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Original Research Article

Diagnostic accuracy of spot urinary protein/creatinine ratio for proteinurea in pregnancy induced hypertension

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ABSTRACT

Background: Hypertensive disorders are the most common medical complications of pregnancy with an incidence of 12-22% and are rampant globally. To assess the diagnostic accuracy of spot urinary protein-creatinine ratio keeping 24 hr urinary protein as gold standard in pregnancy induced hypertension.
Methods: Spot urinary protein-creatinine ratio was determined in a mid-stream urine sample. 24 hours, urine protein was measured. The correlation between the spot urinary protein-creatinine ratio and 24-hour urine protein amount was done. Sensitivity, specificity, positive predictive value and negative predictive value along with diagnostic accuracy was calculated from data.
Results: There was a strong correlation between the spot urinary protein-creatinine ratio and 24-hour urine protein excretion (pearson's correlation coefficient r = 0.824; P <0.0001). The optimal spot P/C ratio cut off point was 0.33, for 300 mg/24 hours of protein excretion, with sensitivity and specificity of 82.8% and 76.1% respectively. Positive and negative predictive value are 58.8% and 91.5%.
Conclusions: Spot urine P/C ratio is an accurate, reliable and steady fast, timesaving test which can be used as an alternative method for evaluation of proteinuria in pregnancy induced hypertension and it can substitute 24 hours urinary protein excretion estimation in clinical practice.

Keywords: 24-hours urine proteinuria, Cutoff point, Urine protein-creatinine ratio

INTRODUCTION

Hypertensive disorders are the most common medical complications of pregnancy with an incidence of 12-22% and are rampant globally. They are the leading and most dreaded cause of both maternal and fetal morbidity and mortality. Of the Hypertensive disorders of pregnancy, pre-eclampsia remains the leading cause of maternal and perinatal mortality and morbidity that complicates 2-8% of all pregnancies.[1] It is a multisystem endothelial disease that leads to glomeruloendotheliosis, and in severe cases it may lead to renal impairment and failure.[2] "Permeability" of the glomerular basement membrane to proteins, including albumin, is key to the diagnosis. The presence of significant proteinuria (in addition to hypertension) predisposes a pregnant woman to coagulopathy, liver disease, and stroke. Serious perinatal morbidity occurs in the form of preterm delivery (often iatrogenic) and fetal growth restriction.[3] Proteinuria is a major indicator of hypertensive disorder of pregnancy and also one of the diagnostic criteria of its severity.[4] Patients with hypertension have only <300 mg proteinuria, those with mild pre-eclampsia have 300 mg to 500 mg and those with severe pre-eclampsia have >5000 mg of urine protein in 24 hours.[5] One of the "cornerstones" of antenatal care includes a screening programme directed at the detection of pre-eclampsia with regular measurements of blood pressure and urinalysis for proteinuria (often using urinalysis dipsticks).[6] The "dipstick analysis," using visual reagent

strips, is quick, portable, and high false positive and false negative rates.[7,9] So it is almost always followed up by the "gold standard" test of 24 hour urine collection. This test is in itself not without problems. The collection is cumbersome, time consuming, inconvenient (to patients as well as hospital staff), and subject to errors such as incomplete collection leading to inaccuracies (in 13-68% of collections).[10] Delays may occur in the institution of a management plan while results are awaited, and verification of diagnosis of pre-eclampsia may not be possible if patients deliver before the urine collection is complete. The laboratory assay methods used also vary widely, and the incidence of significant proteinuria has been shown vary depending on the assay used.[11] A need therefore exists for a rapid, as well as a valid, accurate test to identify significant urinary proteinuria. This may lead to timelier decision making, which is likely to reduce patients' anxiety, shorten length of hospital stay with its associated cost savings, and "target" women with true pathology for treatment.[12] Sufficient evidence from studies shows a strong association between random protein to creatinine ratio and 24 hour protein excretion, and the International Society for the Study of Hypertension in Pregnancy has accepted this test as a method for identification of significant proteinuria3.Protein/creatinine ratio of a single voided urine specimen may have a role in the management of ambulatory women with suspected PIH, which necessitates further research in the field.[13] The main potential benefits of this method is that in institutions where women with suspended PIH are hospitaliized, women with insignificant proteinuria may be identified within a matter of hours and their follow upcare handled on an outpatient basis. The aim of this study was to evaluate the diagnostic value of spot urinary protein-creatinine ratio in single voided urine samples for quantification of proteinuria coorelate to those of a 24 hours sample in patients with hypertensive disorders of pregnancy.

Objectives of this study was to study conducted to compare random spot urine protein: creatinine ratio with 24-hour urinary protein excretion in 100 clinically diagnosed cases of pregnancy induced hypertension. To find the diagnostic accuracy of urinary protein creatinine ratio in diagnosis of pregnancy induced hypertension. To utilize urinary spot protein creatinine ratio as a bedside test, which will be less time consuming for the diagnosis of proteinuria in pregnancy induced hypertension.

METHODS

The present study was conducted in the Department of Obstetrics and Gynaecology, Government Lal Ded Hospital, Srinagar, which is a 500 bedded tertiary care Centre for Obstetrics and Gynaecology and is associated with Government Medical, College, Srinagar, Kashmir. The conducted work was a prospective study and included a total of 100 women taken among the women attending the antenatal clinic (out-patient department) and those admitted in the ward. The study group consists of women with the inclusion criteria given below.

Inclusion criteria

- Singleton pregnancy.
- Age range between 20 and 40 years.
- Gestation age >20 weeks. Gestation age calculated from the first day of last menstrual period.
- All patients diagnosed to have Bp ≥140/90 mmHg or rise of 30 mmHg systolic l5mmHg diastolic pressure on at least two occasions 6 hours apart taken in the sitting position using an appropriate sized cuff and Korotokoff phase - V (disappearance of sound as diastolic blood pressure).

Exclusion criteria

These included women with:

- History of chronic hypertension and proteinuria before conception or development of hypertension before 20 weeks of gestation
- Patients with chronic renal disease, pathological vaginal discharge
- Patients with history of recurrent urinary tract infection
- Molar pregnancy
- Patients who had vulval or vaginal cleansing with antiseptics or skin cleansers like chlorohexidine
- Patients who require delivery before completion of collection of 24-hour urine sample
- Multiple pregnancies.

The patients included in this study were inpatients. On the Fulfilment of selection criteria, they were enrolled in the group. The Women were informed about the procedure and a verbal informed consent was taken before procedure. While evaluating the results of the study relevant clinical data was collected from every patient, which included a detailed history, general systemic and obstetric examinations and baseline investigations including ultrasonography (for confirmation of gestational age and to rule out any congenital anomaly) were performed blood pressure was measured by the sphygmomanometer from right arm while the patient was in semi recumbent position with the arm roughly at heart level. The blood sample was taken from the ante cubital vein of every patient and investigated for: Complete haemogram, time, clotting time, blood sugar, kidney function test (KFT), liver function tests (LFT).

24 hours' urine was collected in all patients with assistance of nursing staff for collection. Each container was marked with patient's name, number of container and collection time. Random urine sample was collected in 10 ml sterilized glass vial along with 24-hours urine

Estimation of urinary protein levels

The concentration of protein in urine was measured in both samples with calorimetric method on Dade Dimension Auto analyzer.

Calculation

The analyzer automatically calculates the urinary protein concentration of each urine sample. Conversion Factor (f) = mg/L x 0.1 = mg/dL; mg/L x0.001 = g/L To calculate 24-hour urine protein excretion: mg/L x total volume (litres per 24 hours) = mg/day.

Estimation of urinary creatinine

The urine creatinine was determined by Kinetic Jaffe method on Hitachi 911 Auto analyser instrument.

Calculation

The auto analyzer automatically calculates the creatinine concentration of each urine sample.

Statistical analysis

Statistical evaluation was done in all the patients. Linear regression was used to determine the correlation between 24-hours protein excretion and spot urine protein / creatinine ratio.

SPSS package used for statistical analysis. Analyses testing of the frequency of adverse events within the groups were done using the Chi-square test.

Birthweights were compared using Student -t test Whilst apgar scores and biochemical indices were compared using Whitney test.

RESULTS

Age distribution

Majority of the patients were found in the age group of 25 to 29 years. A total of 46 patients were in the age group of 25 to 29 years. Out of 24 patients of age ≤24 years, 11 patients developed preeclampsia (37.9% of total preeclampsia patients), and 13 patients had diagnosis of gestational hypertension (18.3 % of total patients with gestational hypertension).

In age group of 25 to 29 years, out of46 patients, 16 patients had diagnosis of preeclampsia (37.9 % of total preeclampsia patients) Whereas 26 patients were diagnosed as cases of gestational hypertension (49.3%). Similarly, in the age group of 30 to 34 years, out of 18 patients, 6 patients were diagnosed as preeclampsia (20.7%) and 12 as gestational hypertension (l6.9%)and in the age group of 35 to 39 years 1 patient had preeclampsia (3.4%) and 11 patients had gestational hypertension (5 .5%).

Table 1: Age and BMI distribution of patients.

Characteristic		N	%
Age (year)	<=24	24	24
	25 to 29	46	46
	30 to 34	18	18
	35 to 39	12	12
	Mean±SD	27.8±4.6 (18, 39)	
Dwelling	Rural	60	60
	Urban	40	40
Gravida	Primi	39	39
	Multi	61	61
Body mass index	Mean±SD	23.8±3.2 (17.3, 2.5)	

Spot urinary protein

In our study, we observed that Mean±SD spot urinary protein (mg/dl) in patients with pregnancy induced hypertension was 18.3±12.2 (mg/dl). In patients with preeclampsia Mean± SD spot urinary protein (mg/dl) was 32.2±10.4.

Whereas, in patients with gestational hypertension it was 12.6±7.3.

The difference in spot urinary protein in patients with preeclampsia and patients with gestational hypertension is statistically significant (p=0.000).

Table 2: Spot urinary protein of patients.

Pregnancy induced hypertension													
	Pre-eclampsia				Gestational hypertension				Total				P-value
	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	
Spot urinary ptotein(mg/dl)	11	45	32.2	10.4	0	28	12.6	7.3	0	45	18.5	12.2	0.000 (sig)

Spot urinary creatinine

In our study Mean±SD urinary creatinine (mg/dl) in patients with pregnancy induced hypertension Was 58.3±8.7. In patients with preeclampsia it was 57.7±9.1 Whereas in patients with gestational hypertension it was 58.6±8.5. The difference Was not statistically significant (p=0.657).

Table 3: Spot urinary creatinine of patients.

Pregnancy induced hypertension													
	Pre-eclampsia				Gestational hypertension				Total				P -value
	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	
Spot urinary creatinine (mg/dl)	45	75	57.7	9.1	40	75	58.6	8.5	40	75	58.3	8.7	0.657 (NS)

Table 4: Spot protein/ creatinine ratio of patients.

Pregnancy induced hypertension													
	Pre-eclampsia				Gestational hypertension				Total				P -value
	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	
Spot protein/ creatinine ratio	166.7	900.0	576.5	211.4	0.0	509.1	217.7	131.0	0.0	900.0	321.7	227.1	0.000 (sig)

Spot protein/creatinine ratio

In patients with pregnancy induced hypertension Mean±SD spot urinary protein creatinine ratio was 321.7±227.1. In patients with preeclampsia it was 576.5±211.4 Whereas in patients with gestational hypertension it was 217.7±131.00. The difference was statistically significant (p=0.000).

24-hours urinary protein

The mean 3±SD 24 hours urine proteinuria in patients into preeclampsia was 1.7±0.8 g/day While as in patients with gestational hypertension, it was 0.2±0.1 g/day. When these values were compared statistically and the results obtained. They were found to be significant.

Table 5: 24 -hours urinary protein of patients.

Pregnancy induced hypertension													
	Pre-eclampsia				Gestational hypertension				Total				P-value
	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	
24 -hours urinary protein	0.3	2.67	1.7	0.8	0	0.29	0.2	0.1	0	2.67	0.6	0.8	0.000 (sig)

Kidney function test

Blood urea

The mean±SD of blood urea (mg/dl) in patients with pregnancy induced hypertension it is 26.4±5.3 mg/dl. In patients with preeclampsia Mean±SD blood urea(mg/dl) was 30.0±5.6.

Whereas in patients with gestational hypertension it was 24.9±4.3 mg/dl.

The difference in the mean urea concentration between the two groups was statistically significant (p=0.00).

Serum creatinine

The Mean±SD serum creatinine in mg/dl in patients with pregnancy induced hypertension was 0.793±0.1912. In patients with gestational hypertension, the Mean±SD plasma creatinine was 0.735±O.1484 Whereas in patients with preeclampsia, it was 0.9±0.2. The difference in plasma creatinine levels was statistically significant (p = 0.000).

Fetal birth weight

The Mean±SD fetal birth Weight in patients with pregnancy induced hypertension was 2592.01±448.642

Whereas in patients with gestational hypertension it was 2631.50±437.640 and in patients with preeclampsia, the Mean±SD birth Weight was 2479.62±469.097. The difference was statistically significant.

Gestational age at the time of delivery

The Mean±SD gestational age at the time of delivery in patients with pregnancy induced hypertension was 37.27 1.830 Whereas in patients with gestational hypertension it was 37.88±1.579 and in patients with preeclampsia it Was 35.54±1.334.

The difference in gestational age at the time of delivery between patients with gestational hypertension and patients with preeclampsia was statistically significant (p 0.000).

Table 6: Blood urea of patients.

Pregnancy induced hypertension													
	Pre-eclampsia				Gestational hypertension				Total				
	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	P value
Blood urea (mg/dl)	20	41	30.0	5.6	17	32	34.9	4.3	17	41	26.4	5.3	0.000 (sig)

Table 7: Serum creatinine of patients.

Pregnancy induced hypertension													
	Pre-eclampsia				Gestational hypertension				Total				P- value
	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	
Serum creatinine (mg/dl)	0.6	13	0.9	0.2	0.5	1.1	0.7	0.1	0.5	1.3	0.8	0.2	0.000 (sig)

Table 8: Fetal birth weights in different group.

Pregnancy induced hypertension													
	Pre-eclampsia				Gestational hypertension				Total				P- value
	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	
Fetal birth weight (gm)	1950	3500	2479.6	469.09	1860	3500	2631	437.642	1860	3500	2592.01	448.6	0.025 (sig)

Table 9: Gestational age at the time of delivery in different groups.

Pregnancy induced hypertension													
	Pre-eclampsia				Gestational hypertension				Total				P- value
	Min	Max	Mean	SD	Min	Max	Mean	SD	Min	Max	Mean	SD	
Gestational age at the time of delivery	34	38	35.6	1.3	34	40	38.0	1.5	34	40	37.3	1.8	0.000 (sig)

DISCUSSION

In the present study, we primarily investigated the correlation between spot urinaryprotein/creatinine ratio and 24-hours proteinuria in patients with hypertensive disorders of pregnancy. The negative predictive value of random urine protein-creatinine ratio was high and did not vary greatly with an increasing cutoff point of protein-creatinine ratio for significant proteinuria detection. In our study, at cut of 300 mg/gm protein creatinine ratio, sensitivity and specificity are 82.8% and 76.1% respectively. Positive and negative predictive value are 58.8% and 91-5%. The spot urine protein/creatinine ratio and the 24-hours protein excretion were significantly correlated (r=0.824 p< 0.0001).

A protein to creatinine ratio ≥400 mg/g in detected significant proteinuria (≥300 mg/ 24 hours), with specificity and positive predictive value of 100%. A protein to creatinine ratio (mg/gm) of ≤ 200 ruled out significant proteinuria (≥300 mg/day) with sensitivity and negative predictive value of 100.

Our observation are in accordance with the Work of Attiqa Amin,Noor-i-Kiran Naeem et al who assessed the diagnostic value of protein creatinine ratio by correlating it to 24 hours urinary protein.[14]

The sensitivity was 73.8% and specificity 94% that is comparable to our study. Similar results were found by Alfredo Leanos Miranda et al.[1] With a cutoff of 0.19 or greater, Rodriguez- Thompson and Lieberman reported a sensitivity of 91% and a specificity of 70%.[15] Durnwald and Mercer reported a sensitivity of 91% and specificity of 48% with a cutoff point of 0.20.[16] Using Bayes' theorem, given a prior probability of 21% for significant proteinuria, a negative predictive value of 97% was estimated from the study of Rodriguez- Thompson15 and 95% from that of Durnwald and Mercer.[16]

Cote MA et al did a systematic review; thirteen studies were reviewed for spot protein creatinine ratio and albumin creatinine ratio as diagnostic test for significant proteinuria in hypertensive pregnant women.[17] They made the conclusion that spot urine protein creatinine ratio is a reasonable "rule out" test for significant proteinuria of 0.3 g/dl or more in pregnancy. Thomas et al conducted a similar study in pre- eclamptic women.[18] They also found strong correlation of random spot protein creatinine ratio with 24 hours urinary protein levels (Pearson r = 0.88) kept cutoff 0.21 (300 mg/24 hours) and 3.0 (5000 mg/24 hours). Rahman MM et al also obtained similar results in non-diabetic chronic renal disease patients.[19]

The Mean±SD of blood urea (mg/dl) in patients with pregnancy induced hypertension. It is 26.4±5.3 (mg/dl). In patients with pregnancy induced hypertension Mean± SD blood urea (mg/dl) was 30.0±5.6 whereas in patient with gestational hypertension it was 24.9±4.3 (mg/dl). The difference in the mean urea concentration between the two groups was statistically significant (p=0.000). The Mean±SD serum creatinine in (mg/dl) in patients with pregnancy induced hypertension was 0.7934±0.1912. In patients with gestational hypertension the Mean±SD plasma creatinine was 0.735±0.1484 whereas in patients with preeclampsia, it was 0.9±0.2. The difference in plasma creatinine levels was statistically significant (p=0.000). Urea, creatinine Were significantly higher in the preeclamptic group. These results are in keeping with the endothelial and renal dysfunction associated with preeclampsia. Our results were similar to those observed by Pervin Vural, C Emil Akgul et al.[20] While studying the gestational age at the time of delivery. It was found that Mean±SD gestational age at the time of delivery in patients with pregnancy induced hypertension was 37.27±930. In case of patients with gestational hypertension it was 37.88±597 Whereas in patients with preeclampsia it was 35.54±1.334. The difference in gestational age at the time of delivery between patients of gestational hypertension and preeclampsia was statistically significant (p=0.000). The lower mean gestational age in patients with preeclampsia can be attributed to various factors related to the disease itself. In some patients, the labor was spontaneous at early stage Whereas in some patient's labor was induced or caesarean section Was done due to maternal or fetal distress. In our study we found that 19 patients (19 %) delivered preterm babies. This observation was in accordance to the observation of Bilgin T et al.[21] In patients with gestational hypertension 21 (n=71), 11 patients (15.5%) delivered preterm babies. Whereas in case of patients with preeclampsia, 8 patients (27.5%) out of 29 delivered preterm babies. The difference was statistically significant. This observation was in accordance to the observation of Bilgin T et al.[21]

In our study it was found that the Mean±SD fetal birth weight in patients with pregnancy induced hypertensionwas 2592.01±448.642 (gms) Whereas in patients with gestational hypertension it Was 2631.50±437.640 (gms) and the Mean±SD birth Weight was 2479.62±469.097 (gms)in babies with preeclampsia. It was statistically significant (p<0.000).

Xiong X, Mayes D et al.[22] In their study on impact of pregnancy induced hypertension on fetal growth found that after adjustment for duration of gestation and other confounders, preeclampsia and severe preeclampsia increased the risk of intrauterine growth restriction and low birth Weight Similar findings were observed by, Ivanov S, Sfiokova et al.[23] In our study on 100 patients with pregnancy induced hypertension, a total of 39 patients delivered babies with low birth Weight (<2500 gms), 29 patients were found to have proteinuria of ≥300 mg /day and were diagnosed as cases of preeclampsia. Out of these 16 (55%) delivered low birth Weight babies and 13 delivered babies with normal birth weight. In patients with gestational hypertension (n=71), 23 patients had babies with birth weight less than 2.5 kg (low birth weight).the difference between the two groups was statistically significant Majundar S et al.[24] Our study showed that spot protein creatinine ratio is an alternative test to 24-hours urinary protein collection which is cumbersome, time consuming, inconvenient and subject to error due to inaccurate timings and/or incompleteness. The method of detection of proteinuria with random protein creatinine ratio is faster and within safe limits to aid diagnosis and in early start of treatment hence ensuring better fetomaternal outcome. Also many studies have stressed on early detection and prompt management of patients with proteinuria that is beneficial for patient and fetus. The random protein-creatinine ratio can be used in serial testing with 24-hour urine collection in mild hypertensive disorders of pregnancy. For a patient with a positive random urinary protein to creatinine ratio, proceeding with collection of a 24-hours urine sample seems a reasonable option.

CONCLUSION

The spot urinary protein creatinine ratio was significantly higher in patients with preeclampsia than patients with

gestational hypertension. The spot urinary protein/ creatinine ratio has a significant correlation with 24-hours urinary protein excretion in patients with pregnancy induced hypertension. The urinary spot protein /creatinine ratio of ≤200(mg/gm) excludes preeclampsia Where as a ratio of ≥400 (mg/gm) detects patients of preeclampsia with 100% sensitivity. The spot urinary protein /creatinine ratio can be used as an alternative to 24-hours urinary protein excretion in patients with pregnancy induced hypertension.

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