

Original Research Article

A HOSPITAL BASED PROSPECTIVE STUDY THE DIAGNOSTIC ACCURACY OF SPOT URINARY PROTEIN CREATININE RATIO COMPARED TO 24 HOURS URINARY PROTEIN EXCRETION IN DIAGNOSED CASES OF PREECLAMPSIA AT TERTIARY CARE CENTRE

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ABSTRACT

Background: Proteinuria is a major indicator of hypertensive disorder of pregnancy and also one of the diagnostic criteria of its severity. Presence of total protein in 24 hours urine of more than 0.3g is considered significant. A need therefore exists for a rapid, as well as a valid, accurate test to identify significant urinary proteinuria. This may lead to early decision making, which is likely to reduce patient's anxiety, cost savings, and "target" women with true pathology for treatment.

Materials & Methods: Our study was a prospective analytical study involving the 100 pregnant women who were diagnosed to have preeclampsia (urine protein with dipstick test 1+ or more) admitted in antenatal ward with the advice of modified bed rest. A detailed history, general physical and systemic examination including the obstetric examination. All were asked to collect 24-hour urine sample for determination of proteinuria.

Results: In the present study showed that the mean age of the subjects studied was 27.45 ± 5.3 years. 80% patients were preeclamptic which included both severe and non-severe, 20% were gestational hypertensives. On applying McNemar chi-square test there is no significant difference found between 24hour urine protein and spot protein/creatinine ratio Mc Nemar chi-square= 0.3460, df=1, p=0.5563. A fair correlation coefficient of $r = 0.8345$ n was observed between the 24 hours urine protein and spot protein/creatinine ratio among 100 study sample which was statistically significant at p value < 0.0001 .

Conclusion: The present study showed that determination of proteinuria by spot protein/creatinine ratio is a rapid and reliable alternative test for 24 hour urine protein, which has been the gold standard in the management of women with preeclampsia.

Keywords: Preeclampsia, Spot urine, Creatinine, Proteinuria.

INTRODUCTION

Hypertensive disorders in pregnancy form one of the deadly triad along with haemorrhage and infections that result in much of the maternal morbidity and mortality. Although its prevalence is still underestimated in some places due to underreporting, preeclampsia is a disease that health professionals

need to know how to deal with and take action. According to the WHO, hypertensive disease during pregnancy is a major cause of material and perinatal mortality and morbidity. Preeclampsia occurring in 3% to 8% of pregnancy is major cause of material mortality, and it accounts for about 15-20% of iatrogenic preterm birth, intrauterine growth retardation & perinatal mortality.^[1]

The incidence of preeclampsia is 5-7% of all pregnancy. For diagnosis and management of preeclampsia presence proteinuria is one of the essential criteria. Although amount of proteinuria is excluded from the factors determining the severity of preeclampsia, it still has an important role in the diagnosis of preeclampsia. In the literature there are studies showing that massive proteinuria has negative effects especially on foetal outcomes and also maternal outcomes.

It is a multisystem endothelial disease that leads to glomerulo endotheliosis, 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 foetal 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 <300mg proteinuria, those with mild pre-eclampsia have 300mg to 500mg and those with severe pre-eclampsia have >5000mg 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.^[7,8] So it is almost always followed up by the "gold standard" test of 24 hour urine collection.

In pregnancy proteinuria is detected and measured either by visual dipstick urine analysis or by 24hour urinary protein measurement. The visual dipstick urine analysis in recent studies has been found inaccurate, giving high number of false positive and false negatives.

The 24hour urinary collection has been the standard in most of the places for quantifying proteinuria. Though reliable indicator it has the disadvantages of being a cumbersome and time-consuming process, for both the patient and laboratory, it is subjected to collection error, requires patient compliance and there is a delay of 24 hours from the time of collection till the decision is made regarding the management. Hence there is need to evaluate other alternative test for quantifying the proteinuria accurately, rapidly and at the same time overcome the limitations of routinely performed tests.

MATERIALS AND METHODS

A Our study was a prospective analytical study involving the 100 pregnant women who were diagnosed to have preeclampsia (urine protein with dipstick test 1+ or more) admitted in antenatal ward with the advice of modified bed rest. The exclusion

criteria were the subjects with chronic hypertension, intrinsic renal disease, pathological vaginal discharge and urinary tract infection and those planned for termination of pregnancy immediately.

Inclusion Criteria

- Singleton pregnancy
- Women aged between 20 and 40 years
- Gestation age >20 weeks with Blood pressure >140/90mmHg on at least two occasions 6 hours apart taken in the sitting position using an appropriate sized cuff and in whom proteinuria is detected.

Exclusion Criteria

- Women with chronic hypertension, chronic renal disease, History of recurrent urinary tract infection, pathological vaginal discharge, gestational diabetes and liver disease
- Multiple pregnancies

Methods

All the patients satisfying the inclusion criteria were selected for the study. The tests were carried out in hospitalized patients. A detailed history, general physical and systemic examination including the obstetric examination. Per speculum examination was done to look for any evidence of vaginal infection clinically.

Procedure: All were asked to collect 24-hour urine sample for determination of proteinuria. They were advised to collect urine at 8.00 am of a day till 8.00 am of the next morning. Random sample for UPCr test and dipstick test were collected in the next day morning after the 24-hour urine collection. The adequacy of urine collection was determined by the creatinine excretion. Subjects with inadequate urine sample and those with urinary tract infection were excluded from the final analysis. Only the subjects who had significant proteinuria i.e. $\geq 300\text{mg}$ in 24 hours urine sample were included in the final analysis.

Urine dipstick test: The dipstick tests were done using the urinalysis strips. Two random samples of urine collected by clean catch or from a urinary catheter and tested with a reagent strip; if the readings are noted as one plus or more when the urinary specific gravity is < 1030 and pH being less than 8, the condition is considered as significant proteinuria (1+ refers to the urinary albumin level as 0.3g/L and 2+ to 1g/L).

24 HUP: The urine was stirred to ensure homogeneity and a 6-mL aliquot sample was obtained. Analysis for protein was performed using a modified Fujita method. The formula used to determine the amount of urinary protein (Up) based on the product of concentration of protein in the test sample (Tp) and the total volume of urine (Uv) is expressed as - $\text{Up (mg/day)} = \text{Uv (dL)} \times \text{Tp (mg/dL)}$. Each sample was tested twice to calculate the mean value and each sample was paralleled with a low control and a high control. Comparison of this assay with other similar commercially available reagents

shows a correlation coefficient of 0.997 for samples containing 1 mg/dl to 128 mg/dl. For those samples with significant proteinuria that exceed this value, the urine was diluted 1:10 with deionised water to maintain the sensitivity of the assay. When the 24 hour urine collection has the total protein of 300 mg or greater, the condition is referred as significant proteinuria.

Creatinine: Modified Jaffe Method was used to estimate the urinary creatinine as per the instructions given in the Kit. The principle behind this test is that when creatinine reacts with picric acid at alkaline pH values, it forms creatine alkaline picrate which has a distinct colour that can be measured photometrically. The serum creatinine was determined by using the same assay with 300 µL of serum. Estimation of the creatinine clearance was calculated by using the formula - urine creatinine (mg/dl) x urine flow rate (ml/min) divided by serum creatinine (mg/dl). The tests were performed by a biochemist working in the laboratory of the hospital.

Statistical analysis: SPSS package 20.0v used for statistical analysis. Analyses testing of the frequency

of adverse events within the groups were done using the Chi-square test.

RESULTS

In the present study showed that the mean age of the subjects studied was 27.45 ± 5.3 years. 80% patients were preeclamptic which included both severe and non-severe, 20% were gestational hypertensives (table 1).

On applying McNemar chi-square test there is no significant difference found between 24hour urine protein and spot protein/creatinine ratio Mc Nemar chi-square= 0.3460, df=1, p=0.5563 (table 2).

In our study Sensitivity and Specificity of P/C ratio is found to be 87.21% and 76.19% respectively. Positive predictive value of the test being 83.33% and Negative predictive value of the test being 81.36%. A fair correlation coefficient of $r = 0.8345$ was observed between the 24 hours urine protein and spot protein/creatinine ratio among 100 study sample which was statistically significant at p value <0.0001 (table 3).

Table 1: Various variables in patients

Variables	No. of patients	Percentage
Age (yrs) (Mean±SD)	27.45±5.3	
Preeclampsia (NSPE/SPE)	80	80%
GEST. HTN	20	20%
Gestational age (weeks)	31.47±2.79	

Table 2: Comparison of 24hour urine protein (Gold std.) and P/C ratio

P/C ratio	24hours urine protein (Gold std.)			P-value
	Gest HTN	PE	Total	
Gest HTN	51	10	61	
PE	7	32	39	>0.05
Total (%)	58 (58%)	42 (42%)	100 (100%)	

Table 3: Sensitivity and specificity of P/C ratio over 24hours urine protein (Gold std.)

Sensitivity	87.21%
Specificity	76.19%
Positive predictive value	83.33%
Negative predictive value	81.36%
Disease prevalence	57.72%

DISCUSSION

Preeclampsia is distinguished from gestational hypertension by the presence of significant proteinuria. An accurate and rapid detection and quantification of proteinuria are essential in the management of hypertensive disorders in pregnancy. This can help us know the severity of the disease much earlier which will be helpful in the course of management.

The gold standard for the diagnosis of significant proteinuria remains the 24hour urine protein. The need for 24hr collection is because of high degree of variation in the urine protein concentration during the course of the day. As the method is having disadvantages of being time consuming, cumbersome and inaccuracy because of incomplete collection, simpler methods which can measure urinary protein

in spot samples like protein/creatinine ratio is proposed. In our study we have correlated this simpler method with the gold standard.

The entity of hypertensive disorders of pregnancy is a major cause of maternal and perinatal mortality worldwide, of which preeclampsia remains the leading cause. Proteinuria with hypertension in pregnancy is associated with greater adverse maternal and foetal outcome. hence detection and frequent monitoring will be helpful in timely decisions. Therefore, reliable quantitative measurement of urinary protein excretion which will be quick and easy to perform and correlate well with the gold standard 24 HUP test is required. Age has an important influence on the incidence of hypertensive disorders of pregnancy with less risk of developing preeclampsia in the age group between 20 to 30 years, whereas the occurrence is more in the teen age

and after 30 years of age during pregnancy in general population.^[9]

In our study, the mean age of preeclampsia was 27.45 years and the maximum being between 20 to 30 years and hence the confounding effect of age factor has been eliminated in the present study; A similar to the data published by Aggarwal N et al,^[10] but in Kumari A et al^[11] study majority of the patients were multigravidas. A systematic review of controlled trials by Duckitt K et al (2005)^[12] observed nulliparity (RR 2.91, 95% CI) as an unadjusted relative risk factor for developing preeclampsia. The mean gestational age was 31.47±2.79 weeks similar to previous studies,^[11,13,14] in Aggarwal N et al^[10] study the mean gestational age was 32 weeks which may be due to a greater number of severe cases.

Spot protein/creatinine ratio has been shown as a good and reliable predictor of proteinuria by various studies. In our study spot protein creatinine ratio yielded the sensitivity of 87.21%, specificity of 76.19%. Positive predictive value was found to be 83.33% and Negative predictive value 81.36%. kappa value of P/C ratio was 0.6394, which was in good agreement with the gold standard. Since the present study included women only with a stable renal function, our study supports the use of spot protein/creatinine ratio in women with normal renal function. But Robert et al^[15] in 1997 and Quadri et al^[16] in 1994 have proved in their studies that the protein/creatinine ratios are independent of renal function and reliable even in the presence of underlying renal disease and have advocated their use to monitor renal function in pregnancy.

CONCLUSION

We concluded that this method for quantification of proteinuria, when properly interpreted, and validated by laboratory can provide valuable information regarding the diagnosis and severity of the disease. Hence for the clinical purposes, spot protein-creatinine ratio is a satisfactory and reliable substitute for 24 hour urine protein in quantification of proteinuria.

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