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Evaluation of a portable urinary pH meter and reagent strips

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ABSTRACT

Objective: To evaluate a portable electronic pH meter and to put its accuracy in perspective with reagent strips read by a layperson, a healthcare professional and an electronic reading device.

Materials and Methods: Based on a pre-analysis on 20 patients, a sample size of 77 urine aliquots from healthy volunteers was necessary to obtain sufficient study power. Measurements of urinary pH were obtained by use of reagent strips, a portable pH meter and a laboratory pH meter (gold standard). Reagents strips were read by a professional experienced in interpreting strips, a layperson, and an electronic strip reader. The mean matched pair difference between measurement methods was analyzed by the paired t-test. The degree of correlation and agreement were evaluated by the Pearson's correlation coefficient and Bland-Altman plots, respectively.

Results: The mean matched pair difference between the gold standard and all other pH measurement methods was the smallest with the portable electronic pH meter (bias 0.01, 95% CI -0.07 to 0.08; p=0.89), followed by strips read by a professional (bias -0.09, 95% CI -0.21 to 0.02; p=0.10), layperson (bias -0.17, 95% CI -0.31 to -0.04; p=0.015) and electronic strip reader (bias -0.29, 95% CI -0.41 to -0.16; p<0.001). The portable electronic pH meter achieved the highest Pearson's correlation coefficient and narrowest 95% limits of agreement, followed by strip interpretation by a professional, the electronic strip reader and the layperson. In order to quantify the ability of pH measurement methods to correctly classify values within a predefined urinary pH target range, we performed classification tests for several stones. The portable electronic pH meter outperformed all other measurement methods for negative predictive values.

Conclusions: Findings of the current study support that the portable electronic pH meter is a reliable pH measuring device. It seems to be more accurate compared to reagent strips readings.

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INTRODUCTION

Kidney stone disease is one of the most frequent urological conditions and its incidence is still increasing.[1] Diet and lifestyle factors play an important role in the pathogenesis of stone formation and need to be adapted to reduce or prevent stone recurrence. To prevent crystallization, urinary pH needs to be monitored accurately in response to medical or dietary interventions.[2] Urine pH should be targeted between 5.8 and 6.2 for preventing ammonium urate and carbonate apatite stones. For uric acid stones, urine pH needs to be adjusted between 6.2 and 6.8 for prevention, and between 6.5 and 7.2 for chemolitholysis. In the prevention of cystine stones, pH should be adjusted between 7.5 and 8.5.[3] Monitoring urinary pH is also important to increase the antibiotic efficacy against bacterial uropathogens[4], to improve the therapeutic efficacy of mitomycin C instillation[5], and to minimize toxicity of high-dose methotrexate therapy.[6, 7] Therefore, it is of utmost importance to measure urinary pH with high accuracy.

For abovementioned indications, urinary pH is most accurately measured with an electrochemical pH meter using a combined glass pH electrode. However, the latter is hardly ever available in the outpatient clinic or in an ambulatory setting. Caregivers and patients usually use urine reagent strips since they are cheap and easy to handle, without the need for calibration or user training. However, several authors published about the inaccuracy of these reagent strips.[8-10] Portable electronic pH meters meant for medical use may serve as an alternative. One of them is the Lit-Control pH Meter (Devicare, Barcelona, Spain) that uses an automatic calibration system and an ion sensitive field effect transistor (ISFET) that was improved during the last years. However, few publications reported about its accuracy.[11]

We aimed to evaluate this portable electronic pH meter and to compare the results with currently available pH measurement methods.

MATERIALS AND METHODS

Subjects and samples

Urine samples were collected from employees working at the urology and nephrology departments over a period of four days. Participants were provided with a sterile specimen

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cup and they were asked to collect the midstream part of the urination, achieving at least 30 mL of urine in the cup. Samples were excluded in case of severe bacteriuria, macrohematuria, volume less than 30 mL or contamination during collection or during manipulation of the samples.

pH measurement devices

Within two hours after collection, the pH of each fresh aliquot was measured consecutively with four pH measurement devices in accordance with the manufacturer's instructions.

pH was measured with reagent strips for urinalysis (Multistix 10G, Siemens Healthcare Diagnostics Inc., Tarrytown, New York, USA). These strips are composed of ten reagents, including pH-metry. They varied in intervals of 1 pH unit between 5.0 and 6.0 and of 0.5 pH units from 6.0 to 8.5. The reactive color of the pH panel was compared to the closest corresponding color on the result chart, according to the recommendations of the manufacturer. This was performed by a healthcare professional experienced in reading strips (strips-professional) and by a non-experienced person (strips-layperson). In order to avoid progress bias, readings were noted by a third person, who also performed other analyses. All evaluators were unaware of the aliquot's origin.

After human interpretation, the strips were read by an electronic strip reader (Clinitek Status Urine Analyzer, Siemens Healthcare GmbH, Erlangen, Germany). This electronic strip reader measured pH with intervals of 0.5 for pH values between 5.0 and 8.5.

Afterwards, pH was read by Lit-Control pH Meter. This portable electronic pH meters measured results in increments of 0.1 pH units, between 4.0 and 8.0. Before each analysis, this device needed to be calibrated with a 40 mL pH 6.8 buffer solution. Between measurements, the pH sensor and container were rinsed with tap water, according to the recommendations of the manufacturer.

Finally, pH was read with a laboratory benchtop T70 Titrator (Mettler-Toledo Inc., Columbus, USA). It measured pH quantitatively down to 0.001 of a pH unit. It was calibrated daily with buffers at pH 4.0 and 7.0. Fifty milliliters of sterile water were added

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to one milliliter of urine before each measurement. Between analyses, the electrode and the container were rinsed with sterile water. Since this analysis method was considered as the most accurate and precise device for urinary pH measurement at our institution, we defined it as gold standard for comparison of all pH measurement methods.

Statistics

Based on a pre-analysis on 20 patients, we found the Strips-Layperson analysis to be the least accurate, with a mean matched pair difference of 0.2 and a standard deviation of 0.6 compared to the gold standard. Considering these values, a sample size of 73 cases was necessary to reach a power of 80%. Additionally, we included a margin of error of 5%, whereby the cases needed to analyze was 77.

The mean matched pair difference between two pH measurement methods was defined as the “bias” and was analyzed by the paired t-test. The degree of correlation between the gold standard and all other pH measuring methods was evaluated by the Pearson’s correlation coefficient. This test offers the advantage to quantify the correlation between two measurement methods. However, it may differ depending on the degree of urinary pH variation in the evaluated cohort. Therefore, Bland-Altman plots were additionally drawn, allowing for a graphical comparison between two measurement methods.

Statistical analyses were performed using GraphPad Prism 6.01 (GraphPad Software, La Jolla CA, USA).

Ethics

This study has been approved by the appropriate ethics committee and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. Informed consent was obtained from all individuals included in the study.

RESULTS

A total of 77 urinary samples were included for analysis. No samples were excluded for this study. Markers for leukocytes, nitrites and blood results were negative for all samples.

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The distribution of the results for each pH measurement method is detailed in Table 1. The mean pH value of the portable electronic pH meter and the gold standard was the same. The bias between the gold standard and all other pH measurement methods was the smallest for the portable electronic pH meter (bias 0.01, 95% CI -0.07 to 0.08; p=0.89). It was followed by strips read by a healthcare professional (bias -0.09, 95% CI -0.21 to 0.02; p=0.10), a layperson (bias -0.17, 95% CI -0.31 to -0.04; p=0.015) and the electronic strip reader (bias -0.29, 95% CI -0.41 to -0.16; p<0.001). This bias was significant for the two latter measurement methods.

The correlation of the gold standard pH readings against the other measurement methods is reported in Figure 1. The strongest correlation was found for the portable electronic pH meter (r=0.89, 95% CI 0.83 to 0.93, p<0.001), followed by strips read by a healthcare professional (r=0.67, 95% CI 0.53 to 0.78, p<0.001), the electronic strip reader (r=0.60, 95% CI 0.44 to 0.73, p<0.001) and a layperson (r=0.57, 95% CI 0.39 to 0.70, p<0.001).

The Bland-Altman plots for the four urinary pH measurements in relation to the gold standard are displayed in Figure 2. The highest precision was revealed by the narrowest 95% limits of agreement for the portable electronic pH meter (-0.6 to 0.6), followed by strips read by a healthcare professional (-1.1 to 0.9), the electronic strip reader (-1.4 to 0.8) and a layperson (-1.4 to 1.0).

Finally, classification tests were done in order to quantify the ability of pH measurement methods to correctly classify values within a predefined urinary pH target range, when compared to the gold standard measurements (Table 2). This was performed for ammonium urate and carbonate apatite stones, and for the prevention and treatment pH ranges of uric acid stones. Classification tests could not be performed for the pH target range of cystinuria patients (pH 7.5 – 8.5), because less than five values lied within that range.

DISCUSSION

This study addresses the reliability of several urinary pH measurement methods in a representative cohort of healthy volunteers. A pH meter designed for home use (Lit-Control pH Meter) showed an unbiased, significantly higher precision than reagent strip

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and the electronic strip reader interpretations. The clinical impact of this precision gain could be verified by the analysis of positive and negative predictive values.

The portable electronic pH meter had the highest Pearson's correlation coefficient and the smallest mean bias and limits of agreement (Table 1, Figure 1 and Figure 2). This means that pH indicated by the portable electronic pH meter was the most accurate to measure urinary pH when compared to other measurement tools. The imprecision of the strip interpretation by both humans and the electronic strip reader may be explained by the rather broad increments of qualitative color changes of 0.5 or 1 pH units. In contrast, the portable electronic pH meter and gold standard measure pH quantitatively down to 0.1 and 0.001, respectively. The electronic strip reader underestimated urinary pH in most cases (Figure 2). This negative distribution of the results from the electronic strip reader may hint a systematic error from a bad calibration. This encourages more frequent calibration of this device.

It is well known that kidney stone formation is influenced by urinary pH, since the pH level of crystallization varies depending on the type of stone.[12] Urinary pH target ranges recommended by international guidelines are rather narrow, when compared to the precision of conventionally available pH meters available for home-use.[3] Remarkably, the positive predictive value of layperson's interpretation of urinary pH reagent strips lied well below 50% for two of the recommended target ranges. For ammonium urate and carbonate apatite stone formers (pH target 5.8 – 6.2), only 27% of the values that would be interpreted to be within the target range would in fact really be in that range. This means that 73% of these patients would unintentionally fail to adapt their urinary pH. For uric acid stone formers (prevention pH target 6.2 – 6.8), 67% of the patients would falsely believe their urinary pH is within the preventive range. For the rather large pH target range of uric acid chemolitholysis, a positive predictive value of ≥ 60% was obtained for all measurement methods.

In contrast, the negative predictive value could be as high as 93% for the portable electronic pH meter to predict a value without the target range of 5.8 – 6.2. The portable electronic pH meter outperformed all other measurement methods for negative predictive

values, i.e. the ability to correctly classify a measurement without the pH target range. The lowest predictive performance and lowest accuracy were found when strips were read by laypersons, especially for low urinary pH levels. These results are comparable with those published by other authors, whereby accuracy of reagent strips was higher for more basic pH levels.9

We used MultiStix 10G reagent strips for urinalysis since most of our patients are using these for self-monitoring their urinary pH. We preferred to interpret the strips by both laypersons (like patients) and experienced healthcare professionals since this is an important difference that has not yet been described in the literature. Not surprisingly, subjective visual comparison was more accurate when performed by healthcare professionals. This may be explained by the progress that professionals have made previously when they could compare their interpretations of a colorimetric dipstick pH scale with more precise pH analyses.

The value of other frequently used portable devices has been questioned in several other studies.[8-10, 13, 14] Our findings are similar to those of authors comparing pH readings between reagent strips, hand-held pH meters and a bench-top laboratory pH machine. For reagent strips, they all concluded that clinically relevant discrepancies occurred with an unacceptable frequency when analyzing predictive values.

Limitations of our study were the fact that the interpretation of reagent strips were only performed by two persons. As well, we used reagent strips that measured in 0.5 pH unit increments. Reagent strips using smaller increments or from other brands may be more accurate.[9] Moreover, predictive values according to the pH target range should be interpreted with caution since these are based on only one sample. Urinary pH varies throughout the day and the decision to acidify or alkalize urine is generally not based on an isolated urine sample.[15-17]

It is important that caregivers and patients possess accurate pH measuring devices. Since pH is a logarithmic scale, an increase in one pH unit means a tenfold decrease in acidity or hydrogen-ion concentration. Urinary pH readings by the portable electronic pH meter came closest to the gold standard according to our findings. Thus, this device of pH

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measurement may be considered to monitor urinary pH. These results changed our clinical practice. From now on, nurses are using the portable electronic pH meter instead of reagent strips when measuring urinary pH before mitomycin C instillation. As well, several patients are using this device for self-monitoring their pH during chemolitholysis or for prevention of new stone formation. Compared to urinalysis strips, the downside of the portable electronic pH meter is that it can only measure urinary pH, it is more expensive and calibration is necessary. Although reagent strips have been found to provide high negative predictive value for detecting albuminuria and urinary tract infection[18, 19], they seem to be insufficiently accurate at the level of pH indication for guiding clinical decision making, especially if users are not trained.

CONCLUSIONS

Findings of the current study support that the Lit-Control pH Meter is a reliable pH measuring device. It is more accurate compared to reagent strips interpreted by a layperson, a healthcare professional, and the electronic strip reader.

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AUTHOR DISCLOSURE STATEMENT

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Table 1: Distribution of study population pH values for various measurement methods

n=77	Mean	SD	Min	Max	Mean bias (95% CI)	p-value
gold standard	6.1	0.6	4.9	7.6	NA	NA
portable electronic pH meter	6.1	0.4	5.2	7.2	0.01 (-0.07 to 0.08)	0.89
strips-professional	6.0	0.6	5.0	7.5	-0.09 (-0.21 to 0.02)	0.10
strips-layperson	5.9	0.7	5.0	8.0	-0.17 (-0.31 to -0.04)	0.015
electronic strip reader	5.8	0.6	5.0	8.5	-0.29 (-0.41 to -0.16)	<0.001

All values are pH units. NA = not applicable.

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Table 2 : Comparison of pH measurement methods with the gold standard for several recommended target pH ranges[3]

pH target range	Type of stone former	pH measurement method	Sensitivity, %	Specificity, %	PPV, %	NPV, %	Accuracy, %
5.8 - 6.2	Ammonium urate, Carbonate apatite	portable electronic pH meter	85	74	53	93	77
		strips-professional	80	49	36	88	57
		strips-layperson	55	47	27	75	49
		electronic strip reader	30	77	32	76	65
6.2 - 6.8	Uric acid (prevention)	portable electronic pH meter	74	74	48	90	74
		strips-professional	26	88	42	78	73
		strips-layperson	16	90	33	76	71
		electronic strip reader	21	95	57	79	77
6.5 - 7.2	Uric acid (chemo-litholysis)	portable electronic pH meter	62	91	72	86	83
		strips-professional	52	93	73	84	82
		strips-layperson	38	91	62	80	77
		electronic strip reader	33	96	78	79	79

PPV = positive predictive value, NPV = negative predictive value

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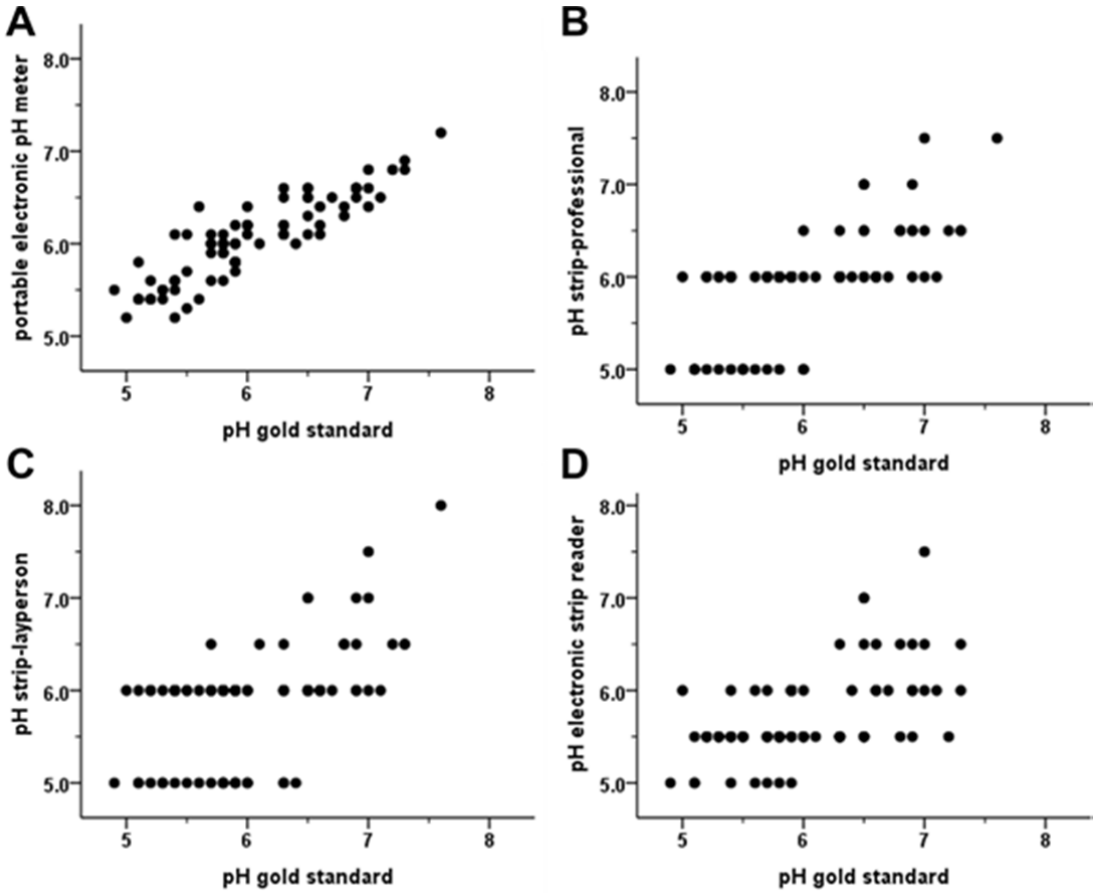

Figure 1 : Correlation of gold standard versus other pH measurement methods

Scatter plots correlating gold standard urinary pH readings against results from four other measurement methods: a portable electronic pH meter (A), urinary strips read by a healthcare professional (B), by a layperson (C) or by an electronic strip reader. Each dot corresponds to a urinary sample. For graph D: one urinary sample is not displayed (pH 8.5 against 7.6 for electronic strip reader against gold standard value, respectively.

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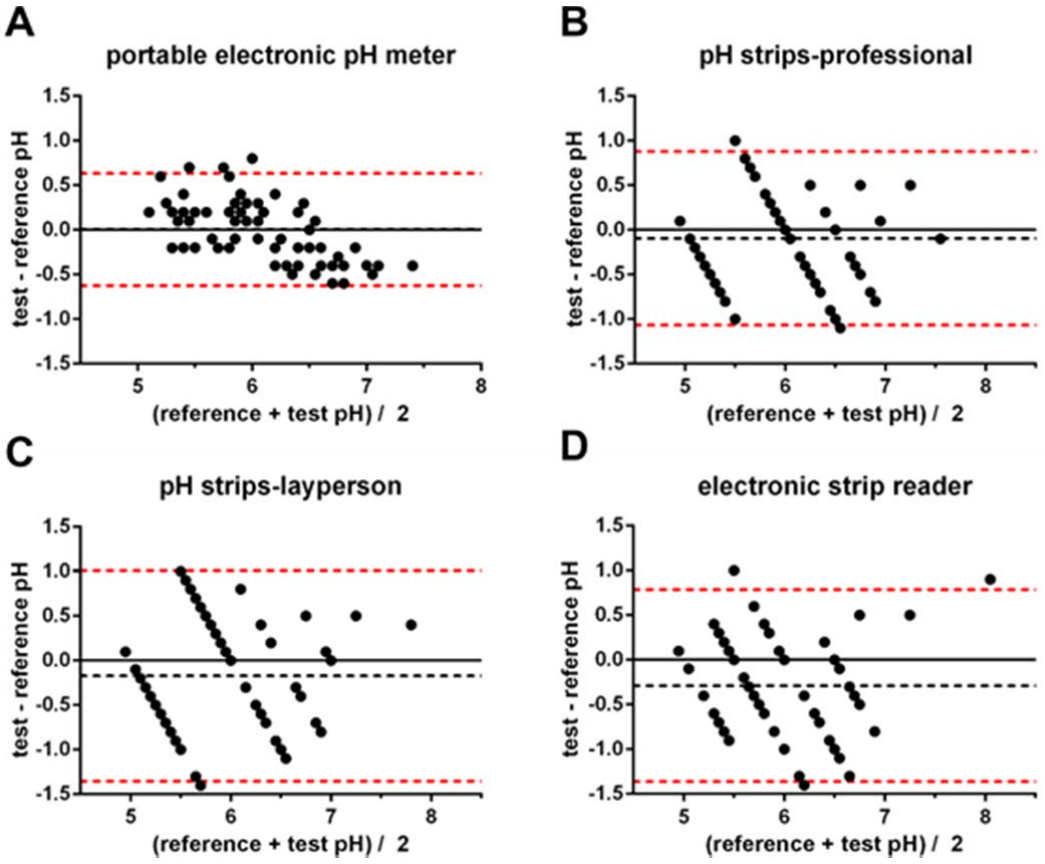

Figure 2: Bland-Altman plots

Bland-Altman plots assessing agreement between gold standard urinary pH readings (reference) and results from four other measurement methods (tests): a portable electronic pH meter (A) and urinary strips read by a healthcare professional (B), by a layperson (C) or by an electronic strip reader. Each dot corresponds to a urinary sample. Black dotted lines: bias between two evaluated methods. Red dotted lines: 95% limits of agreement.

Abbreviations used:

ion sensitive field effect transistor : ISFET

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