



## Original Research Article

## Low dose spinal anaesthesia for caesarean section in parturients having pregnancy induced hypertension: Effect on haemodynamic response and vasopressor requirement: A prospective randomized double blind case control study

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## ABSTRACT

**Introduction:** Currently, the safety of spinal anaesthetic techniques is well established for caesarean section in pregnancy induced hypertension (PIH) patient. Addition of fentanyl to local anaesthetic allows achievement of adequate anaesthesia with lower dose of local anaesthetic in spinal anaesthesia, thereby reducing the occurrence of hypotension and need for vasopressor.

**Materials and Methods:** A prospective, randomized, double blind, case control study was carried out in 80 parturients having PIH undergoing caesarean section in spinal anaesthesia were randomized into 2 groups depending on intrathecal drug received by them as Group C (Conventional dose group- received hyperbaric bupivacaine 10 mg) and Group L {low dose group, hyperbaric bupivacaine (7.5 mg) with fentanyl (25 mcg)} and compared regarding sensory- motor block characteristics, incidence of hypotension (fall in MAP > 25% from baseline) vasopressor requirement Phenylephrine and Ephedrine.

**Result:** Patient in Group L had significantly less number of hypotension episodes as compared to Group C (20 vs 31, p= 0.011). Hence vasopressor requirement was also significantly less in Group L than in Group C [Phenylephrine (1600 mcg vs 2500 mcg, p=0.044), Ephedrine (66 mg vs 18 mg, p= 0.030)].

**Conclusion:** Low dose spinal anaesthesia using 7.5 mg hyperbaric bupivacaine with 25 mcg fentanyl seems to be superior alternative to conventional dose of 10 mg hyperbaric bupivacaine for caesarean section in parturients having pregnancy induced hypertension, because it was associated with better hemodynamic stability, reduced vasopressor requirement.

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### 1. Introduction

Hypertension affects about 10% pregnant women, including those with pre-existing hypertension, chronic hypertension that is first diagnosed during pregnancy and pregnancy induced hypertension (gestational hypertension, preeclampsia, eclampsia).<sup>1</sup> Pregnancy induced hypertension (PIH) complicates 5-7% of all pregnancies which increases both maternal and foetal mortality with occurrence of eclampsia in 0.04-0.05% and an estimated annual mortality rate of 50,000 parturients every year worldwide.<sup>2</sup> Pregnancy induced hypertension (PIH) has a complex etiology, there

is an abnormal trophoblastic invasion of the maternal spiral arteries with impaired uteroplacental perfusion. Functional imbalance between the endogenous vasodilator (PGI<sub>2</sub>) and vasoconstrictors (Thromboxane A<sub>2</sub>) leads to arterial vasospasm and hypoperfusion of vital organs with endogenous dysfunction.<sup>3</sup>

The choice of anaesthesia for caesarean section in parturient having PIH is debated for years. Both general anaesthesia (GA) as well as regional anaesthesia (RA) techniques have been used weighing risk and benefits of both.<sup>4</sup> GA might be risky because of compromised oedematous difficult airway, exaggerated hemodynamic response to laryngoscopy, intubation that may lead to

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cerebral haemorrhage, pulmonary oedema and raised catecholamine level further decrease uteroplacental flow.<sup>5</sup> However, GA is favoured in patients having CNS irritability, coma, seizures or in emergency.

Currently, the safety of regional anaesthesia (RA) techniques is well established in PIH patients, as they avoid complications associated with GA; improve uteroplacental circulation and neonatal outcome if chosen properly and profound hypotension is avoided.<sup>6</sup> However, it is essential to rule out underlying coagulopathy or a significant declining trend in platelet count prior to performing neuraxial block. Initially there were controversies regarding spinal anaesthesia in preeclampsia in view of risk for profound hypotension that could further compromise an already compromised foetus owing to faster establishment of block.<sup>7</sup> Infact, recent literature favours the use of spinal anaesthesia because it is easy, has faster onset, with fewer complications. It was also observed that preeclamptic women experience less hypotension following spinal anaesthesia than normotensive women.<sup>8,9</sup> This might be due to the fact that failure to vasodilate is a common factor in PIH.<sup>10</sup>

Addition of opioids as adjuvant allows achievement of adequate anaesthesia with lower dose of local anaesthetic in spinal anaesthesia, thereby further reducing the chances and severity of hypotension.<sup>11</sup> According to recent ACOG guidelines 2013,<sup>12</sup> women with preeclampsia who require anaesthesia for caesarean section with a clinical situation that permits sufficient time for establishment of anaesthesia, the administration of neuraxial anaesthesia is recommended. Many studies in normal pregnancies have shown that low dose spinal anaesthesia with opioids is associated with minimal hemodynamic changes<sup>13,14</sup> but limited data is available with PIH.<sup>15</sup>

We wanted to test the hypothesis that lowering the dose of bupivacaine in spinal anaesthesia (7.5 mg hyperbaric bupivacaine with 25 mcg Fentanyl as compared to 10 mg hyperbaric bupivacaine) for caesarean section could decrease the incidence and severity of hypotension and requirement of vasopressors in parturient having PIH. If it is proved, then low dose spinal anaesthesia can become a standardized technique for caesarean section in such patients.

## 2. Material and Methods

After taking institutional ethical committee clearance, and informed written consent from the patients for participation, present study was carried out in the Department of Anesthesia in obstetric operating theatre at Panna Dhari Hospital attached to RNT Medical College, Udaipur (Raj) during a period of one year from 1Feb 2017 to 31 January 2018.

### 2.1. Study design

A prospective, randomized, double blind case: control study.

### 2.2. Sample size

A previous study by Jain K et al<sup>15</sup> demonstrates a 50% reduction in the incidence of hypotension in low dose group. To aim for an equimagnitude reduction with a power of 80% and Type 1 error of <5%, 36 patients in each group were required. We took 40 patients in each group to compensate for dropouts.

### 2.3. Study population

PIH was defined as new onset Hypertension >140mmHg systolic or >90mmHg diastolic after 20 weeks of pregnancy with or without proteinuria and severe features like renal or liver involvement, neurological or hematological complications. The study was carried out in 80 parturients, who were confirmed to be having PIH by obstetrician, and were taken up for cesarean section (NICE category I-IV)<sup>16</sup> under spinal anesthesia for various indications like previous cesarean section, IUGR, breech, oligohydramnios, cephalopelvic disproportion, pregnancy following infertility treatment, post dated pregnancy, cord around neck, non-progress of labour were included in our study.

### 2.4. Exclusion criteria

Were patient refusal, coagulation abnormalities, associated systemic illness, contraindications for spinal anesthesia, history of seizures, coma, neurological signs or symptoms, allergy to study drug, Obesity (weight >100 Kg), short stature, spinal deformity etc. Indication of emergency cesarean section like antepartum hemorrhage, placenta previa, abruptio placentae, severe fetal distress, severely obstructed labour, umbilical cord prolapse, hand prolapsed, eclampsia that required induction with general anesthesia and patient in labor pains were also excluded.

### 2.5. Group allocation

Grouping of patients was done using sealed envelope technique as follows (Chart 1)

Group C (control group, n=40) - received 2ml 0.5% hyperbaric bupivacaine (10mg).

Group L (low dose group, n=40) - received 1.5ml 0.5% hyperbaric bupivacaine (7.5mg) with 0.5ml fentanyl (25mcg).

#### 2.5.1. Drugs used were

1. Inj. Bupivacaine - Bupivacaine hydrochloride dextrose injection USP, Each ml contains

2. Bupivacaine hydrochloride 5mg, Dextrose 80mg, Samarth life science Pvt. Ltd. India.
3. Inj. Fentanyl - Fenstud<sup>R</sup> fentanyl citrate injection IP 2ml. Each ml contains 50mcg fentanyl, Rusan health care Pvt. Ltd. India.

## 2.6. Double blindness

Drugs were prepared by one anaesthesiologist who was not further involved in the study. Another anaesthesiologist who performed subarachnoid block and recorded data, was not aware about which drug regime had been administered to the patient. Patient, surgeon, and postoperative ward nurse were also not aware of group allocation.

Primary outcome of the study was occurrence of hypotension and vasopressor requirement in two groups. Secondary outcome of study were sensory-motor block characteristics (onset, extent, duration), success rate, maternal- neonatal outcome and complications.

Fasting status, demographic data (age, weight, height, booked/unbooked), past obstetric/ gestational data (gravida, parity, history of abortions, live births), details of present pregnancy (gestational age, any significant history), history of hypertension, antihypertensive medication, presence of severe features in PIH were recorded. Methods of sensory-motor block assessment were explained to the patient prior to anaesthesia.

## 2.7. Spinal anaesthesia technique

After shifting patient to the OT table, was wedge applied under the right hip. Patient was secured with 20G peripheral I.V. cannula, preloading with 500 ml Ringer lactate was done. Standard monitoring including non-invasive blood pressure (NIBP), pulse-oximetry (SpO<sub>2</sub>) and electrocardiography (ECG) were attached and baseline vital parameters were recorded. Baseline BP was taken as average of three reading taken 2 minute apart on OT table. Hypertension in PIH is graded as, Mild (140-149/90-99), Moderate (150-159/100-109), and Severe (>160/110mmHg).<sup>1</sup> The name of drug, dose and timing of last dose of antihypertensive received by patient was recorded. If BP is more than 170/110 mmHg<sup>17</sup> or MAP  $\geq$  130 mmHg, acute treatment of hypertension with 20 mg Labetalol was given as slow intravenous injection in 5 mg aliquots over 10 min with titration.

Taking full aseptic precaution, lumbar puncture was done in left lateral position in L<sub>3</sub> -L<sub>4</sub> space via midline approach using 25 G Quincke's spinal needle and after getting free flow of CSF intrathecal drug was injected as per group allocation. Time of end of intrathecal injection was taken as zero for further data recording.

Sensory block (loss of pinprick) and motor block (using modified Bromage score<sup>18</sup> [0=no motor block, able to flex hip/knee, ankle; 1=able to move knee and

ankle, unable flex hip i.e. unable to raise extended legs(partial motor block); 2=able to flex ankle, unable to flex hip/knee(almost complete motor block); 3 =unable to move any part of the lower limb (complete motor block)] were assessed at 2 minute interval till 10 minutes after SAB and postoperatively every 30 minutes till complete block recovery. Time to reach T<sub>6</sub> (sensory onset), peak sensory level, maximum Bromage score, time to reach maximum Bromage score (motor onset), were noted. Vital parameters like systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP), heart rate (HR) and SpO<sub>2</sub> were recorded after SAB at every 2 min till 10 min and every 5 min till end of surgery. Fall in MAP of >25% from baseline value was taken as hypotension and treated using inj. Phenylephrine 50mcg, every 2 min till MAP returns to within 25% of baseline. Inj. ephedrine 6 mg was given, if MAP did not return after 3 incremental doses of inj. Phenylephrine or HR <65, along with hypotension at any time. Bradycardia, (HR<60/min) was treated with Inj Atropine 0.4mg i.v. duration of surgery, need for anaesthetic supplementation, adverse effect and complication, were recorded.

Post operatively, block characteristics and haemodynamics were noted every 30 minutes till complete block recovery occurred. Sensory block duration (Time taken to return to S<sub>1</sub>), Motor block duration (Time taken to return to Bromage score 0), Duration of analgesia (Time to first rescue analgesia), Maternal outcome and Neonatal outcome (birth weight, APGAR score at 1 and 5 minutes) and complication were noted.

### 2.7.1. Statistical analysis

Data were entered in MS EXCEL and analyzed using SPSS version 20 [International Business Management (IBM), Corporations, Newyork, USA]. Categorical data were presented as number (proportion), and compared with chi-square test. Continuous variable were presented as Mean $\pm$ SD and compared using t-test. P <0.05 was considered statistically significant.

## 3. Results

### 3.1. Baseline characteristics

Both groups were comparable regarding mean age, weight, height, gestational age, booked/unbooked, onset of PIH (early/late) & duration of PIH, indication of caesarean section, duration of surgery (Table 1). Patients were equally distributed in two groups regarding grading of hypertension (P=0.794), proteinuria (P=0.122), pedal edema, and presence of severe features (P=0.945) (Table 2).

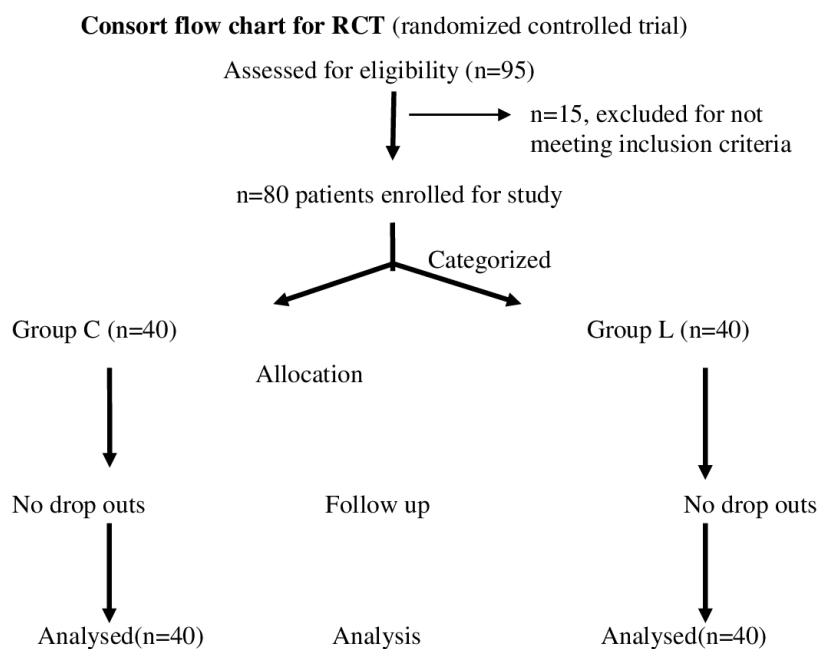


Chart 1:

**Table 1:** Comparison of age, weight and height, gestational age of patients

Variable	Group C (n=40)	Group L (n=40)	value
1 Age (Yrs.)	24.97 ± 3.46	25.37 ± 3.76	0.622
2 Weight (Kg)	67.8 ± 9.66	66.85 ± 8.86	0.648
3 Height (cm)	155.97 ± 6.6	155.4 ± 7.08	0.708
4 Gestational Age (wk)	36 ± 0.96	35.77 ± 1.16	0.349
5. Onset and duration of PIH			
Booked* n=59	Early onset (<34 wks)	8	9
	Patient distribution, n=17		
	Duration of PIH	108.75 ± 61.73 (60-240 days)	110 ± 39.37 (60-240 days)
	Late onset (>34 wks)	22	20
	Patient distribution, n=42		
	Duration of PIH	13.81 ± 10.55 (1-45 days)	11.04 ± 9.92 (1-30 days)
Unbooked# n=21	Onset and duration of PIH not known, n=21	10	11
Booked* n=59	Early onset (<34 wks)	8	9
	Patient distribution, n=17		
	Duration of PIH	108.75 ± 61.73 (60-240 days)	110 ± 39.37 (60-240 days)
	<b>Late onset (&gt;34 wks)</b>	22	20
	Patient distribution, n=42		
	Duration of PIH	13.81 ± 10.55 (1-45 days)	11.04 ± 9.92 (1-30 days)
Unbooked# n=21	Onset and duration of PIH not known, n=21	10	11

Booked-underantenatal supervision, hence onset and duration of PIH known

#Unbooked -came to institute for first time nearlabour, hence onset and duration of PIH not known

**Table 2:** Comparison of preoperative sign/symptoms of PIH with severe features

Variable	Group C (n=40)	Group L (n=40)	Value
Hypertension	Normal (<140/90)	16(40%)	0.794
	Mild (140-149/90-99)	6(15%)	
	Moderate (150-159/100-109)	7(17.5%)	
	Severe ( $\geq$ 160/110)	11(27.5%)	
Proteinuria	No	21(52.5%)	0.122
	+	14(35%)	
	++	03(7.5%)	
	+++	02 (5%)	
Pedal edema	40 (100%)	40 (100%)	
Presence of severe features			
B.P. $\geq$ 160/110	11(27.5%)	12(32.5%)	
Raised ALT ( $>2\times$ normal)	2(5%)	1(2.5%)	0.945
Platelet count $<1$ lac	1(2.5%)	1(2.5%)	
Pulmonary edema.	1(2.5%)	1(2.5%)	

### 3.2. Antihypertensive treatment

All PIH patients were on antihypertensive treatment preoperatively, most of the patients were on Tab. Labetalol 100 mg alone [n=63 (78.75%)], or with methyldopa [n=3 (3.75%)], with nifedipine [n=1 (1.25%)], or both [n=1 (1.25%)] during antenatal period. As per study protocol, 11 (27.5%) patients in Group C and 12 (30%) patients in Group L received acute treatment for preoperative hypertension on operation table, as i.v. injection Labetalol (20-30mg), because they had BP  $>170/110$  mmHg or MAP  $>130$  mmHg. It was comparable in two groups,  $p=0.574$ .

### 3.3. Sensory-motor block characteristics

Desired sensory level of T<sub>6</sub> and maximum Bromage score (MBS) of 3 (complete motor block), was achieved by all patients in both groups. There was no significant difference in sensory onset (time to T<sub>6</sub>) and motor onset (time to Bromage score 3) in two groups, ( $p>0.05$ ). None of the patient required intra-operative supplement due to inadequate block.

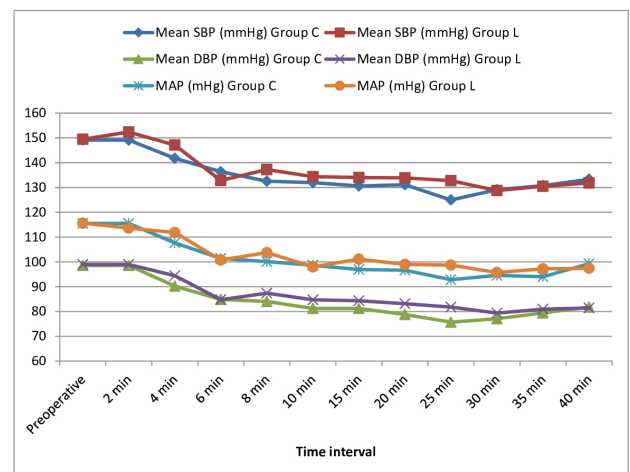
Duration of analgesia (time to first pain) and sensory block duration (time to S1 regression) were significantly longer in Group L as compared to Group C,  $P < 0.001$ ; however, duration of motor block (time to return to Bromage 0) was comparable in two groups,  $P=0.325$  (Table 3)

### 3.4. Hemodynamic characteristics

There was no significant intergroup difference for mean value of SBP, DBP, MAP and HR, at all time intervals  $p > 0.05$  (Figure 1)

As compared to baseline, maximum fall in SBP, DBP, MAP in Group C was 16.19%, 23.2%, 19.67% respectively while in group L it was 13.84%, 19.8%, 17.23% respectively. Maximum fall in Blood Pressure, was little more in Group C (conventional dose) than in Group L (low dose), but could not reach statistically significance,  $p>0.05$ ,

(Table 4).

**Fig. 1:**

### 3.5. Occurrence of hypotension and vasopressor requirement

16 (40%) patients in Group C and 14 (35%) patients in Group L had hypotension after SAB, and received vasopressors, which was comparable,  $p=0.676$ . However, patients in Group C had significantly higher number of hypotensive episodes as compared to Group L (31 Vs 20),  $p=0.011$ . Total duration of hypotension was also significantly more in Group C (190 min) than in Group L was (106 min),  $P=0.000$ .

Consumption of Phenylephrine (50 mcg per dose) in terms of number of doses and total dose in mcg was significantly more in Group C (50 doses, 2500 mcg) as compared to Group L (32 doses, 1600 mcg),  $P=0.044$ . Additional doses of ephedrine (6 mg per dose) given in Group C (11 doses, 66 mg) were significantly higher as

**Table 3:** Comparison of sensory and motor block characteristics

Variable		Group C (n=40)	Group L (n=40)	Value
1. Sensory onset (min)		4.9±1.01	4.7±0.97	0.368
2. Peak sensory level n (%)	T4	38 (95%)	37 (92.5%)	0.644
	T6	02 (5%)	03 (7.5%)	
3. Motor onset (min)		8.15±1.72	8±1.69	0.695
4. Bromage score of 3, n (%)		40	40	
5. Duration of analgesia(min)		132±15.05	157.37±11.05	<0.001
6. Duration of sensory block(min)		144.5±21.71	165.37±20.17	<0.001
7. Duration of motor block(min)		208.75±18.14	212.5±15.64	0.325

Data are presented as Mean ± SD or n (%)

**Table 4:** Comparison of maximum fall in blood pressure in two groups

Variable	Group C	Group L	p value
Systolic BP			
Baseline	149.12±18.33	149.47±17.06	0.931
Lowest value	124.97±17.12	128.77±18.32	0.934
Maximum fall from baseline (%)	16.19%	13.84%	
Diastolic BP			
Baseline	98.57±14.06	98.97±15.48	0.904
Lowest value	75.70 ±19.68	79.37±15.99	0.565
Maximum fall from baseline(%)	23.20%	19.80%	
Mean arterial Pressure			
Baseline	115.55±15.76	115.65±16.05	0.983
Lowest value	92.82±21.04	95.72±16.42	0.781
Maximum fall from baseline(%)	19.67%	17.23%	

compared to given in Group L (3 doses, 18 mg), P=0.030.

### 3.6. Complications

Incidence of bradycardia [1 (2.5%) in Group C and 3 (7.5%) in Group L, p= 0.318] and shivering [3 (7.5%) in Group C and 2 (5%) in Group L, p = 0.642] were minimal and comparable, in two groups. No other complication (nausea, vomiting, headache, itching etc.) were reported in any patient in both groups.

### 3.7. Maternal & neonatal outcome

Maternal outcome of all patients was good, no ICU admission or death was reported in the study. Mean weight of babies in two groups was comparable. Mean value of APGAR score at 1 min and 5 min was also comparable, p >0.05. All patients had good neonatal outcome. No neonatal deaths were reported. Only 7 babies of low birth weight (<2 kg) admitted in ICU for observation [3 in Group C and 4 in Group L, P=0.692], they all survived.

## 4. Discussion

Present study showed that low dose bupivacaine (7.5mg) with 25mg fentanyl in spinal anaesthesia is a safe and effective regime for caesarean section in PIH patients.

Addition of fentanyl allowed lower doses of local anaesthetics and was associated with lesser sympathetic block, therefore both hypotension and of vasopressor requirement was less in low dose group. As we know hypotension following spinal anaesthesia is dependent on local anaesthetic (LA) doses. If lesser doses of LA are used, there is reduction in incidence of hypotension, requirement of vasopressor and episodes of nausea and vomiting, but lower dose of local anaesthetic may reduce quality of block and may cause breakthrough pain. After the discovery of opioid receptors in spinal cord, it was found that local anaesthetics and opioids act synergistically when administered intrathecally. We also observed that use of fentanyl also caused prolongation in sensory block and post operative analgesia without affecting motor block duration.

Similarly, Jain K et al<sup>15</sup> in their study in PIH patients also reported that incidence of hypotension was less in low dose group (7.5mg bupivacaine + 25 mcg fentanyl) as compared to conventional dose group (10 mg bupivacaine) group (41.6% vs 91.6%, p=0.009). Duration of hypotension was significantly longer in conventional dose group compared to low dose group (p=0.005). Hypotension episodes requiring vasopressors were more frequent in conventional dose group 1.5[1-3] vs.0[0-1],(p=0.01). Requirement of Phenylephrine (mcg) per patient was also more in conventional dose group [175(100-290) mcg] as compared to low dose group [0-100mcg], p=0.006.

**Table 5:** Occurance of hypotension and vasopressor requirement in two groups

Variable	Group C (n=40)	Group L (n=40)	Value
Incidence of hypotension, n(%)	16(40%)	14(35%)	0.676
Total episodes of hypotension	31	20	0.011
Total duration of hypotension episodes	190 min	106min	0.000
Phenylephrine consumption (1 dose=50mcg)	50(2500mcg)	32(1600mcg)	0.044
Total no. of doses (total dose in mcg), Ephedrine consumption (1 dose=6mg)	11(66mg)	3(18mg)	0.030
Total no. of doses (total dose in mg),			

One important point to highlight is that incidence of hypotension in preeclamptic women is less as compared to normal parturient as reported by many authors [Aya et al,<sup>8</sup> (16.6% vs. 53.3%), Nikooseresht et al<sup>19</sup> (55.8%) vs. 89.2%] respectively. This reduced incidence of hypotension after SAB in preeclamptic patients is attributed to altered vascular response mainly due to humoral factors. In preeclampsia, vascular endothelial damage occurs, which produces increased amount of endogenous vasoconstrictors like thromboxane and endothelin that are responsible in maintaining vessel tone. Sympathetic block following SAB does not alter this vascular response, limiting the excessive fall in BP in preeclampsia compared to normal pregnant woman. ACOG 2013<sup>12</sup> guideline also recommends, preferable use of spinal anaesthesia in PIH patients, if time and coagulation profile permits.

In our study, maternal and neonatal outcome was good in all patients as observed by many others in PIH patients.<sup>15,20</sup>

There were some limitations of the study, firstly we assessed neonatal outcome only on clinical basis in terms of birth weight, APGAR score, NICU admission, and mortality. Umbilical cord blood gas analysis was not done because of unavailability of ABG machine in obstetric OT complex. Secondly We assessed hemodynamic changes by non-invasive measurement, we didn't use invasive BP just for the sake of study because it could increase the morbidity of patients, as they already have generalized edema, deranged thrombotic profile etc.

## 5. Conclusion

We conclude that spinal anaesthesia using 7.5 mg hyperbaric bupivacaine with 25mcg fentanyl results in better hemodynamic stability, reduction in vasopressor requirement, and provides better post operative analgesia as compared to 10 mg bupivacaine for caesarean section in parturients having pregnancy induced hypertension. Hence we suggest that low dose spinal anaesthesia should be used as a routine regime in caesarean section in PIH patients.

## 6. Acknowledgment

Nil

## 7. Conflict of interest

None.

## 8. Source of funding

None.

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