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Comparison of 12-hour Urine and Protein: Creatinine Ratio to 24-hour Urine for the Diagnosis of Preeclampsia (Poster)

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Comparison of 12-hour Urine and Protein: Creatinine Ratio to 24-hour Urine for the Diagnosis of Preeclampsia Christina Tun, MD¹; Joanne Quiñones, MD, MSCE¹; Anita Kurt, PhD¹; John Smulian, MD, MPH¹; Meredith Rochon, MD¹ ¹Obstetrics and Gynecology, Lehigh Valley Health Network, Allentown, Pennsylvania

Abstract

OBJECTIVE: The standard threshold value of proteinuria in the setting of hypertension for the diagnosis of preeclampsia is a 24-hour urine protein (24-hr) \geq 300mg. Equivalent values have been generated for more convenient and/or costeffective tests, such as the 12-hour urine protein (12-hr) and protein:creatinine ratio (PCR), but these have not been tested prospectively. The purpose was to compare the performance of the 12-hr and PCR to a standard 24-hr \ge 300mg for the diagnosis of preeclampsia.

STUDY DESIGN: This was a prospective observational study of women admitted to the Lehigh Valley Health Network from 7/1/2010 to 12/31/2011 for diagnosis and/or management of preeclampsia. For each patient, PCR, 12-hr and 24-hr urine specimens were collected. Only the 24-hr result was used for clinical management. Test characteristics for identifying 24-hr \geq 300mg were calculated. Cutoff values were based on previously published data.

RESULTS: A total of 102 patients were enrolled during the study period, 12 of which were subsequently excluded (11 delivered prior to completion, 1 was excluded due to lab error) for a final cohort of 90 patients. Twenty-eight (31%) of the final cohort had 24-hr \ge 300mg. Both 12-hr > 165mg and PCR > 0.15 correlate significantly with 24-hr \geq 300mg (r=0.99, p<0.001 and r=0.54, p<0.001, respectively). Test characteristics for 12-hr > 165mg and PCR > 0.15 are shown in Table 3.

CONCLUSION: 12-hr > 165mg performed well as a predictor of 24-hr \ge 300mg, with the benefit of a shorter evaluation time. The high negative predictive value of PCR suggests that it may be most useful in identifying patients that do not have 24-hr \geq 300mg. Use of both these tests can be considered in the evaluation and management of patients with suspected preeclampsia.

Background

Protein excretion is variable in the setting of preeclampsia, therefore it is recommended that a 24-hour urine be used for the diagnosis (1-3). Other tests for the diagnosis of preeclampsia have been proposed, including 12-hour urine protein > 165mg and/or protein:creatinine ratio (PCR) > 0.15 (4-7), but have not been prospectively tested.

Objective

To determine the performance of 12-hr urine protein > 165mg and PCR > 0.15 for predicting 24-hr urine protein \geq 300mg.

Methods

- Inclusion criteria: All pregnant women > 20 weeks' gestation admitted to the Lehigh Valley Health Network antepartum unit undergoing a 24hour urine protein for diagnosis and/or management of preeclampsia from 7/1/2010 – 12/31/2011.
- Exclusion criteria: Prepregnancy renal disease (defined as 24-hr urine protein \geq 300mg), clinical indication for delivery at the time of admission, age<18 or >55, non-english speaking or previous enrollment in the study.
- Primary outcome: test performance of 12-hr urine protein and PCR to predict 24-hr urine protein \geq 300mg.
- PCR, 12-hr urine protein, and 24-hr urine protein were collected on each subject. Providers were blinded to the 12-hr and PCR results. Care was otherwise routine. Urine collection was initiated at the time of admission. Subjects were on modified bedrest.
- Data were analyzed using STATA 9.2 statistical software. A p-value of <</p> 0.05 was considered statistically significant.
- IRB approved.

Results



Table 2. Urine collection charact 24-hr urine protein (mg) 24-hr urine volume (ml) 24-hr urine CrCl (ml/min) 12-hr urine protein (mg) 12-hr urine volume (ml) 12-hr urine protein > 165mg Protein:creatinine ratio Protein:creatinine ratio > 0.15 Data are in median (range) or n (%). C





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Table 1. Baseline maternal characteristics by 24 hour urine protein result					
	24-hr protein < 300 mg (N=62)	24-hr protein ≥ 300 mg (n=28)	P-value		
Maternal age (yrs)	29 (19-42)	30 (19-38)	0.76		
Race/Ethnicity Caucasian Black Asian Hispanic	49 (79%) 2 (3%) 3 (5%) 1 (2%0	22 (79%) 3 (11%) 0 (0%) 1 (4%)	0.41		
Private insurance	45 (73%)	20 (71%)	0.91		
Multiparous	29 (47%)	20 (71%)	0.03		
Multiple gestation	8 (13%)	3 (11%)	0.77		
BMI	33.1 (19.5-69.9)	36.4 (25.4-54.9)	0.13		
Gestational age (wks)	34.3 (29.9-39.0)	32.8 (24.0-35.4)	0.007		
Smoking	13 (21%)	4 (14%)	0.45		
Comorbidity (any)* cHTN gHTN or preeclampsia Pregestational diabetes Gestational diabetes	57 (91%) 12 (19%) 15 (24%) 1 (2%) 9 (13%)	26 (93%) 8 (29%) 7 (25%) 1 (2%) 4 (14%)	0.88 0.33 0.93 0.015 0.30		
Indications for admission* Elevated blood pressure Proteinuria Symptoms^ Lab abnormalities Fetal growth restriction Other+	51 (82%) 16 (26%) 28 (45%) 7 (11%) 10 (16%) 9 (15%)	26 (93%) 19 (68%) 14 (50%) 11 (39%) 3 (14%) 6 (21%)	0.19 <0.001 0.67 0.002 0.50 0.42		
Median SBP during collection	131 (99-165)	136 (105-152)	0.11		
Median DBP during collection	76 (53-98)	78 (55-99)	0.41		

Data are in median (range) or n (%). BMI, body mass index. *Subject may have more than one. cHTN. chronic hypertension. gHTN, gestational hypertension. ^Includes headache, scotomata, abdominal pain, and significant weight gain associated with edema. +Includes shortness of breath, seizure of uncertain origin, oligohydramnios, visual changes other than scotomata. SBP, systolic blood pressure. DBP, diastolic blood pressure.

stics by 24 hour urine protein result					
hr protein < 300 mg (N=62)	24-hr protein ≥ 300 mg (n=28)	P-value			
175 (90-290)	520 (310-6360)	<0.001			
2300 (700-4700)	1825 (600-5100)	0.23			
153 (59-272)	135 (80-283)	0.51			
70 (40-150)	255 (120-2640)	< 0.001			
1050 (40-2300)	1050 (300-3050)	0.97			
0 (0%)	27 (96%)	<0.001			
0.16 (0.07-0.5)	0.35 (0.14-4.57)	< 0.001			
30 (52%)	24 (89%)	0.001			
rCl, creatinine clearance.					

Table 3. Test characteristics of 12-hr urine protein > 165 mg and protein: creatinine ratio > 0.15 for the prediction of 24-hr urine protein \ge 300 mg						
	12-hr urine protein >165mg	PCR > 0.15				
Sensitivity	96 (90-99)	89 (81-94)				
Specificity	100 (96-100)*	49 (39-59)				
PPV	100 (96-100)*	32 (23-42)				
NPV	98 (93-100)	91 (84-96)				
Data are in % (95% confidence interval). PCR, protein:creatinine ratio. PPV, positive predictive value. NPV, negative predictive value.						
*Confidence interval is 97.5%.						

Figure 2: 12-hour urine protein vs. 24-hour urine protein

Figure 3: ROC for 12-hour urine protein









Conclusions

- 12-hr urine protein > 165mg is a good surrogate for 24-hr urine protein ≥ 300mg with the potential benefit of earlier diagnosis and treatment of preeclampsia
- Protein:creatinine ratio > 0.15 may be most useful as a screening tool to rule out 24-hr urine protein \geq 300mg due to its high negative predictive value
- Applying these results to the management of patients with suspected preeclampsia has the potential to:
 - Improve compliance with outpatient collection
 - Decrease healthcare costs by decreasing the number of admissions and length of admissions
 - Decrease morbidity by decreasing time to diagnosis

Strengths

- "Real life" study design generalizable to clinical practice
- First study to prospectively test previously generated cutoffs
- Inpatient setting allowed consistency and compliance with collection technique

Weaknesses

- Small sample size lacks power to correlate with maternal and fetal outcomes
- May not be generalizable to outpatient setting uncertain impact of hospitalization (diet, sleep pattern, activity)

Future Studies

- Develop and prospectively study a clinical algorithm for the diagnosis of preeclampsia incorporating 12-hr urine protein and protein: creatinine ratio in both the inpatient and outpatient settings
- Correlate these test cutoffs with maternal and fetal outcomes

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