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To Evaluate the Predictive Value of Oxygen Saturation in Adverse Maternal Outcome in Women with Hypertensive Disorders of Pregnancy

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Abstract: ***Background: Hypertension, perhaps, is the most common medical problem during pregnancy. In pregnancies complicated by hypertension, owing to compromised cardiac outputs and intravascular volumes, the oxygen saturation is affected more adversely and thereby could be responsible for adverse events during pregnancy. Owing to a high potential of causing hypoxia[4], the role of oxygen saturation as a maker for adverse outcomes in pregnancies complicated by hypertension has generated interest among researchers in recent years[5] Objectives: The present study targets to evaluate efficacy of oxygen saturation as a predictor of adverse outcome in women with hypertensive disorders in the pregnancy at a tertiary care centre in Northern India. Study Design: A total of 86 pregnant women with preeclampsia/hypertensive disorders in pregnancy (HDP) and gestational age >28 weeks were enrolled as cases and an equal number of matched pregnant women without preeclampsia/HDP were enrolled as controls. At admission oxygen saturation was measured. Adverse events within 48 hours and throughout the continuation of pregnancy were noted. Data was analyzed using SPSS 21.0 using Chi-square and Independent samples 't'-test. Receiver-operator characteristic curves were also drawn. Results: Mean age of cases was 24.88±3.24 years. Majority of cases were gravida 1 (62.8%) and maximum (43.0%) presented at >37 weeks. There was no significant difference between cases and controls for age, gravid and gestational age. Incidence of adverse events in cases was 14% at 48 hr and 33.7% during the entire period. No adverse event was recorded in controls. Mean oxygen saturation of cases (94.57±2.60%) was significantly lower as compared to that of controls (99.19±1.10%). All the women having adverse events at 48 hour had oxygen saturation ≤95% while 25/29 (86.2%) of those having adverse events throughout the pregnancy. Oxygen saturation <93% was projected to have a sensitivity and specificity of 91.7% and 77% for adverse events at 48 hr and <94% had a sensitivity and specificity of 72.4% and 82.5% for adverse events throughout pregnancy. Conclusion: Despite a good sensitivity and specificity, we feel that the usefulness of oxygen saturation as the sole risk predictor may confound, however, hence usefulness of oxygen saturation in multivariate predictive models should be investigated further.***

Keywords: Preeclampsia, hypertension during pregnancy, adverse events, oxygen saturation

1. Introduction

Hypertension, perhaps, is the most common medical problem during pregnancy. It affects up to 10% of pregnancies and is the greatest cause of maternal and prenatal morbidity and mortality[1]. Elevated blood pressure (BP) in pregnancy may represent chronic hypertension (occurring before 20 weeks' gestation or persisting longer than 12 weeks after delivery), gestational hypertension (occurring after 20 weeks' gestation), preeclampsia, or preeclampsia superimposed on chronic hypertension[1].

Hypertension during pregnancy is responsible for a number of complications such as abnormal placentation, oxidative stress with release of vasoactive substances, increased thromboxane and/or cytokines triggered vascular and organ dysfunction[2].

A number of physiological changes take place during pregnancy. In a normal pregnancy too systemic hemodynamics is affected that result in an increase in cardiac output however in pregnancies complicated by hypertension cardiac outputs and intravascular volumes are relatively lower and systemic vascular resistance and cardiac after load is higher as compared to normal control pregnant subjects[3]. During pregnancy, there is an increase in tidal volume of approximately 40%, a decrease in the functional residual capacity by 25%, and an increase in oxygen consumption as a result of increased metabolic needs of the mother and the fetus. The combination of the decreased functional residual capacity and the increased oxygen consumption diminishes the oxygen reserve of the mother[4]. In pregnancies complicated by hypertension, owing to compromised cardiac outputs and intravascular volumes, the oxygen saturation is affected more adversely and thereby could be responsible for adverse events during pregnancy.

Owing to a high potential of causing hypoxia[4], the role of oxygen saturation as a maker for adverse outcomes in pregnancies complicated by hypertension has generated interest among researchers in recent years[5-8]. Although, preliminary results show a significant association of oxygen saturation with hypertensive pregnancy and subsequently to a probable adverse maternal and perinatal outcome yet the number of studies on this issue is quite limited and requires further strengthening of evidence.

Keeping in view the need to build more concrete evidence, the present study was carried to find out the efficacy of

oxygen saturation as a predictor of adverse outcome in women with hypertensive disorders in the pregnancy at a tertiary care centre in Northern India.

2. Method

A total of 86 pregnant women with hypertensive disorders of pregnancy and an equal number of normotensive women presenting at gestational age >28 weeks were enrolled in the study conducted at Department of Obstetrics and Gynaecology, Saraswati Medical College, Lucknow after seeking the approval from Institutional Ethics Committee and after obtaining informed consent from the patients.

The sample size estimation was based on the study of Payne *et al.*[7] who had obtained an area under curve value of 0.91 for oxygen saturation as a predictor of adverse events in hypertensive pregnancies. The sample size estimates were done at 95% confidence and 90% power after allowing for 10% data loss.

For cases, the following case definitions were used:

1) **Pre-Eclampsia** - Blood pressure ≥140/90mmhg (measured on two occasions at least four hours apart, after 20 weeks gestation) and proteinuria (of ≥1+ by dipsick ,>0.3g/l in 24 hour urine collection, or >30 mg/mmol by spot urinary: creatinine ratio) or hyperuricemia.
2) **Chronic Hypertension –** hypertension present before 20 weeks of pregnancy or diagnosed preconceptionally or that persists >12 weeks of postpartum is also considered as chronic hypertension.
3) **Gestational Hypertension-** developing after 20 weeks of gestation, during labour, or in first 24 hour postpartum without proteinuria or any other systemic features of pre-eclampsia, in a previously nor-motensive non-proteinic woman and blood pressure resolves within 6 weeks of postpartum.
4) **HELLP** syndrome severe form of pre-eclampsia characterised by hemolysis(abnormal peripheral blood smear, bilirubin ≥1.2 mg/dl), thrombocytopenia(<100,00/mm) and elevated liver enzymes (AST>70 U/L, LDH >600 U/L).
5) **Superimposed pre-eclampsia**: Diagnosed when one or more features of pre-eclampsia develop for first time during pregnancy after 20 weeks, in women of pre-existing hypertension.

Healthy normotensive women matched demographically and for gestational age were included as controls.

Women having a history of adverse event during current pregnancy, anaemic women, those with thyroid disorders, bronchial asthma and COPD were excluded from the assessment.

A detailed history regarding their demography, obstetrical and medical history along with thorough general and obstetrical examination was recorded. Anthropometric measurements were made and body mass index (BMI) was calculated. On admission routine investigation, hematological, biochemical including PIH profile assessment was carried out.

On admission, oxygen saturation was assessed by pulse oxymetry. Symptoms (headache, visual disturbance, chest pain, dypnea, abdominal pain, with vaginal bleeding, epigastric pain, nausea, and vomiting) were enquired.

The primary outcome of this study was to evaluate maternal morbidity within 48 hours of admission in one or more system, *viz.*, CNS, CVS, Respiratory, Renal, Hepatic, Hematological, Maternal mortality. Secondary outcome was complications throughout the continuation of pregnancy from the date of enrolment.

Data was analyzed using Statistical Package for Social Sciences (SPSS) 21.0. Chi-square test and Independent samples 't'-test were used to compare the data between two groups. ROC analysis was performed to deduce a cut-off point to estimate the predictive value of oxygen saturation.

3. Results

Age of women enrolled in the study ranged from 18 to 40 years. Mean age of cases and controls was 24.88±3.24 and 25.41±3.51 years respectively. Among cases, majority of cases (62.8%) and 46.5% of controls were gravida 1. There were only 10.5% Gravida 3 or above in cases as compared to 26.7% of those in controls. Mean SBP and DBP values were 153.30±15.51 and 100.03±16.29 mmHg respectively in cases as compared to 122.79±6.45 and 77.21±16.78 mmHg respectively in controls thus showing a significant difference between two groups ($p<0.001$). Among cases, only 6 (7.0%) patients had urinary protein levels Nil or Traces whereas among controls except for 3 (3.5%) women having urinary protein levels 1+ all the others had urinary protein levels Nil or traces. Statistically, this difference between two groups was significant ($p<0.001$). Abdominal pain and bleeding, headache/visual changes and chest pain, nausea/vomiting were the presenting complaints in 18.6%, 34.9% and 22.1% cases as compared to 0%, 3.5% or 0%. Statistically, this difference between two groups was significant ($p<0.001$) Proportion of those presenting in 28-32 weeks and 38-40 weeks was higher among cases (24.4% and 32.6% respectively) as compared to that of controls (22.1% and 25.6% respectively) whereas proportion of those presenting in >37 weeks of pregnancy was lower in cases (43%) as compared to that in controls (52.3%) however this difference was not significant statistically ($p=0.449$). (Table 1).

Mean oxygen saturation of cases was 94.57±2.60% whereas it was 99.19±1.10%. Statistically, the difference between two groups was significant ($p<0.001$).Within 48 hours adverse events were seen in only 12 out of 86 (14%) of cases as compared to none of the controls. Overall adverse events were seen in 29 (33.7%) of cases as compared to none of the controls. Statistically, the rate of adverse events was significantly higher in cases as compared to controls for both the comparisons (Table 2).

At 48 hours, the most common adverse event was renal insufficiency (n=7) followed by placental abrupriton (n=6), eclamptic seizure and PPH (4 cases each) and hepatic dysfunction (n=3) respectively. Overall too, most common adverse event was renal insufficiency (n=10), followed by

hepatic dysfunction, eclamptic seizure, abruption placentae and PPH (n=8 each), IUGR (n=7) and fetal death (n=2) respectively (Table 3).

On evaluating the role of oxygen saturation as a predictor of within 48-hr after enrolment adverse events among pregnant women with hypertensive disorders, the area under curve value was observed to be 0.894. Correspondingly, under high sensitivity, high specificity and balanced considerations, the cut-off values derived were ≤93.5%, ≤91.5% and ≤92.5% respectively. For high sensitivity consideration, the projected sensitivity and specificity was 100% and 60.8%. For high specificity consideration, the projected sensitivity and specificity were 41.7% and 93.2% respectively whereas under balanced consideration, the projected sensitivity and specificity values were 91.7% and 77% respectively (Fig. 1; Table 4).

On evaluating the role of oxygen saturation as a predictor of adverse events throughout the continuation of pregnancy among pregnant women with hypertensive disorders, the area under curve value was observed to be 0.799. Correspondingly, under high sensitivity, high specificity and balanced considerations, the cut-off values derived were ≤96.5%, ≤91.5% and ≤93.5% respectively. For high sensitivity consideration, the projected sensitivity and specificity was 93.1% and 28.1%. For high specificity consideration, the projected sensitivity and specificity were 27.6% and 96.6% respectively whereas under balanced consideration, the projected sensitivity and specificity values were 72.4% and 82.5% respectively (Fig. 2; Table 4).

4. Discussion

In present study, the presenting complaint profile of cases shows abdominal pain and bleeding (18.6%), headache and visual changes (34.9%) and chest pain, nausea, vomiting (22.1%). On the other hand controls in general had no complaints and were on their routine antenatal visit, only 3 (3.5%) controls complained of headache and visual changes. Hypertensive pregnancy is often characterized by features such as Headaches, tinnitus, visual disorders, brisk tendon reflexes, and vigilance disorders are related to cerebral edema; oliguria to acute renal failure; uterine contraction, vaginal bleeding to placental abruption; vomiting to HELLP syndrome; band-like epigastric pain to subcapsular hepatic hematoma; and dyspnea to cardiac failure[9]. Thus showing that the hypertensive pregnancies might be associated with a high incidence of severe complications, however, at the time of enrolment only those women having a stable clinical profile were enrolled and thus the presenting profile was of mild disorders only.

In present study, no adverse event was noted in control group within 48 hours of presentation, however, among cases, a total of 12 (14%) women experienced adverse events. Thus, the 48-hr adverse event rate was 14% in the case group. Compared to this, Millman *et al.*[5] and Yen *et al.*[10]in their study reported a 48-hour adverse event rate of 6.4%. However, one must not forget that their study was carried out in one of the most well-equipped centres in Western countries. Compared to this the adverse event rate is relatively higher in developing countries like ours. In a study conducted in India, Agarwal and Maitra[11]had reported an adverse event rate of 18.3%. In another study from India, Srivastava *et al.*[13] reported an adverse event rate of 16.8%. The 48-hr adverse event rate in present study was thus close to that reported in the studies from India. Payne *et al.*[7] who conducted their study in a multicentric trial done at South Africa and Pakistan reported the combined 48-hr adverse event rate of 14% which is exactly same as observed in present study. The variability in adverse event rate in different studies shows a possible role of environment on the adverse event rate.

Among cases, the most common adverse event was renal insufficiency (8.1%) followed by placental abruption (7.0%), eclamptic seizure and PPH (4.7%) and hepatic dysfunction (3.5%) respectively. In our study, there were some cases with multiple adverse effects. Srivastava *et al.*[13] in their study reported the spectrum of adverse outcomes that included blood and blood products transfusion (2.4%), pulmonary edema (0.8%), acute renal failure (0.8%), cerebrovascular accident (1.6%), placental abruption (1.6%), hepatic dysfunction (1.6%), low platelet count (<50,000/ml) (1.6%), intubation need (1.6%), ionotropic support (0.8%) and eclamptic seizures (1.6%). In their study, there was 1 case (0.8%) of maternal death too. In their study, Millman[5] reported non-respiratory adverse outcomes in 67/94 (71.3%) of their cases while cardiorespiratory adverse outcomes were seen in remaining 28.7% cases. However, in present study, no cardiorespiratory adverse outcome was noted within 48 hours of admission. Payne *et al.*[7] in their study, similar to our study showed multiplicity of events. Out of 119 adverse events noted in their study, most common were transfusion of any blood product (38.7%), postpartum hemorrhage (20.2%), pulmonary edema (19.3%), severe ascites (12.6%) and eclampsia (20.8%). Thus profile of adverse events in different case series varies substantially.

In present study, overall adverse event rate throughout the continuation of pregnancy was 33.7% which was nearly 2.41 times higher than the 48-hr adverse outcome rate. Compared to this overall adverse event rate in HDP women was reported to be only 13.1% in the study by Millman *et al.*[5] which was more than twice the 48 hr-adverse event rate (6.1%). However, Payne *et al.*[7] reported the overall adverse event rate as 17.3% which was only 1.24 times higher than 48-hr adverse event rate. One of the reasons for relatively lower adverse event rate in the study of Payne *et al.**7*** could be a higher gestational age at admission. Payne *et al.* ***7*** in their study reported mean gestational age of Pakistani and South African cohort as 37.2 and 34.6 weeks respectively. Contrary to this in present study, 57% patients had presented before 37 weeks, thus showing a greater gap between enrolment and final outcome.

The hypertensive group in present study was marked by lower oxygen saturation as compared to control group. The lower oxygen saturation levels in HDP cases could be attributed to a host of factors including pulmonary vasospasm and inflammation may result in decreased pulmonary vascular perfusion and a ventilation-perfusion mismatch[12]. Incidentally, none of the studies reviewed by us followed a case-control design and hence the findings of present study for the first time categorically establish a

significant difference in mean oxygen saturation values of HDP women and normotensive pregnant women. In present study, all the normotensive women had oxygen saturation levels >95%, and subsequently they did not have any side effect either at 48 hour or throughout the continuation of pregnancy. On evaluating the adverse event rate in cases too, none of the cases having oxygen saturation >95% experienced any adverse event within 48-hr of admission, thus establishing that oxygen saturation >95% could be termed to be a safe cut-off value for healthy pregnancy.

Similar to present study, Srivastava *et al.*[13] in their study also showed that within 48 hr adverse event rates among HDP women were 45.5%, 12.9% and 10.8% respectively among women having oxygen saturation levels 90-93%, 94-97% and >97% respectively. Payne *et al.*[7] too in their study showed 48-hr adverse event rate of 39.7%, 18.2%, 12.0% and 5.6% respectively for oxygen saturation levels ≤92%, 94-95%, 96-97% and ≥97% respectively, thus showing a similar trend as observed by us.

In present study, for adverse outcomes at 48-hr and any time throughout the continuation of pregnancy, ROC analysis was done to evaluate the discriminant role of oxygen saturation. Receiver operator characteristic (ROC) analysis for discriminant value of oxygen saturation as a predictor of adverse outcome showed an area under curve value of 0.894. At a cut-off value ≤93%, the projected sensitivity and specificity of oxygen saturation was 91.7% and 77% for prediction of adverse event within 48 hours. Receiver operator characteristic (ROC) analysis for discriminant value of oxygen saturation as a predictor of adverse outcome throughout the continuation of pregnancy showed an area under curve value of 0.799. At a cut-off value ≤94%, the projected sensitivity and specificity of oxygen saturation was 72.4% and 82.5% for prediction of adverse events throughout the continuation of pregnancy. Similar to present study, Srivastava *et al.*[13] found oxygen saturation in range 90-93% to be 83.33% sensitive, however, Payne *et al.*[7] in their study found it to be only 39.7% sensitive to predict adverse outcome within 48 hours. However, despite these variances, the predictive role of oxygen saturation for adverse events in pregnant women with hypertensive disorders cannot be ruled out. Although a number of studies have previously evaluated the role of oxygen saturation as a co-variant in assessment of adverse outcome[7,14,15], however, the present study was one of the first studies to evaluate the role of oxygen saturation as an independent predictor of outcome among HDP cases. The present study was unique as it compared oxygen saturation levels between normotensive as well as hypertensive pregnancies, a fact, ignored by some of the previous studies. Hence, further studies are recommended to understand the role of oxygen saturation in determining the outcome of hypertensive and other disorders of pregnancy in a larger sample size in both univariate as well as multivariate scenario.

Despite a good sensitivity and specificity, we feel that the usefulness of oxygen saturation as the sole risk predictor may confound, hence usefulness of oxygen saturation in multivariate predictive models should be investigated further.

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Table 1: Demographic and Clinical Profile of Cases and Controls

SN	Variable	Cases (n=86)	Controls (n=86)	Statistical significance
3.	Mean SBP±SD (mmHg)	153.30±15.51	122.79±6.45	't'=16.85; p<0.001
4.	Mean DBP±SD (mmHg)	100.03±16.29	77.21±16.78	't'=122.79; p<0.001
5.	Urinary protein levels			
	Nil	2 (2.3%)	68 (79.1%)	χ^2=140.76; p<0.001
	Traces	4 (4.7%)	15 (17.4%)	
	1+	28 (32.6%)	3 (3.5%)	
	2+	25 (29.1%)	0	
	3+	19 (22.1%)	0	
	4+	8 (9.3%)	0	
6.	Presenting complaints			
a)	Abdominal pain and bleeding	16 (18.6%)	0 (0%)	χ^2=17.64; <0.001
b)	Headache and visual changes	30 (34.9%)	3 (3.5%)	χ^2=23.34; <0.001
c)	Chest pain, nausea, vomiting	19 (22.1%)	0 (0%)	χ^2=21.36; <0.001
7.	Gestational Age at enrolment			
	28-32 weeks	21 (24.4%)	19 (22.1%)	χ^2=1.60; p=0.449
	33-37 Weeks	28 (32.6%)	22 (25.6%)	
	>37 Weeks	37 (43.0%)	45 (52.3%)	

Table 2: Comparison of oxygen saturation at admission and adverse events at 48 hrs after admission and throughout the continuation of pregnancy

SN	Variable	Cases (n=86)	Controls (n=86)	Statistical significance
1.	Mean O_2Saturation±SD (Range)	94.57±2.60 (90-99)	99.19±1.10 (96-100)	't'=15.179; p<0.001
2.	Adverse events at 48 hrs	12 (14.0%)	0 (0%)	χ^2=12.9; p<0.001
3.	Adverse events throughout the continuation of pregnancy	29 (33.7%)	0 (0%)	χ^2=34.9; p<0.001

Table 3: Description of adverse events at 48 hours and throughout the continuation of pregnancy*

SN	Adverse Events	No.
1.	At 48 hours	
	Eclamptic seizure	4
	Hepatic dysfunction	3
	Renal insufficiency	7
	Placental abruption	6
	PPH	4
2.	Throughout the continuation of pregnancy	
	Fetal death	2
	IUGR	7
	Eclamptic seizure	8
	Hepatic dysfunction	8
	Renal insufficiency	10
	Placental abruption	8
	PPH	8

*Some of the women had more than one adverse event

Table 4: Receiver-Operator Curve Analysis for Predictive value of Oxygen saturation for adverse events at 48 hours and throughout the continuation of pregnancy

Area under curve	Consideration	Projected cut off value (≤)	Projected sensitivity	Projected Specificity
(a) At 48 hours				
0.894	High sensitivity	93.5	100%	60.8%
	High specificity	91.5	41.7%	93.2%
	Balanced	92.5	91.7%	77.0%
(b) Throughout the continuation of pregnancy				
0.799	High sensitivity	96.5	93.1%	28.1%
	High specificity	91.5	27.6%	96.5%
	Balanced	93.5	72.4%	82.5%

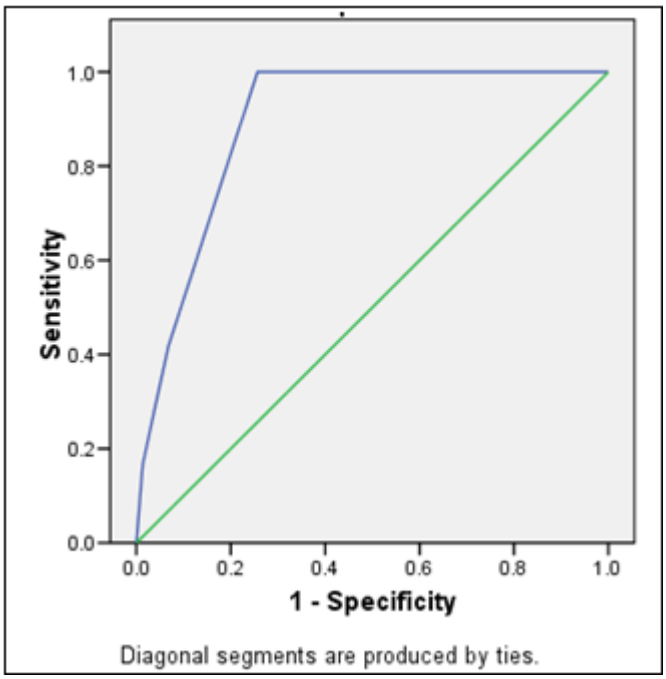

Figure 1: Receiver-operator characteristic curve showing area under curve for prediction of adverse event within 48 hours after enrolment among women with hypertensive disorders of pregnancy

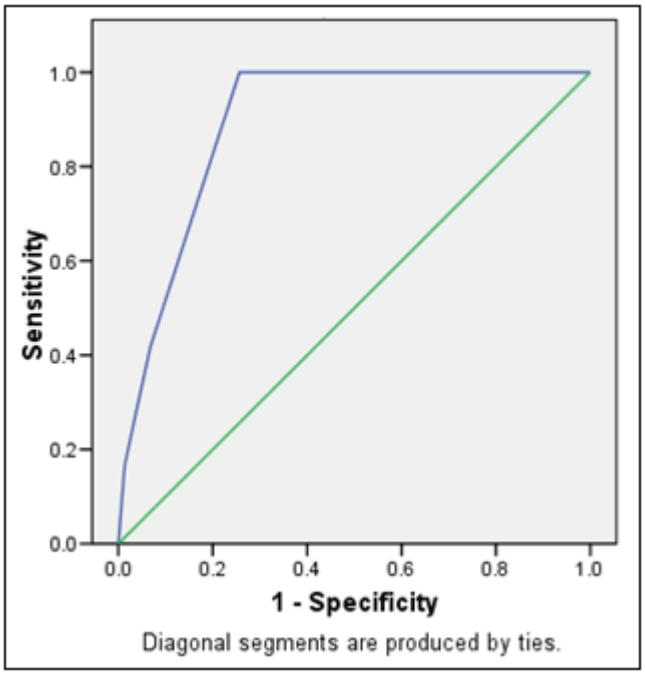

Figure 2: Receiver-operator characteristic curve showing area under curve for prediction of adverse event throughout the continuation of pregnancy among women with hypertensive disorders of pregnancy