) with a significant p-value ($p<0.01$). No untoward side effects were noted associated with IM or rescue Phenylephrine in either group.

Onset of hypotension has a negative relationship with age and weight while it has a positive correlation with baseline heart rate and SBP. Similarly, total rescue doses used have no, positive and negative correlation with age, weight and baseline heart rate and SBP respectively.

Hypotension occurred earlier in those whose baseline SBP was lower. Comparison of drop in systolic pressure from baseline in P4-group and P8-group is shown in figure 2. More rescue doses of Phenylephrine were used in participants having lower normal baseline SBP. Baseline SBP had strong positive and negative correlation with onset of hypotension and total rescue doses of Phenylephrine respectively. Comparison of number of rescue doses of Phenylephrine used in hypotensive patients in P4-group and P8-group is reflected in figure 3.

DISCUSSION

This study showed that combined incidence of hypotension in the two

TABLE I: DEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF P4-GROUP AND P8-GROUP

| Factors No. | P4-Group (n=30) | P8-Group (n=30) | P-value (Kruskal-Wallis Test) |
|-------------------------------------------------------------------------------|-----------------|-----------------|-------------------------------|
| Age (Years) | 28.10±4.39 | 28.33±4.95 | 0.60 |
| Weight (kg) | 78.50±12.89 | 77.86±12.07 | 0.72 |
| Baseline Systolic Blood Pressure (mm Hg) | 123.43±9.31 | 123.63±10.65 | 0.96 |
| Baseline Heart Rate (per minute) | 100.86±17.05 | 98.53±13.11 | 0.56 |
| Mean Arterial Pressure (mm Hg) | 91.76±12.96 | 91.78±8.29 | 0.79 |
| Duration of surgery (minutes) | 61.56±14.61 | 60.81±14.44 | 0.85 |
| Time to use first dose of rescue Phenylephrine/Onset of hypotension (minutes) | 4.78±1.76 | 6.00±3.67 | 0.96 |
| Rescue dose of Phenylephrine used (mcg) | 143.33±183.23 | 46.66±110.58 | 0.01 |

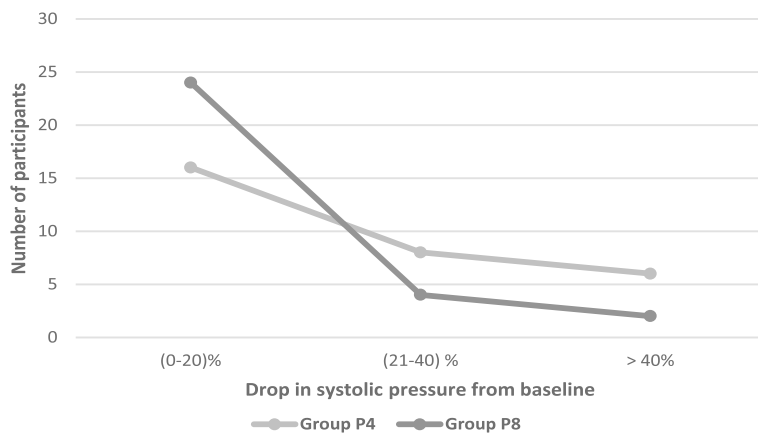


Figure 2: Comparison of drop in systolic pressure from baseline in P4-group and P8-group

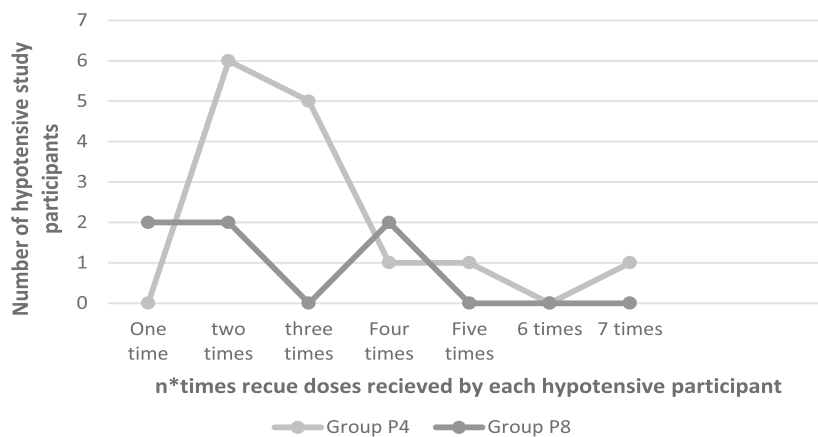


Figure 3: Comparison of number of rescue doses of Phenylephrine used in hypotensive patients in P4-group and P8-group

groups is 33.3%, which is lower than the incidence of hypotension in SA without any intervention.¹ Hypotension occurred in 46.7% of patients in P4-group in which 04 mg of Phenylephrine was administered

while P8-group showed superior results with incidence of only 20% of hypotension. Use of higher dose (08 mg) of pre-emptive Phenylephrine is preferred to avoid hypotension. The study findings

are supported by a study done in 2018 by Dalai CK, et al.¹⁷ Compared to other studies in which IM Phenylephrine was used as intervention drug, the incidence of hypotension is higher in our study. Somayaji AS and Bhat G conducted a study in which SA with IM Phenylephrine 04 mg, Ephedrine 45 mg, Mephentermine 30 mg and placebo had caused 30%, 40%, 46.6% and 73.3% hypotension respectively. But they had not discussed the inclusion and exclusion criteria and contrary to our study, they have assessed hypotension via MAP (MAP levels <60 mmHg or 25% less than the baseline).¹⁸ In another study by Ashutosh Singh et al, the fall in hypotension (measured via MAP) was 23.3%, 43.3% and 70% in IM Phenylephrine 4mg, Ephedrine 30mg and placebo group respectively. In this study, the inclusion and exclusion criteria matched our study with comparable baseline SBP, MAP, but there is a difference in baseline heart rate (99.7 vs 92.5) and weight (78.1 kg vs graph showing just above 50 kg) in Phenylephrine group.¹⁹ Assuming no major difference in height, the BMI in our group is higher and so the dose calculated as per BMI is lesser in our study. Participants with high BMI need higher dosage of Phenylephrine to prevent hypotension.²⁰ Another study done in China by Chao Xu, et al showed that incidence of hypotension in intramuscular Phenylephrine 05 mg was 12%. Inclusion and exclusion criteria and basic demographic characteristics like age (28.2 vs 30), weight (78.1 vs 75.1), SBP (123.5 vs 120.5) were similar with exception of heart rate (99.7 vs 77.2).¹¹ The lesser protection offered by intramuscular Phenylephrine may be attributed to the fast heart rate in our study. A known predictor for intraoperative hypotension is preoperative fast heart rate. Other factors which might be responsible for the change in incidence of hypotension are demographic and clinical characteristics, inclusion criteria, method of measuring hypotension, definition of hypotension, level of sensory block above T4, low baseline systolic BP or MAP, and variance in regional drug effect/ pharmacokinetics.²¹

In our study, hypotension occurred after 4.78±1.76 minutes and 6.00±3.67 minutes in P4-group and P8-group respectively with insignificant p-value (0.96) meaning whereas, the dose of Phenylephrine does not affect the onset of hypotension in the participants of identical weight. Similar results were obtained from

another study in which the onset of hypotension was 8.7 ± 7.6 minutes and 7.5 ± 4.8 minutes for prophylactic intramuscular Phenylephrine and placebo after spinal anesthesia. The drugs were given simultaneously with spinal anesthesia.²² However, this difference in onset of hypotension cannot be compared with our study because of the difference in timings of administration of study drugs. In our study, P8-group consumed a lesser amount of averaged rescue Phenylephrine with a significant p-value (0.01). They recovered fast from hypotension compared to P4-group and maintained their hemodynamic status stable for a longer time. This is similar to the study done by Chao Xu et al.¹¹ Our study showed that there is no correlation between age of the study groups and total doses of rescue Phenylephrine used. It also showed that baseline SBP has positive and negative correlation with onset of hypotension and total rescue doses of Phenylephrine used respectively. These effects need further investigation as our study population had an age range of 25-31 years interquartile range (IQR) and SBP of 117-131 mm of Hg IQR which can't be generalized for all age groups and hypertensive patients respectively

LIMITATIONS OF THE STUDY

Our study has the main limitation that the parturients who will receive IM Phenylephrine, to counter the hypotensive effect of SA, must receive effective SA within the stipulated period.

CONCLUSION

We conclude that Phenylephrine is a good agent for preemptive control of hypotension after SA for CS when given IM in a larger dose of 08 mg, 05 to 06 minutes before administering SA in fit parturients. Further studies are suggested to determine appropriate IM Phenylephrine dose for hemodynamically unstable, obese parturients and those destined for emergency CS

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AUTHOR'S CONTRIBUTION

Following authors have made substantial contributions to the manuscript as under:

MS & RUJ: Concept and study design, acquisition, analysis and interpretation of data, drafting the manuscript, critical review, approval of the final version to be published.

SR, FA, SJ & MS: Acquisition, analysis and interpretation of data, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

CONFLICT OF INTEREST

Authors declared no conflict of interest

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DATA SHARING STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request



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