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CLINICAL RESEARCH

Diagnostic Performance of a Saliva Urea Nitrogen Dipstick to Detect Kidney Disease in Malawi

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Introduction: Kidney disease (KD), including acute kidney injury, is common, severe and leads to significant mortality in the developing world. However, simple tools to facilitate diagnosis and guide treatment are lacking. We studied the diagnostic performance of saliva urea nitrogen (SUN) measured by dipstick to diagnose KD in a low-resource setting.

Methods: Medical admissions to a tertiary hospital in Malawi had serum creatinine tested at presentation; SUN was measured using a dipstick. Patients with serum creatinine above normal range underwent serial measurements of SUN and blood urea nitrogen for up to 7 days. Hospital outcome was recorded in all patients.

Results: A total of 742 patients were included (age 41 ± 17·3 years, 56.1% male); 146 (19.7%) had KD, including 114 (15.4%) with acute kidney injury. SUN >14 mg/dl had a sensitivity of 0.72 and a specificity of 0.87 to diagnose KD; specificity increased to 0.97 when SUN levels were combined with self-reported urine output. The diagnostic performance of SUN was comparable with the one of blood urea nitrogen (SUN area under curve, 0.82; 95% confidence interval, 0.78–0.87; blood urea nitrogen area under curve, 0.82; 95% confidence interval, 0.59–1.0). SUN >14 mg/dl on admission was an independent predictor of all-cause mortality (hazard ratio = 2.43 [95% confidence interval, 1.63–3.62]).

Discussion: SUN measured by dipstick can be used to identify patients with KD in a low-resource setting. SUN is an independent predictor of mortality in this population.

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Acute kidney injury (AKI) is common worldwide, causing high morbidity and mortality, particularly in the developing world.[1,2] Here, AKI primarily affects young patients with limited comorbidity, is predominantly community acquired, and is commonly caused by infective illnesses, volume depletion, and nephrotoxicity.[3,4]

Many deaths resulting from AKI in low-resource settings (LRS) may be preventable.[5] However, a number of major challenges exist when managing AKI in these areas: (i) a disparity in health care resources available in urban compared with rural areas; (ii) poor awareness among patients and health care workers of AKI and the need for its early detection and treatment; (iii) a scarcity of trained personnel and resources for renal replacement therapy; and (iv) a lack of reliable and cost-effective tools to diagnose AKI.[5,6]

The lack of medical and laboratory infrastructure in LRS makes the development of an inexpensive, noninvasive, and reliable bedside diagnostic tool to identify patients with kidney disease (KD), including AKI, essential.[5] Saliva urea nitrogen (SUN) was first

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described in the 1840s,[7] and several studies have since evaluated the diagnostic capability of SUN to detect renal impairment.[8–11] SUN parallels blood urea nitrogen (BUN) and urea reaches saliva by diffusive transport from the salivary glands. Alongside bicarbonate, it is responsible for the buffering capacity of saliva.[12] SUN concentration can vary according to stimulation of the salivary glands and the amount of saliva produced. SUN can be measured by laboratory techniques but also by a simple dipstick method.[13]

The SUN dipstick has been suggested as a potential screening tool for acute and chronic KD.[14,15] Indeed, in our previous studies in developed settings, SUN strips demonstrated good diagnostic performance to detect kidney dysfunction, especially at the higher levels of BUN.[14] In the present study, we aimed to explore the diagnostic performance of this tool in a LRS, where access to laboratory measurements of renal function is often limited, and where the SUN test may be of greatest value.

METHODS

Study Design, Setting, and Participants

We conducted a prospective observational study at Queen Elizabeth Central Hospital in Blantyre, Malawi, one of the poorest countries in the world. Queen Elizabeth Central Hospital acts as both a district hospital and a tertiary hospital for the southern region of Malawi, although the majority of patients admitted are from Blantyre district itself, with a population of approximately 1 million.

All patients aged 14 years or older admitted to the general medical wards between 27 April 2015 and 17 July 2015 were eligible. Patients unable to give informed consent, patients transferred to the medical ward from another ward or hospital, and patients who were unable to provide a sufficient volume of saliva (including those with significantly reduced level of consciousness) were excluded from the study.

Patients enrolled were screened for KD with serum creatinine (sCR) measurement. Concomitantly, we measured SUN levels using a dipstick (Integrated Biomedical Technology, Elkhart, IN). Those with sCR above the local laboratory reference range (>90 μmol/l in women; >104 μmol/l in men) were managed by the nephrology team and followed with serial SUN, BUN, and sCR measurements for a period of up to 7 days or until hospital discharge if sooner. Demographic and clinical data, including signs and self-reported symptoms (increased thirst and reduced urine output) of altered volume status, were also recorded. Hospital outcome was recorded in all patients.

Data Collection

Saliva and blood samples were collected simultaneously on admission (day 0) for the measurement of SUN and sCR, and then at 24 hours (day 1) and every 48 hours thereafter (days 3, 5, and 7) for the measurement of SUN, BUN, and sCR.

SUN Measurement

SUN was assessed using a dipstick (Integrated Biomedical Technology). Subjects were asked to refrain from drinking and eating for at least 15 minutes prior to saliva collection. Unstimulated saliva was collected in a plastic cup and approximately 50 μl of saliva was used to moisten the test pad of a colorimetric SUN dipstick. The dipstick test pad contains a urease enzyme in a bound form that cleaves SUN when moistened with saliva; this leads to the formation of ammonia and hydroxyl ions resulting in a change in pH which, by a pH indicator substance, consequently changes color of the test pad. After 1 minute, the color of the test pad is compared with 6 reference pads indicating increasing SUN concentrations: 5–14 mg/dl (pad 1), 15–24 mg/dl (pad 2), 25–34 mg/dl (pad 3), 35–54 mg/dl (pad 4), 55–74 mg/dl (pad 5), and ≥75 mg/dl (pad 6) (Figure S1).[15]

sCR and Urea Measurement

sCR was measured by the Jaffe method[16] and BUN by the urease method[17] (either by Flexor Junior Clinical Chemistry Analyzer [Vital Scientific, Dieren, The Netherlands] or by Mindray Chemistry Analyzer BS-120 [Shenzhen Mindray Bio-Medical Electronics Company, Shenzhen, China]) in a local laboratory.

Definitions

AKI, acute kidney disease/disorder (AKD) without AKI, and chronic kidney disease were diagnosed and staged by Kidney Disease Improving Global Outcomes criteria.[1,18] KD is used to refer to AKI, AKD without AKI, and stable chronic kidney disease. AKD incorporates both confirmed AKI and AKD without AKI (Figure S2).

Outcome Measures

The primary outcome measure was the diagnostic performance of the SUN dipstick to detect KD, alone and in combination with self-reported changes in urine output and thirst. Secondary outcome measures were the agreement of SUN with BUN at presentation and during management of KD, and the ability of SUN to predict in-hospital mortality in this population.

Statistical Analyses

For the statistical analyses, urea results were converted to BUN (mg/dl) and SUN was transformed to a

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