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Prevalence and Pregnancy Outcome of Preeclampsia Using International Society for the Study of Hypertension in Pregnancy 2018 Criteria in Comparison to 2001

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ABSTRACT

Introduction: Criteria of preeclampsia (PE) have evolved over years to increase the prediction of adverse pregnancy outcomes. Revised International Society for the Study of Hypertension in Pregnancy (ISSHP) 2018 criteria incorporates organ system dysfunction with or without proteinuria. This study aims to determine changes in prevalence and pregnancy outcome of PE diagnosed by revised criteria compared to traditional ones.

Methods: This was a cross-sectional study conducted in the department of Obstetrics and Gynecology from July to October 2021. Women with hypertensive disorders in pregnancy (HDP) were classified according to ISSHP 2001 and 2018 criteria to study the prevalence and pregnancy outcomes. Data were analyzed using Statistical Package for the Social Sciences version 21.

Results: There was an increase in the prevalence of PE applying ISSHP 2018 criteria (12.6% vs 4.6%). The proportion of cases of PE in HDP increased from 19.4% to 52.7%. Preterm delivery was more in the group diagnosed using old criteria compared to revised criteria (52% vs 33.8%). Maternal morbidity like operative delivery, severe hypertension, eclampsia, abruptio, intrauterine growth restriction, were more in women diagnosed only with proteinuria. Low birth weight, Apgar less than 7 at one and five minutes, perinatal morbidity and mortality, were also more in PE diagnosed using old criteria compared to revised criteria.

Conclusion: The prevalence of PE increased without changes in the pregnancy outcome when revised ISSHP 2018 criteria were applied over the traditional 2001.

***Keywords**: Preeclampsia; Pregnancy Outcome; Proteinuria*

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INTRODUCTION

About 2 to 8 % of all pregnancies are complicated by preeclampsia (PE) worldwide.[1,2] In Nepal 1.8 to 3.3% of pregnancies are complicated by PE.[3-5] They contribute to maternal and fetal morbidity and mortality with approximately 30,000 maternal deaths and 5,00,000 perinatal deaths occurring yearly due to hypertensive disorder in pregnancy (HDP) including PE.[6,7]PE is a disease of many theories, pathogenesis with changing criteria and classification over the years.[8] Previously well-known classification system adopted by National High Blood Pressure Education Programme (NHBPEP) Working group 1990 was endorsed by many medical organizations. Subsequently, there have been many amendments and updates in the criteria and classification system over the years.[8] So, different societies used different criteria and classification systems for the diagnosis of HDP.

Diagnosis of PE was based on the presence of proteinuria which was adopted by the International Society for the Study of Hypertension in Pregnancy (ISSHP) 2001 and American College of Obstetricians and Gynaecologists (ACOG) 2002 in the past.[9] Currently as revised by ACOG (2013), ISSHP (2014) and ISSHP (2018) the diagnosis of PE can be made in the presence of organ system damage incorporating renal insufficiency, liver involvement, neurological/hematological complications, and uteroplacental dysfunction with or without proteinuria.[10-12] This update was needed as maternal and fetal complications were found in non-proteinuric hypertensive mothers, which helps in diagnosing pregnancies at increased risk of developing adverse outcomes. Studies have shown an increase in the prevalence of PE when using the new criteria.[9,13,14] The revised broad criteria is also found to have identified women who are likely to develop adverse pregnancy outcomes in some studies.[14,15]

In others, the inclusion of non-proteinuric cases has only increased the number of milder cases. [16, 17]The use of the revised criteria for the diagnosis of PE is new to us. Thus, it is essential to find out the clinical impact of using new criteria and its ability to identify women with adverse pregnancy outcomes in our country since there has been no such study. Hence, this study aims to determine the prevalence and pregnancy outcome of PE using revised ISSHP 2018 criteria compared with the traditional ISSHP 2001.

METHODS

This was a cross-sectional analytical study conducted in the department of Obstetrics and Gynaecology, Manipal Teaching Hospital. The study was conducted after ethical approval was obtained (MEMG/453/IRC). It was conducted from July 2021 to October 2021. Informed consent was taken from all the patients before collecting the data and after explaining to them the purpose and nature of the study. If the patient was unable to give consent by herself as in cases of PE with severe symptoms, informed consent was taken from the person available and nearest to the kin.

The sample size was calculated using the formula, $n = Z^2 \times p(1-p)/d^2$, where, n is the sample size, Z is the statistic corresponding to a level of confidence, P is expected prevalence, and d is precision (corresponding to effect size). The level of confidence of 95% was taken with a precision of 5%. Prevalence of 3% is taken with previous studies in Nepal reporting prevalence ranging from 1.8 to 3.3%.[3-5] Sample size was calculated to be 45. However, a total of 68 women with PE could be enrolled during the study period.

The study population was women with HDP. Among them, women with PE as diagnosed by ISSHP 2001 or/and ISSHP 2018 criteria were included in the study. The inclusion criteria according to ISSHP 2001 and 2018 were as follows.

ISSHP 2001 Criteria for PE[9]

New onset of hypertension (blood pressure ≥ 140 mmHg systolic and /or ≥90 mmHg diastolic) after 20 weeks of gestation and proteinuria (spot protein creatinine ratio 0.3 mg/mg or ≥ 300 mg/ day or at least 1+ dipstick testing)

ISSHP 2018 Revised Criteria for PE[12]

New onset of hypertension (blood pressure ≥ 140 mmHg systolic and /or ≥90 mmHg diastolic) after 20 weeks of gestation accompanied by one or more of the following new-onset conditions at or after 20 weeks of gestation:

- Proteinuria
- Maternal organ dysfunction
    a. Renal insufficiency (creatinine > 1 mg/dl)
    b. Liver involvement (elevated transaminases with or without right upper quadrant or epigastric abdominal pain)
    c. Neurological complications (includes eclampsia, altered mental status, blindness, stroke, severe headaches, persistent visual scotomas)
    d. Hematological complications (thrombocytopenia with a platelet count below 150,000/ cubic mm, DIC, hemolysis)
    e. Uteroplacental dysfunction (such as fetal growth restriction, abnormal umbilical artery Doppler wave)

Women having only proteinuria were classified as PE according to ISSHP 2001 (Group I) and those having organ dysfunction with or without proteinuria were classified as PE according to ISSHP 2018 (Group II). A cohort of the same women would belong to both groups if they had proteinuria and also features of organ dysfunction as per the diagnostic criteria.

A detailed history was taken and thorough general and obstetric examinations were done. Laboratory investigations like urine for protein (dipstick), complete blood count, renal function test including uric acid, liver function test, lactate dehydrogenase, coagulation profile, were sent. Obstetric ultrasound was done. Doppler of the umbilical artery and middle cerebral artery and non-stress was done when intrauterine growth restriction was clinically suspected. Management of the patients was done according to the hospital protocol for managing HDP. Patients were followed up during the delivery and until discharge.

For the maternal outcome of pregnancy, gestational age at delivery, preterm delivery, the severity of hypertension, mode of delivery, the occurrence of abruptio placenta, hemolysis, elevated liver enzymes, low platelet count (HELLP) syndrome, eclampsia, renal failure, pulmonary edema, postpartum hemorrhage (PPH) were studied. For the perinatal outcome, low birth weight, Apgar score, neonatal morbidities such as intraventricular hemorrhage, hypoxic-ischemic injury, respiratory distress syndrome, and necrotizing enterocolitis, need for neonatal intensive care unit (NICU) admission, and perinatal death were analyzed.

All the data were recorded in the proforma. Data were entered in the Excel chart sheet and analyzed using IBM Statistical Package for Social Sciences (SPSS) Statistics for Windows, version 21 (IBM Corp., Armonk, N.Y., USA). Discrete categorical data were presented as percentage (%), continuous data were presented as mean ± standard deviation. The student's t-test was used to compare the mean of two groups for continuous data. Proportions (outcome) were compared using the Chi-square test or Fisher's exact test depending on their applicability. A p-value less than 0.05 was considered statistically significant.

RESULTS

There were a total of 129 women with HDP during the study period. The total number of deliveries during the study period was 541 deliveries giving a prevalence of HDP as 23.8%.

Classification of the same cohort of women with HDP was done using two different criteria – revised ISSHP 2018 and old ISSHP 2001 criteria. The classification of women with HDP was done according to ISSHP 2001 and 2018 criteria are presented in Table 1.

Table 1: HDP according to ISSHP 2001 and ISSHP 2018 Criteria

Classification of HDP N = 129	ISSHP 2001	ISSHP 2018
Gestational Hypertension	96 (74.4)	52 (40.3)
Preelampsia	25 (19.4)	68 (52.7)
Chronic Hypertension with superimposed preeclampsia	7 (5.4)	7 (5.4)
Chronic hypertension	1 (0.8)	2 (1.6)

Figures in the parenthesis indicate the percentage
HDP: Hypertensive disorder in pregnancy
ISSHP: International Society for the Study of Hypertension in Pregnancy

Table 2: Organ system involvement in PE according to ISSHP 2018 and 2001 Criteria

Organ System Involved	ISSHP 2001 (n=25)	ISSHP 2018 (n=68)	p-value
Renal System	4 (16)	5 (7.4)	1.00
Hepatic System	9 (36)	32 (47.1)	0.36
Hematological System	5 (20)	12 (13.6)	0.77
Neurological System	6 (24)	16 (23.5)	1.00
Uteroplacental System	8 (32)	20 (29.4)	1.00

Figures in the parentheses indicate the percentage.
(*Involvement of more than one organ system in some cases*)
ISSHP: International Society for the Study of Hypertension in Pregnancy

The proportion of cases of PE in HDP has increased while using broader revised criteria according to ISSHP 2018; 19.4% versus 52.7%. Inclusion of the non-proteinuric cases according to ISSHP 2018 has increased in the proportion of PE and decreased in cases of gestational hypertension.

According to ISSHP 2001, there were 25 cases of PE, giving a prevalence of PE as 4.6% of all deliveries. There were 68 cases of PE according to ISSHP 2018 criteria, giving a prevalence of PE as 12.6% of all deliveries. One or more organ system involvement was noted in 13 (52%) /25 proteinuric women diagnosed as PE with proteinuria (ISSHP 2001).

According to ISSHP 2018, women were diagnosed with PE when they had organ system involvement with or without proteinuria. Hence, 25 women who were diagnosed with PE according to ISSHP 2001 also fell in this group as well. Along with these, there were 43 non-proteinuric women who had organ system involvement, so included as PE, thus total number PE was 68 according to ISSHP 2018 criteria.

Different organ system involvement in these women diagnosed as PE according to ISSHP 2001 and 2018 is presented in Table 2.

The liver was the commonest organ involved in both groups. The proportion of different organ systems involved was more when PE was diagnosed using ISSHP 2001 criteria compared to when ISSHP 2018 criteria were used except for the hepatic system. The maternal outcome of the PE diagnosed according to revised and old criteria is presented in Table 3.

Preterm delivery and those that occurred before 32 weeks of pregnancy were also more in PE diagnosed using old criteria compared to one using new criteria. Maternal morbidity like operative delivery, severe hypertension, eclampsia, abruption were more in PE diagnosed by proteinuria only compared to those diagnosed according to revised criteria, which included PE diagnosed if any organ system was involved with or without proteinuria. However, the difference was not significant statistically.

The perinatal outcome of the PE diagnosed according to ISSHP 2001 and 2018 criteria are presented in Table 4.

The mean birth weight was lower in PE diagnosed using old ISSPH criteria compared to revised 2018 criteria. Similarly, low birth weight babies were more common in women diagnosed with PE applying old criteria.

Babies with Apgar score less than 7 at one and five minutes were also more in ISSHP 2001

group compared to the 2018 group. Perinatal morbidity, NICU admission, and perinatal mortality were also more in the PE diagnosed by ISSHP 2001 compared to those diagnosed using ISSHP 2018 criteria for PE. Though the poorer perinatal outcome was noted in the group diagnosed using traditional criteria, the difference was not statistically significant.

Table 3: Maternal Outcome of PE according to ISSHP 2001 and ISSHP 2018 criteria

Maternal Outcome Parameters	ISSHP 2001 (n =25)	ISSHP 2018 (n = 68)	p-value
Gestational age at birth			
< 32 weeks	4 (16)	7 (10.3)	0.39
32-34 weeks	4 (16)	7 (10.3)	
34-37 weeks	5 (20)	9 (13.2)	
≥37 weeks	12 (48)	45 (66.2)	
Mode of delivery			
Vaginal	4 (16)	17 (24.6)	0.57
Assisted vaginal	-	1 (1.4)	
Cesarean section	21 (84)	50 (72.5)	
Total amount of blood loss (ml ± SD)	314 ± 70	288 ± 66	0.57
Maternal Morbidity			
Severe Hypertension	17 (68)	38 (55.9)	0.35
Eclampsia	3 (12)	7 (10.3)	1.00
HELLP syndrome	3 (4.4)	6 (8.8)	0.69
Abruptio placentae	4 (16)	5 (7.4)	0.24
IUGR	8 (32)	20 (29.4)	1.00
Use of $MgSO_4$	8 (32)	17 (25)	0.59
Use of antihypertensives	22 (88)	57 (83.8)	0.75

ISSHP: International Society for the study of Hypertension in Pregnancy, HELLP: Hemolysis, elevated liver enzyme, and low platelet, IUGR: Intrauterine growth retardation, $MgSO_4$: Magnesium Sulphate

Table 4: Perinatal Outcome of PE according to ISSHP 2001 and ISSHP 2018 criteria

Perinatal Outcome	ISSHP 2001 (n = 25)	ISSHP 2018 (n = 68)	p- value
Gestational age at delivery (weeks ± SD)	35.3 ± 3.5	36.5 ± 3.6	0.16
Preterm delivery	12 (48)	22 (32.4)	0.22
Mean Birth weight (gm ± SD)	2096 ± 798	2386 ± 852	0.13
Birth weight			
<1000 gm	2 (8)	4 (5.9)	0.48
1000-1500gm	4 (16)	7 (10.3)	
1500 –2500 gm	10 (40)	21 (30.9)	
>2500 gm	9 (36)	36 (52.9)	
APGAR at one minute			
<7	8 (32)	13 (19.1)	0.48
≥7	17 (68)	55 (80.9)	
APGAR at five minutes			
<7	4 (16)	6 (8.8)	0.45
≥7	21 (84)	62 (91.2)	
NICU admission	9 (36)	22 (32.4)	0.89
Neonatal morbidity	9 (36)	22 (32.4)	0.89
Perinatal Mortality			
Intrauterine fetal death	2 (8)	4 (5.9)	0.65
Early Neonatal death	4 (16)	4 (5.9)	0.20

ISSHP: International Society of the Study of Hypertension in Pregnancy, NICU: Neonatal intensive care unit

DISCUSSION

The criteria of PE have been evolving for many decades, the reason being the ability of any criteria to detect the clinical syndromes associated with it.[18] Though hypertension with proteinuria has been the commonly practised and time-tested criteria of PE, many scientific researchers have focused on other factors for diagnosis and prediction of adverse outcomes. The latest criteria recommended is one by ISSHP 2018, which has been endorsed by many societies and is currently advocated to be used in diagnosing PE. This study held the similar aim to see if pregnancy outcomes varied in women with PE diagnosed using these criteria compared to the old criteria.

Using the new criteria, the prevalence of PE increased; 4.6% according to the old criteria to 12.6% according to new criteria. The proportion of cases of PE amongst HDP also increased from 19.4% to 52.7%. There has been a shift of cases of gestational hypertension to PE due to the inclusion of non-proteinuric cases as PE. Similar findings were reported by other studies, where an increase in the prevalence of PE was noted when the revised ISSHP 2018 criteria were used for diagnosing PE.[9,13-17] Higher prevalence of the disease is expected as the new ISSHP 2018 criteria include cases with other organ system involvement apart from proteinuria. This updated ISSHP 2018 criteria has used the same criteria as that of 2014 but has made a lower threshold for inclusion of cases with organ system involvement. This has also led to an increase in the cases of PE. Non-proteinuric PE has been identified as a new phenotype of the disease with adverse pregnancy outcomes and hence this change has evolved.[9]

In this study, only 25 (36.8%) cases had proteinuria – half of these women had organ system involvement as well while the remaining half had only proteinuria. Liver was the common organ system involved followed by uteroplacental and neurological system. Criteria for liver involvement has been updated in 2018 with rise in transaminases more than 40 U/l to be included as preeclampsia and this may be the reason for liver involvement being most common organ system to be involved. Proportion of women with organ system involvement was more even when presence of proteinuria was used for diagnosis of preeclampsia.

It was found in this study that preterm delivery was more common in women diagnosed with PE using old criteria. Likewise, maternal complications like operative delivery, severe hypertension, abruptio placentae were more common in PE diagnosed traditionally than with revised criteria. The occurrence of HELLP syndrome and eclampsia were almost the same when diagnosed by old or revised criteria. There was no change in the maternal complications in PE diagnosed by revised criteria in other studies.[9,13,14] Poorer maternal outcome in PE diagnosed by old ISSHP 2001 criteria was seen in other studies similar to ours.[15, 17] Preterm delivery was also more in PE diagnosed by old criteria same as that shown in the other studies.[13, 16,17]

The perinatal outcome in terms of low birth weight, Apgar score less than 7 at one and five minutes, NICU admission, perinatal morbidity and mortality was poor in PE diagnosed by old criteria compared to new criteria. Similar findings were noted by Lai J et al. Reddy M et al.[15,17] Studies on the impact of the revised ISSHP criteria showed an increase in the prevalence of the disease but of the milder form of the disease. [13,16,17] Some other studies analyzing the sensitivity and detection rate of PE, using the broader criteria to diagnose PE have shown that the revised criteria with broader criteria for inclusion can detect more number of cases with adverse pregnancy outcome.[14,15]

The introduction of broader criteria of organ system involvement apart from proteinuria is targeted to identify more women with adverse pregnancy outcomes. However, from this study, the revised criteria did not adequately identify women with poor pregnancy outcomes. PE diagnosed with proteinuria

has been shown to identify such cases better indicating proteinuria as an important criterion for diagnosis of PE.This was a small single-centered study conducted for a short duration. A study of large scale involving multiple centers and allowing longer follow up of patients would give stronger evidence.

CONCLUSION

The prevalence of PE increased using ISSHP 2018 criteria without change in the maternal and perinatal outcome with a milder form of the disease as the additional cases. It may be recommended to use the revised ISSHP 2018 criteria for the diagnosis of PE to increase the prevalence; however, the advantage of this application remains uncertain in identifying the increased number of adverse pregnancy outcomes thus, necessitating a larger study involving multiple study sites to provide a stronger recommendation.

CONFLICT OF INTEREST

None

SOURCES OF FUNDING

None

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