Diagnostic Accuracy of Urine Dipstick for Proteinuria in Pre-Eclampsia

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ABSTRACT

OBJECTIVE: To evaluate the diagnostic accuracy of dipstick urine analysis in single voided urine by using quantification of urinary proteins in 24 hours collection as gold standard in pre-eclamptic patients.
STUDY DESIGN: Cross sectional survey.
PLACE AND DURATION OF STUDY: This study was conducted in Obstetrics and Gynaecology Unit-I, Sir Ganga Ram Hospital, Lahore,during the period of six months from February 2009 to July 2009.
SUBJECTS & METHODS: Two hundred and twenty five cases of preeclampsia were included in this study and were clinically examined in Out-patient and Emergency Departments. In all these patients urinary protein was assessed by researcher using urine dipstick in (+2 or more) single voided urine as well as in 24 hours urinary collection (gm/24 hours) which was analyzed in laboratory of Sir Ganga Ram Hospital, Lahore. The results of both techniques were compared in all patients.
RESULTS: The mean standard deviation was 25.78±3.94 years. Twenty four hour urine is the gold standard for the evaluation of proteinuria with a sensitivity of 82% for pre-eclampsia patients, specificity had 62%, the positive predictive value was 77%, negative predictive value was 69% and accuracy rate was 73.78% The values for the 24-hour for patients with urinary protein.
CONCLUSION: All women with hypertension during pregnancy should have a 24 hour urine protein measurement. There may be a role in doing 6 or 12 hour urine collections to screen for proteinuria. Therefore, current practice at the labouratory should change to doing 24 hour urinary protein measurements on all hypertensive pregnant women.

KEY WORDS: Pre-eclampsia, Proteinuria, Hypertension, Urine dipstick.

INTRODUCTION

Pre-eclampsia is a common hypertensive disorder of pregnancy affecting 3-14% of pregnancies worldwide.[1] That is characterized by development of hypertension with proteinuria after 20 weeks of gestation.[2] Pre-eclampsia is associated with increased maternal and perinatal mortality and morbidity.[3]

Complications of hypertension is the 3rd leading cause of pregnancy related death. Pre-eclampsia is associated with increased risk of placental abruption, acute renal failure, cardiovascular and cerebrovascular complications, DIC and maternal death. With worsening proteinuria, there is increased risk of adverse maternal and fetal outcome.[4]

Diagnostic criteria for pre-eclampsia is blood pressure 140mmHg or higher systolic or 90mmHg or higher diastolic in a previously normotensive women and proteinuric 0.3gm or more in 24 hours urine collection[5] or clean catch midstream or catheter specimen of urine collected with >2 + on reagent strip.

In hypertensive disorder of pregnancy especially in pre-eclampsia. The urinalysis for proteinuria by quantification of urinary protein in 24 hours urine specimen play an important role.[6] However, most commonly used method for proteinuria in antenatal period is semiquantitative dipstick urine analysis with sensitivity 84% and specificity of 61%.[7]

Accuracy of dipstick urinalysis with threshold +1 in prediction of significant proteinuria is poor and the results of dipstick urinalysis for proteinuria are more accurate at higher threshold for proteinuria. So to increase the diagnostic accuracy proteinuria should be +2 or more.[8-10]

The importance of my study is to use urine dipstick as an accurate screening method for early diagnosis of pre-eclampsia so it can be used as an alternative to quantification of urinary proteins in 24 hours urinary proteins and its results. Urine dipstick method can give us an early assessment

of proteinuria in pre-eclamptic patients specially for emergency management and also helpful in close observation and prevention of pre-eclampsia.

PATIENTS AND METHODS

This cross sectional survey was carried out in the department of obstetrics & gynaecology unit I,Sir GangaRam hospital/Fatima Jinnah Medical College Lahore, during period of six months from February 2009 to July 2009.

A total of 225 pre eclamptic women with singleton pregnancy on ultrasound. Patients with UTI, chronic renal disease or molar pregnancy were excluded. In each case detail evaluation was carried out by complete history, general physical and systemic examination. In all these patients urinary protein was assessed by researcher using urine dipstick in (+2 or more) single voided urine as well as in 24 hours urinary collection (gm/24 hours) which was analyzed in laboratory of Sir Ganga Ram Hospital, Lahore. The results of both techniques were compared in all patients. All this information was collected on pre-designed proforma.

All the data was entered and analyzed by SPSS version 16, computer based software programme. Diagnostic accuracy, specificity, sensitivity, positive, predictive and negative predictive value of urine dipstick was calculated by using 2x2 table and 24 hours urinary proteins was taken as gold standard. Age was presented by mean±standard deviation.

RESULTS

In this study two hundred and twenty five pre-eclamptic patients were included who fulfilled the inclusion and exclusion criteria. This study was carried out in the Department of Gynaecology/Obstetrics Unit-I at Sir Ganga Ram Hospital/Fatima Jinnah Medical College, Lahore.

Out of 225, 111 (49%) patients were in age group between 20-25 years and most of the patients fall in this group. Eighty five (38%) patients were in age group between 26-30 years and remaining 29 (13%) patients were between 31-35 years of age. The mean standard deviation was 25.78±3.94 years of age (Table 1).

Table 2 shows the diagnostic accuracy of urine dipstick in 24 hours urinary protein in pre-eclamptic patients. The 24-hour urine is the gold standard for the evaluation of proteinuria with a sensitivity of 82% for pre-eclampsia patients, specificity had 62%, the positive predictive value was 77%,

negative predictive value was 69% and accuracy rate was 73.78%

Table 1: Age Distribution of Patients (n=225)

Age in years	No. of Patients	Percentage
20 – 25	111	49.0
26 – 30	85	38.0
31 – 35	29	13.0
Total	225	100.0

Mean±SD = 25.78±3.94
Key word: SD = Standard Deviation

Table 2: Diagnostic Accuracy of Urine Dipstick in 24 hours Urinary Protein in Pre-eclamptic Patients

24 hour urinary protein (Gold standard)				
				Total
Urine Dipstick	Positive	TP 111	FP 34	145
	Negative	FN 25	TN 55	80
		136	89	225

Sensitivity	82.0%
Specificity	62.0%
Positive predictive value	77.0%
Negative predictive value	69.0%
Diagnostic accuracy	73.78%

Key words:
TP   True positive FP   Fall positive FN
Fall negative TN   True negative

DISCUSSION

The present study shows that 111 (49%) patients out of 225 were in age group between 20-25 years. Eighty five (38%) patients were in age group between 26-30 years and remaining 29 (13%) patients were between 31-35 years of age. The mean standard deviation was 25.78±3.94 years of age. Most of the patients fall in the age group between 26-30 years. In a study carried out by Eigbefoh which is comparable with our study. The socio-demographic variables shows that the peak age range was 20-29 years (75.6%), primigravidae contributed the commonest parity (54.7%) and the peak gestational age was at term (74.4%).[8] Primigravidae have been demonstrated by numerous workers to be at high risk of developing pre-eclampsia.[9] The peak age of 20-29 years may

be reflective of the fact that most first deliveries in this environment occur at that age and not necessarily of any special contribution of this age bracket to the aetiology of the disease. Majority of the deliveries occur at term hence the 74.4% that had their deliveries at term is not surprising.[10] A study done by Shahbazian the mean age was 26.5±3.6 years (range 17-36 years).[11]

In a study presented by Waugh et al, the several investigators have explored other means of quantifying proteinuria in a shorter period. In this study a comparison of the protein and the urinary dipstick test with the standard 24 hour protein estimation using the various indices of validity was quite revealing. Sensitivity, Specificity, Positive and Negative predictive Values, and False Positive and Negative rates were the indices used. Sensitivity sometimes termed the detection rate is the ability of a test to find those with the disease or the proportion of true positive correctly identified. The sensitivity of a diagnostic test is the probability that patients with significant proteinuria (as assessed by 24 hour urine protein estimation) will have a positive test result.[11,12]

Specificity of a diagnostic test is the probability that patient without significant proteinuria will have a negative test result. The urine dipstick had the lowest specificity of 47%. The protein has a specificity of 86% a false positive rate of 14%. Dipstick tests had a false positive rate of 53% which is over three times that of the spot urinary protein. This implies that greater than 50% of patients without proteinuria are incorrectly identified in a clinical setting if urine dipstick test is relied upon. This is in agreement with numerous studies that have demonstrated that false positive reactions may occur with concentrated urine, highly alkaline urine (pH>8), contamination of urine with vaginal discharge and antiseptics like chlorhexidine.[13]

The negative predictive value of dipstick is higher than its positive predictive value (71% versus 59%). This has significant implications for clinical practice. Hence the probability that a negative dipstick reaction is genuinely negative is much higher than the probability that a positive result is positive-a negative result is more reliable than a positive one. However, the negative predictive value of dipstick test was found to be lower (71%) than for the protein, hence, a negative result with these rapid diagnostic tests has a higher probability of being genuinely negative. In terms of accuracy which is the measure of a test to

accurately detect or rule out the disease, this was expectedly higher for the protein, compared to the urine dipstick test (63%).[12]

In another study carried out by Maybury, the more recently dipstick manufacturers have combined semiquantitative creatinine pads onto multipad urine dipsticks, offering the potential for a point of care dipstick test for proteinuria. Preliminary studies of these dipsticks in pregnancy have been performed and results suggest that the dipsticks offer real improvements in diagnostic accuracy. In attempting to predict 300mg protein 24 hour in 24 hour urine, the dipstick had significantly improved sensitivity (94.5% vs 82%) and specificity (95.7% vs 81%) compared to automated dipstick urinalysis.[15] A study conducted by Gangaram, that the reliability of a random urinary dipstick for protein compared with 24 hour urine analysis and also determined if a shorter interval of collection is reliable in screening for proteinuria in hypertensive disorders of pregnancy. They found random urinary dipstick analysis to have a sensitivity of 84% and a specificity of 61%.[7,16]

The present study shown the positive predictive value is 77% while negative predictive value is 69% which is comparable with the above mentioned studies.

The advantage of the dipstick test is that it can be done anywhere by any trained paramedical or medical personnel while the urinary protein, require laboratories and trained laboratory personnel. The protein urine sample from pregnant women has been shown to correlate significantly with a 24-hour collection for patients with proteinuria. The result of this study demonstrate that in hospital with appropriate laboratory personnel and where patients can afford it, routine use of either the protein/creatinine ratio for quantitation of proteinuria in patients with pre-eclampsia could be adopted. The continued use of the dipstick for the screening and diagnosis of preeclampsia cannot be justified. Continued dependence on it especially in clinical setting is fraught with hazards. There is an urgent need for its replacement with test such as the protein/creatinine ratio which has better correlation with the 24 hour urine protein. The protein/creatinine ratio especially is reliable, relatively faster and accurate for proteinuria correlating well with 24 hour urinary protein excretion; they also show that it is much more reliable than the dipstick test on every test of

effectiveness measured, and therefore should substitute the urine dipstick test for protein estimation in clinical practice.[17]

CONCLUSION

- It is concluded that all women with hypertension during pregnancy should have a 24 hour urine protein measurement. There may be a role in doing 6 or 12 hour urine collections to screen for proteinuria. Protein/creatinine ratio testing may be useful in screening for proteinuria.
- Urine dipstick analysis done on the 24 hour urine collection has a negative predictive value of 69%. Therefore, current practice at the laboratory should change to doing 24 hour urinary protein measurements on all hypertensive pregnant women regardless of the urine dipstick result.
- With increasing proteinuria, there is increased risk of adverse maternal and fetal outcomes.

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