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ORIGINAL PAPER

Diagnostic performance and cost-effectiveness of portable digital pH meters and traditional dipsticks for urine pH monitoring in patients at risk of recurrent urolithiasis

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Summary

Introduction: Urolithiasis affects up to 10% of the population and recurs in more than 50% of cases within ten years. Urinary pH plays a pivotal role in the stone prevention, but dipstick testing, the most commonly used method, lacks accuracy, precision and reliability. Only portable digital pH meters classified as medical devices offer superior accuracy, sensitivity, specificity, and resolution, enabling more reliable urinary pH monitoring than dipstick testing. Nevertheless, their comparative cost-effectiveness remains unclear.
Methods: We conducted a systematic review and cost-effectiveness analysis comparing a portable digital pH meter with dipsticks for urinary pH monitoring in recurrent stone formers. Following PRISMA 2020 guidelines, studies reporting on accuracy, precision, or costs were included. Data were pooled using random-effects models. Cost estimates were derived from European market sources and adjusted for inflation. Outcomes included analytical validity, cost per effective unit, number needed to treat (NNT), and cost per quality-adjusted life-year (QALY) gained.
Results: Thirteen studies involving 2,801 participants were included in the quantitative synthesis. The portable digital pH meter consistently outperformed dipsticks across all evaluated parameters, demonstrating higher explained variance (r^2 0.97 vs 0.54), finer resolution (0.1 vs 0.5 pH units), and lower systematic bias (0.06 vs 0.36). The cost per effective unit was lowest for the portable digital pH meter (€ 179) compared with once-daily (€ 354) and twice-daily dipstick testing (€ 708). In compliance-adjusted models, the cost per lithiasis episode prevented was € 590 for the portable digital pH meter versus €1,169 and € 2.337 for dipsticks. In a simulated 1.,000-patient cohort, the portable digital pH meter yielded the lowest total costs (€ 601.376) and the greatest QALY gain (17.84), demonstrating a dominant result, being both more effective and less costly than all alternatives.
Conclusions: The portable digital pH meter demonstrated superior analytical performance and cost-effectiveness compared with dipsticks for urinary pH monitoring. Its broader implementation may enhance preventive strategies, reduce stone recurrence, and decrease the overall healthcare burden associated with recurrent urolithiasis. Considering these findings, the portable digital pH meters may warrant consideration for inclusion in major clinical guidelines on urolithiasis and for reimbursement by healthcare systems, potentially supporting its broader adoption in clinical practice.

KEY WORDS: Urolithiasis; Urinary pH; Digital pH meter; Dipsticks; Cost-effectiveness.

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INTRODUCTION

Urolithiasis is a highly prevalent condition, affecting approximately 10% of individuals during their lifetime, with recurrence rates exceeding 50% within 10 years of the first episode (1, 2). Among the modifiable risk factors contributing to stone formation, urinary pH plays a pivotal role in determining the type and likelihood of crystallization. An acidic urinary environment favors the formation of uric acid and cystine stones, whereas an alkaline urine promotes precipitation of phosphate-containing stones, such as calcium phosphate or magnesium ammonium phosphate (struvite), the latter often associated with urinary tract infections. Consequently, sustained regulation of urinary pH within the non-lithogenic range (5.50-6.20) has become a cornerstone of nephrolithiasis management (3, 4). Given that maintaining urinary pH within the non-lithogenic range is a central strategy in the prevention of stone recurrence (5), reliable pH monitoring becomes essential to ensure effective implementation of preventive interventions.

Clinical guidelines recommend urinary pH monitoring to guide dietary and pharmacological interventions aimed at maintaining an optimal pH range (6). This is particularly relevant in patients receiving alkalinizing or acidifying therapies, as their therapeutic efficacy depends on achieving and maintaining specific pH targets. However, despite its recognized importance, implementation of routine pH monitoring in clinical practice remains limited. A major barrier is the widespread use of semi-quantitative dipsticks, which suffer from poor accuracy, limited precision, low resolution, and substantial inter-observer variability (7, 8). These limitations compromise therapeutic decision-making but may reduce long-term adherence to pH-targeted regimens, especially in outpatient settings (7).

Pharmacological interventions, such as thiazides and citrate supplements, have been shown to reduce recurrence by up to 75% (9, 10), but optimal benefits are achieved only when therapy is guided by effective monitoring, including consistent urinary pH control.

The recent introduction of the Lit-Control® pH Meter, a portable digital pH meter classified as medical device, offers a potentially more accurate, reproducible, and reliable alternative for point-of-care urine pH measurement (11). This device provides high-resolution digital readouts, minimizes inter-observer variability, and allows data logging for remote monitoring via Bluetooth connectivity with a mobile app called myLit-Control® (12). Real-time feedback to patients and clinicians via this system may enhance adherence to dietary and pharmacological interventions (13). However, its adoption has been hampered by uncertainties regarding cost-effectiveness compared with traditional dipsticks, and the economic impact of integrating it into preventive strategies for urolithiasis has not been quantified.

This study was undertaken to assess the diagnostic performance and cost-effectiveness of the portable digital pH meter compared with traditional dipsticks (once-daily and twice-daily use) for urine pH monitoring in patients at risk of recurrent urolithiasis. Specifically, our objectives were to: (1) perform a systematic review of the accuracy, precision, resolution, and analytical validity of both methods, and, if feasible, a meta-analysis; (2) analyze and compare the cost of the three urinary pH monitoring strategies; and (3) analyze the cost-effectiveness of the four preventive strategies, including urinary pH monitoring and pharmacological treatment, compared with no-prevention, from the perspective of the Spanish *National Health System* (NHS).

METHODS

Systematic review

Search strategy

We performed a systematic literature review to identify studies that assessed the performance and cost of urinary pH measurement devices (specifically, Lit-Control® pH Meter or test strips). The methodology for evidence identification, selection, and synthesis adhered to the PRISMA-2020 guidance (14). The search was initially conducted in July 2024 and updated in November 2024. The electronic databases PubMed, Embase, and Google Scholar were searched using a predefined strategy that included the combination of the following keywords: ("urinary pH" OR "urine pH" OR "pH measurement") AND ("pH meter" OR "digital pH meter" OR "portable pH meter") OR ("dipstick" OR "test strip" OR "urine test strip") AND ("accuracy" OR "precision" OR "reliability" OR "sensitivity" OR "specificity" OR "predictive value" OR "cost" OR "economic evaluation" OR "cost effectiveness"). Reference lists of relevant articles were also screened to identify additional studies.

Studies were eligible if they met the following criteria:

- Evaluated the accuracy, precision, reliability, or diagnostic performance of Lit-Control® pH Meter or test strips compared with the gold standard (a laboratory calibrated pH-meter), in clinical or home settings for managing or monitoring urolithiasis or related conditions.
- Reported quantitative data on relevant outcomes, such as precision, resolution, accuracy, sensitivity, specificity, predictive values, cost, or cost-effectiveness parameters.
- Represented original research articles, including randomized controlled trials, observational studies, diagnostic accuracy studies, and validation studies.
- Published in peer-reviewed journals in English.

Data extraction and quality assessment

Two reviewers independently extracted data using a standardized form, collecting information on study design, population characteristics, device specifications, calibration procedures, and all numerical outcome measures. Specifically, we recorded the following metrics: shared variance as the degree of variance in pH measurement attributable to device accuracy, resolution as the smallest detectable change, systematic bias as the mean absolute deviation from the reference standard, correct identification as the proportion of measurements falling within the correct clinical pH range, precision as a measure of repeatability, inter-observer agreement as an index of concordance between readers or users, and variance-ratio (reliability) as a composite indicator of dispersion. When multiple estimates were reported, priority was given to summary statistics (means and medians) along with corresponding measures of dispersion (standard deviations and confidence intervals). For studies reporting only ranges, approximate means and standard deviations were calculated using established formulas when justified. The overall study quality was evaluated using the Newcastle-Ottawa Scale (15).

Data synthesis and analysis

Because this analysis focused on estimating the pooled parameters for each device category rather than comparing them directly in head to head meta analyses, studies reporting data on Lit-Control® pH Meter were aggregated separately from those reporting on test strips. Data were either extracted directly or calculated from the included studies. When fewer than three were available for a given parameter, a weighted mean was computed. For parameters with three or more available values, a meta-analysis was performed to estimate the overall effect and assess heterogeneity. Random-effects models were applied to account for the expected variability in patient populations, device types, and methodologies across studies. Heterogeneity was quantified using Tau^2 and I^2 statistics to evaluate the consistency and reliability of the findings for each device category. All statistical analyses were performed using the R software (meta package).

Cost analysis and cost-effectiveness

A one-year cost analysis and cost-effectiveness analysis was

Table 1.
Prices of different commercial urine test strips.

Brand	Product	Price (€)	Cost per Unit (€)
Siemens	Multistix 10 SG Urine Test Strips, 100 units	32.15	0.325
GIMA	Urine Analysis Strips, 11 parameters, Box of 100	12.50	0.125
Welnia	pH Strips 0-14 1.09535 PQ, 100 units	33.00	0.330
Merk	pH Indicator Strips pH 6.5 - 10.0	28.00	0.280
Bayer	Uristix Urine Dipsticks	39.00	0.390
Average	Average Price and Cost per Unit	29.02	0.290

conducted comparing four preventive strategies: (1) "No Prevention", (2) Drug only (3) "Prevention with the Lit-Control® pH Meter," (4) "Prevention with Test Strips Once Daily," and (5) "Prevention with Test Strips Twice Daily."

Cost

Only direct healthcare costs were considered in the analysis, including Lit-Control® pH Meter and strip costs, pharmacological treatment acquisition and medical and/or surgical costs associated with lithiasis episodes. All costs are expressed in euros (€ 2024). The medical devices costs were obtained from European distributors and online catalogues. Table 1 shows the prices and unit costs of various brands of the pH test strips.

The average product price was € 29.02, with an average cost per strip of € 0.29, resulting in a total annual cost of € 105.85 for once-daily use, and € 211.70 for twice-daily use. The initial retail price for the new version 2.0 of Lit-Control® pH Meter, which connects to a mobile app via Bluetooth, is € 200, with an annual maintenance cost of € 100 for subsequent years. Considering a useful life of five years, the annualized cost is calculated as (€ 200 + € 400) ÷ 5, resulting in € 120 per year.

The price of available Lit-Control® treatments, used to modulate urinary pH of stone-forming patients and inhibit urine crystallization, is € 24 per box of 60 capsules, providing one month of treatment. Therefore, the annual treatment cost is € 288. Medical and/or surgical costs associated with lithiasis episodes vary widely (16). For this analysis in patients with recurrent lithiasis, we used the episode cost of € 4.267 reported by *Lotan et al.* (2013) (17), adjusted by a cumulative price increase of 22% in the *Consumer Price Index* (CPI) from 2013 to 2024 (18), resulting in a final cost of € 5.226.39.

Assumptions for effectiveness evaluations

Effectiveness parameters for preventing recurrent nephrolithiasis were derived from a comprehensive meta-analysis conducted by *Fink et al.* (2013) (9) and a systematic review of randomized controlled trials conducted by *Ferraro et al.* (2017) (10). These studies provide robust evidence to support the efficacy of various interventions in reducing the risk of kidney stone recurrence. The meta-analysis by *Fink et al.* (2013) reported *risk ratios* (RR) for different pharmacological treatments.

Specifically, for patients with multiple previous calcium stones, moderate-strength evidence showed that thiazides [RR, 0.52 (95% CI, 0.39 to 0.69)] and citrate supplements [RR, 0.25 (95% CI, 0.14 to 0.44)] significantly reduced the risk of stone recurrence compared with placebo or control (9).

To calculate the *Number Needed to Treat* (NNT) for urinary pH-modulating therapies, data from *Ferraro et al.* (2017) (10) were used. This review found that recurrence rates were highest among untreated patients (26 per 100 person-years) and lowest among those receiving pharmacological therapy alone or in combination with pH monitoring (8 per 100 person-years). These figures correspond to an NNT of 5.55 [1/(26%-8%)] and a prevention rate of 69.2% ((26%-8%)/26%) (10).

Galán Llopis et al. (2019) (5) conducted a study on 143 patients treated with alkalinizing (45.5%) and acidifying (54.5%) agents. Both treatments effectively normalized urinary pH, with up to 54.9% of patients achieving non-lithogenic pH by day 60 ($p < 0.00001$). Patients were classified as "*compliant*" if they consumed more than 80% of their prescribed treatment and "*non-compliant*" otherwise. Compliance significantly influenced outcomes: 80.6% of compliant versus 57.8% of non-compliant patients achieved non-lithogenic pH (*odds ratio* (OR) = 3.03, 95% CI: 1.29 to 6.66). Cox regression analysis demonstrated that achieving a non-lithogenic pH at day 90 (*hazard ratio* (HR) = 0.428, 95% CI: 0.193 0.947) and treatment compliance at day 60 (HR = 0.428, 95% CI: 0.189 0.972) were both independently associated with colic free survival (5).

Table 2 summarizes the effectiveness parameters used for further economic analyses, providing quantitative estimates of the clinical impact of pH monitoring and treatment in preventing urolithiasis. Detailed calculations derived from the three referenced studies are described in Box 1.

Table 2.
Effectiveness parameters of preventive treatment and urinary pH monitoring.

Parameter	Value
Prevention Rate	0.692
NNT to prevent 1 episode	5.55
Compliance effect (OR, 95% CI)	3.030 (C.I. 1.29-6.66)
pH Success Rate	0.549
Prevention Rate among Compliants	0.806
Prevention Rate among Non-compliants	0.578
NNT among Compliants	4.77
NNT among Non-compliants	6.66

CI: confidence interval; NNT: number needed to treat; OR: odds ratio.

Utility values

To capture the impact of nephrolithiasis on patients' *health-related quality of life* (HRQoL), we used health utility measures that quantify the reduction in well-being associated with each lithiasis episode. The disutility value for lithiasis episode was standardized at -0.08 (range: -0.06 to -0.10), as derived from SF 6D and EQ 5D scores reported by *Polotti et al.* (2020) (19).

Box 1. *Calculations derived from bibliographic references for effectiveness estimates.*

Effectiveness in Preventing Stones

The effectiveness parameters for the prevention of recurrence were derived from a systematic review (Ferraro et al., 2017) [10]:

$prevention = 69.2\%$

Effectiveness of pH Normalization (pH_success_rate)

- **Definition: The percentage of patients who achieved non-lithogenic pH at day 60.**
- **Value: Based on Galán-Llopis et al. [5], 54.9% of patients normalized their pH by day 60.**

$pH\_success\_rate = 54.9\%$

Effectiveness of Compliance in Achieving Non-Lithogenic pH (compliance_effect)

- **Definition: The odds of compliant patients achieving non-lithogenic pH versus non-compliant patients at day 60.**
- **Value: The odds ratio for compliance effect is 3.03 (95% CI: 1.29–6.66) based on Galán-Llopis et al., 2019 [5].**

$compliance\_effect = 3.03$

Effectiveness of pH Control in Colic-Free Survival (HR_pH_colic_free)

- **Definition: The hazard ratio for colic-free survival for patients who achieved non-lithogenic pH at day 90.**
- **Value: Achieving non-lithogenic pH reduces the risk of colic by 57.2% based on Galán-Llopis et al. [5].**

$HR\_pH\_colic\_free = 0.428$

Effectiveness of Compliance in Colic-Free Survival (HR_compliance_colic_free)

- **Definition: The hazard ratio for colic-free survival for patients who were compliant with treatment at day 60.**
- **Value: Compliance at day 60 reduces the risk of colic by 57.2% based on Galán-Llopis et al.**

$HR\_compliance\_colic\_free = 0.428$

The analyses conducted by Ferraro et al. [10] and Galán-Llopis et al. [5] provide the basis for deriving key effectiveness parameters related to the urinary pH control and patient compliance. These parameters will serve as the foundation for further economic analysis, providing quantitative estimates of the clinical impact of pH management in preventing urolithiasis.

To calculate the effectiveness and Number Needed to Treat (NNT) for compliant and non-compliant groups, we start with an overall effectiveness of 69.2% and an odds ratio (OR) of 3.03 between these groups.

Step 1: Calculating the Effectiveness

Given that the odds ratio (OR) between compliant and non-compliant groups is 3.03 and the overall effectiveness is 69.2%, we use the formula relating OR to the probabilities:

$$\frac{\frac{p_{\text{compliant}}}{1-p_{\text{compliant}}}}{\frac{p_{\text{non-compliant}}}{1-p_{\text{non-compliant}}}} = 3.03$$

We also have:

p**global** $=p$**compliant** $\times x + p$**non-compliant** $\times (1-x)$

where x is the proportion of compliant patients, assumed to be 50% here. By solving these equations, we find:

- **Effectiveness for compliant patients: 80.6%**
- **Effectiveness for non-compliant patients: 57.8%**

Step 2: Calculating NNT

The formula for NNT is:

$$\text{NNT} = \frac{1}{\text{ARR}}$$

Where ARR is the Absolute Risk Reduction compared to no intervention. Assuming a baseline risk of 26% p(control = 0.26), the ARR values are calculated as follows:

For compliant patients:

$$\text{Relative Risk Reduction (RRR)}_{\text{compliant}} = 80.6\% = 0.806$$
$$p_{\text{intervention\_compliant}} = p_{\text{control}} \times (1 - \text{RRR}_{\text{compliant}})$$
$$p_{\text{intervention\_compliant}} = 0.26 \times (1 - 0.806) = 0.26 \times 0.194 = 0.0504$$
$$\text{ARR}_{\text{compliant}} = p_{\text{control}} - p_{\text{intervention\_compliant}} = 0.26 - 0.0504 = 0.2096$$
$$\text{NNT}_{\text{compliant}} = \frac{1}{\text{ARR}_{\text{compliant}}} = \frac{1}{0.2096} \approx 4.77$$

For non-compliant patients:

$$\text{Relative Risk Reduction (RRR)}_{\text{non-compliant}} = 57.8\% = 0.578$$
$$p_{\text{intervention\_non-compliant}} = p_{\text{control}} \times (1 - \text{RRR}_{\text{non-compliant}})$$
$$p_{\text{intervention\_non-compliant}} = 0.26 \times (1 - 0.578) = 0.26 \times 0.422 = 0.109$$
$$\text{ARR}_{\text{non-compliant}} = p_{\text{control}} - p_{\text{intervention\_non-compliant}} = 0.26 - 0.109 = 0.150$$
$$\text{NNT}_{\text{non-compliant}} = \frac{1}{\text{ARR}_{\text{non-compliant}}} = \frac{1}{0.150} \approx 6.66$$

Therefore, the NNTs are:

- **NNT for compliant patients: approximately 4.77**
- **NNT for non-compliant patients: approximately 6.66**

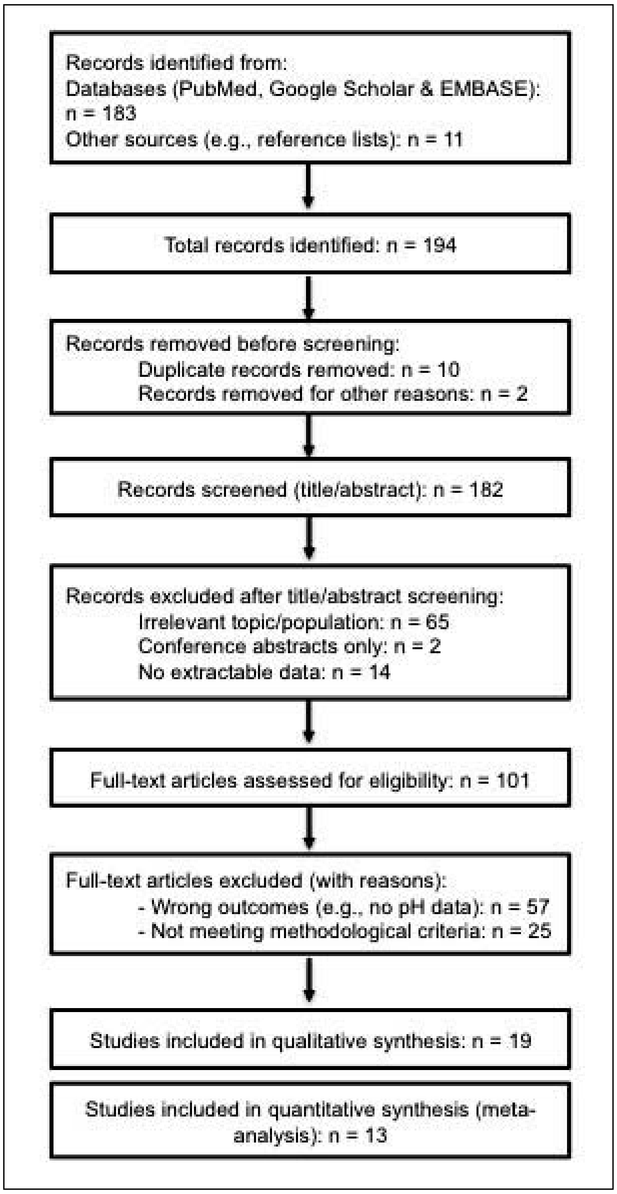

Figure 1.
PRISMA flowchart illustrating the process of screening and selection of studies.

Cost and cost-effectiveness analysis

Cost-performance indices were calculated by dividing the annual device cost by each pooled performance metric. The cost-effectiveness analysis considered one-year horizon in a simulated cohort of 1.000 recurrent stone formers receiving drug prophylaxis with or without urinary pH monitoring. For each of the strategies, total costs and *quality-adjusted life-years* (QALYs) were estimated. Efficiency was expressed as an *incremental cost-utility ratio* (ICUR), calculated as the difference in total costs between two strategies divided by the difference in QALYs. Although in Spain, there is no officially established threshold of willingness to pay, a strategy is usually considered cost-effective when the ICUR versus the alternative option is below a cost-utility threshold of € 25.000/QALY gained (20).

RESULTS

Systematic review and study selection

The literature search initially identified 194 records, from which 10 duplicates and 2 non-relevant entries were removed. After screening the titles and abstracts, 101 articles were selected for full-text evaluation. Of these, 82 studies were excluded due to irrelevant outcomes, insufficient methodological quality, or incomplete data.

Ultimately, 19 studies were included in the qualitative synthesis, and 13 met the criteria for quantitative analyses (Figure 1).

The included studies (7, 11, 21-31) involved a total of 2.801 subjects and evaluated the portable digital pH meter alongside urinary test strips in both clinical and home-use settings. Newcastle-Ottawa scores are shown in Table 3 and detailed study characteristics are described in Table 4.

Table 3.
Prices of different commercial urine test strips.

Author, Year	Selection (max 4)	Comparability (max 2)	Outcome (max 3)	Total NOS score	Overall quality
De Coninck et al., 2018	3	2	1	6 / 9	Good
Angerri et al., 2020	3	2	1	6 / 9	Good
Kwong et al., 2013	3	2	1	6 / 9	Good
Grases et al., 2014	3	2	1	6 / 9	Good
Desai & Assimos, 2008	3	2	1	6 / 9	Good
Johnson et al., 2007	3	2	1	6 / 9	Good
Hekmatynia et al., 2019	3	1	1	5 / 9	Moderate
Ilyas et al., 2015	3	2	1	6 / 9	Good
Omar et al., 2016	3	2	1	6 / 9	Good
Abbott et al., 2017	3	2	0	5 / 9	Moderate
Strohmaier et al., 1997	3	2	1	6 / 9	Good
Wockenfus et al., 2013	3	2	1	6 / 9	Good
Devicare Validation Report, 2016	3	2	1	6 / 9	Good

NOS: Newcastle-Ottawa Scale. Scores are presented as stars awarded per domain according to NOS criteria for non-randomized studies. Studies scoring 6-9 stars were considered good quality, while those scoring 5 stars were considered moderate quality.

Table 4.
Characteristics of included studies assessing urinary pH measurement methods.

Author, Year	Intervention	Comparator	Outcomes (analytical-performance parameters)
De Coninck et al, 2018	Bench pH meter (gold-standard)	Portable digital pH meter (Lit-Control®) Reagent strips (professional and lay reading, electronic strip reader)	Shared variance (R^2): pH meter 0.792 *vs* strips 0.320; Resolution: 0.1 *vs* 0.5 pH units; Bias: 0.010 *vs* 0.170; Correct identification: 78% *vs* 65.7%; Precision (SD) 0.4 *vs* 0.6; Inter-observer agreement: 1.00 *vs* 0.626
Angerri et al, 2020	Bench pH meter (gold-standard)	Portable digital pH meter (Lit-Control®) Multiple reagent strip brands	Shared variance (R^2): pH meter 0.965 *vs* strips 0.924; Resolution: 0.1 *vs* 0.545 pH units; Bias: 0.124 *vs* 0.273; Correct identification: 100% *vs* 50.4%; Precision (SD) 0.23 *vs* 0.61; Inter-observer agreement: 1.00 *vs* UK
Kwong et al, 2013	Bench pH meter (gold-standard)	Reagent strips with electronic reader	Shared variance (R^2): pH meter NA *vs* strips 0.792; Resolution: NA *vs* 0.5 pH units; Bias: NA *vs* 0.281; Correct identification: NA *vs* 58.6%
Grases et al, 2014	Bench pH meter (gold-standard)	Portable digital pH meter (Lit-Control prototype) Reagent strips	Shared variance (R^2): pH meter 0.986 *vs* strips 0.850; Resolution: 0.1 *vs* UK pH units; Correct identification: 100 *vs* 48%
Desai et al, 2008	Bench pH meter (gold-standard)	Reagent strips (3 brands)	Resolution: pH meter NA *vs* 0.5 pH units; Bias: NA *vs* 0.317 to 0.492; Correct identification: NA *vs* 43.2% to 67.2%; Precision (SD): NA *vs* 0.398 to 0.483
Johnson et al, 2007	Bench pH meter (gold-standard)	Reagent strips and pH paper	Shared variance (R^2): pH meter NA *vs* strips 0.884; Bias: NA *vs* 0.239
Hekmatynia et al, 2019	Bench pH meter (gold-standard)	Dipsticks (2 brands)	Shared variance (R^2): pH meter NA *vs* strips 0.167; Inter-observer agreement: NA *vs* 0.860
Ilyas et al, 2015	Bench pH meter (gold-standard)	Strip of pH paper	Bias: pH meter NA *vs* strips 0.388; Correct identification: NA *vs* 36%; Precision: NA *vs* 0.4
Omar et al, 2016	pH meter by electrode (gold-standard)	Dipsticks	Shared variance (R^2): pH meter NA *vs* strips 0.194; Bias: NA *vs* 0.520; Precision (SD): 0.450
Abbott et al, 2017	24 h urine with pH meter (gold-standard)	Multiple dipstick readings	Shared variance (R^2): pH meter NA *vs* strips 0.568; Resolution: NA *vs* 0.500 pH units; Bias: NA *vs* 0.862; Precision (SD): 0.996
Strohmaier et al, 1997	24-h urine pH by dipsticks	Spot urine pH by dipstick	Correlation analyses between spot and 24 h measurements
Wockenfus et al, 2013	Bench pH meter (gold-standard)	Reagent strips with electronic reader	Bias: pH meter NA *vs* strips 0.400; Correct identification: NA *vs* 51.6%; Precision: NA *vs* 0.3
Devicare Validation Report (2016)	Reference laboratory pH meter	Portable digital pH meter (Lit-Control®)	Shared variance (R^2): pH meter 0.994 *vs* strips NA; Resolution: 0.1 *vs* NA pH units; Bias: 0.063 *vs* NA; Correct identification: 96.4% *vs* NA; Precision (SD) 0.098 *vs* NA; Inter-observer agreement: 1.00 *vs* NA

NNA: Not applicable; UK: Unknown.

Analysis of aggregated data

The digital pH meter consistently outperformed reagent strips across all key analytical validity and reliability parameters (Table 5).

Compared with reagent strips, the explained variance with respect to the reference method was 1.8-fold higher, while the systematic bias was 6-fold lower. Moreover, the digital pH meter exhibited near-perfect inter-observer concordance, in contrast to the moderate agreement observed with test strips ($\kappa \approx 0.8$), highlighting its superior precision and reproducibility.

Cost and cost-effectiveness analysis

Table 6 shows the annual cost-effectiveness analyses for the three urinary pH monitoring strategies. The digital pH meter exhibited markedly superior analytical validity (0.970) compared with test strips (0.540), yielding a substantially lower cost-to-validity x reliability ratio (€ 123.70) than either once-daily (€ 245.00) or twice-daily (€ 490.04) test strip use. Assuming an equal effectiveness in pharmacological stone prevention of 0.692 across all methods, the pH meter emerged as the most cost efficient option, with a cost per effective unit of € 178.76, compared to € 354.05

Table 5.
Prices of different commercial urine test strips.

Attribute	Definition	pH meter	Test strips
Shared variance (r^2)	Proportion of explained variance (↑)	0.970	0.540
Resolution (pH units)	Smallest detectable change (↓)	0.100	0.505
Systematic bias (pH units)	Mean absolute deviation from the reference method (↓)	0.060	0.360
Correct identification (%)	Fraction of measurements in the correct clinical band (↑)	95.0	53.0
Precision (SD, pH units)	Dispersion of replicate readings (↓)	0.160	0.450
Inter-observer agreement	Concordance between observers (↑)	1.000	0.800
Variance-ratio (reliability) *	Composite dispersion metric (↑)	1.000	0.126

** Reliability measure is based on the ratio of dispersion of all the performance parameters studied $1/(\sigma^2$ strips$/\sigma^2$ pH meter).*

and € 708.15 for once- and twice-daily test strip usage, respectively. When accounting for the adjunctive use of prophylactic pharmacotherapy, the pH meter consistently remained the most economical strategy, regardless of patient adherence. Among compliant patients (≥ 80% adherence to prescribed doses, with a prevention rate of 80.6%), the pH meter achieved a cost of € 153.47 per episode prevented, approximately half and one-quarter of that required for once- and twice-daily strips, respectively. Although non-compliance (lower prevention rate: 57.8%) increased the absolute costs for all modalities, the relative economic advantage of the pH meter was preserved. Even under reduced adherence, its annual cost-effectiveness rose modestly to € 214 per episode prevented, while still outperforming the alternative monitoring methods by comparable proportional margins.

The Validity × Reliability index was calculated by multiplying the shared variance (r^2) by the inter-observer agreement. The odds ratio for effectiveness in compliant vs. non-compliant patients (3.03) was applied to an effectiveness of 0.692 to estimate the effectiveness of the two groups, assuming an equal group size (w = 0.5).

The economic advantage of the digital pH meter became even more pronounced when the cost savings per prevented lithiasis episode were considered (see Table 6). Among compliant users, the pH meter prevented an episode at a cost of € 590, representing only 25% of the expenditure required for twice-daily strips monitoring and 50% of that for once-daily use. Even under non-compliance conditions, the pH meter consistently remained the most cost-effective preventive strategy. From a healthcare system perspective, the net savings per lithiasis episode prevented exceeded € 4.500 with the pH meter, compared to € 2.500 with the twice-daily strips monitoring (Table 7).

Table 6.

Annual cost-effectiveness according to the performance of pH monitoring devices.

Device/Usage	Annual Cost (€)	Validity × Reliability	Cost-Validity × Reliability (€)	Effectiveness in prevention*	Cost-Effectiveness (€)
pH meter	120.00	0.970	123.70	0.692	178.76
1 test strip/day	105.85	0.432	245.00	0.692	354.05
2 test strips/day	211.70	0.432	490.04	0.692	708.15
According to compliance (Yes/No):					
pH meter (Yes)	120.00	0.970	123.70	0.806	153.47
1 test strip/day (Yes)	105.85	0.432	245.00	0.806	303.97
2 test strips/day (Yes)	211.70	0.432	490.04	0.806	607.99
pH meter (No)	120.00	0.970	123.70	0.578	214.01
1 test strip/day (No)	105.85	0.432	245.00	0.578	423.88
2 test strips/day (No)	211.70	0.432	490.04	0.578	847.82

** This parameter corresponds to the relative reduction in stone recurrence. According to the recurrence rates reported by Ferraro et al. (10), recurrence was 26 episodes per 100 person-years in untreated patients and 8 episodes per 100 person-years in patients receiving pharmacological prevention alone or in combination with pH monitoring (26%-8%)/26% = 0.692 (69.2%). When effectiveness in prevention was stratified by compliance status, the values were taken directly from the real-world observational study by Galán-Llopis et al. (5), which evaluated the impact of treatment adherence on achieving and maintaining a non-lithogenic urinary pH. In that study, 80.6% of compliant patients (defined as ≥ 80% adherence to prescribed therapy) achieved a non-lithogenic pH, compared with 57.8% of non-compliant patients. Thus, expressed as probabilities the values are 0.806 for compliant patients and 0.578 for non-compliant patients.*

Validity refers to the analytical validity of the urinary pH measurement method and is expressed as the proportion of variance explained with respect to the reference laboratory pH meter (shared variance, r^2); Reliability reflects the reproducibility and consistency of measurements rated by the inter-observer agreement; Cost by Validity × Reliability (€) represents the annual monitoring cost divided by the composite performance index (Validity × Reliability), providing a normalized cost per unit of analytical performance; Effectiveness in prevention represents the probability of preventing a lithiasis episode over one year under pharmacological prophylaxis, adjusted for treatment compliance when applicable; Cost-Effectiveness (€) was calculated as the ratio between the annual monitoring cost and the effectiveness in prevention, representing the cost per effective prevention unit.

Table 7.

Cost and saving per lithiasis episode prevented.

Device/Usage	Annual Cost (€)	Cost-Validity × Reliability	NNT	Cost per episode prevented (€)*	Savings per episode prevented (€)
pH meter	120.00	123.70	5.55	686.53	4.536.86
1 test strip/day	105.85	245.00	5.55	1.359.75	3.863.64
2 test strips/day	211.70	490.04	5.55	2.719.72	2.503.67
According to compliance (Yes/No):					
pH meter (Yes)	120.00	123.70	4.77	590.05	4.633.34
1 test strip/day (Yes)	105.85	245.00	4.77	1.168.65	4.054.74
2 test strips/day (Yes)	211.70	490.04	4.77	2.337.49	2.885.90
pH meter (No)	120.00	123.70	6.66	823.84	4.399.55
1 test strip/day (No)	105.85	245.00	6.66	1.631.70	3.591.69
2 test strips/day (No)	211.70	490.04	6.66	3.263.67	1.959.72

** NNT: Number needed to treat.*

** Cost per Episode Prevented is calculated by multiplying the Cost Validity x Reliability by the NNT (Number Needed to Treat to prevent an episode).*

Table 8.
Incremental Cost-Utility Ratio analysis of prevention strategies for urolithiasis (1-year horizon, 1,000 patients).

Strategy	No Prevention	Drug only	Drug + pH Meter	Drug + Strips 1/day	Drug + Strips 2/day
Probability of Lithiasis Episode	0.260	0.080	0.037	0.053	0.045
Total episodes	260	80	37	53	45
Episodes Prevented	0	180	223	207	215
NNT (patients/episode prevented)	-	5.55	4.48	4.84	4.66
Prophylactic Treatment Cost (€)	0	288,000	288,000	288,000	288,000
pH Monitoring Cost (€)	0	0	120,000	105,850	211,700
Lithiasis Treatment Cost (€)	1,358,081.40	418,111.20	193,376.43	276,998.67	235,187.55
Total Cost (€)	1,358,081.40	706,111.20	601,376.43	670,848.67	734,887.55
QALY Loss	20.80	6.40	2.96	4.24	3.60
Versus no prevention					
Incremental Cost (€)	-	-652,210.20	-757,484.97	-688,012.73	-623,973.85
QALYs gained	-	14.40	17.84	16.56	17.20
Incremental Cost-Utility Ratio)		Dominant	Dominant	Dominant	Dominant
Versus Prophylaxis + pH Meter					
Incremental Cost (€)	757,484.97	104,734.77	-	69,472.24	133,511.12
QALYs gained	-17.84	-3.44	-	-1.28	-0.64
Incremental Cost-Utility Ratio)	Dominated	Dominated	-	Dominated	Dominated

NNT, number needed to treat; QALY, quality-adjusted life-years.
Probability of lithiasis episode was derived from published annual recurrence rates: 26% for untreated patients and 8% for patients receiving pharmacological prophylaxis, as reported by Ferraro et al. (10).
Monitoring strategies were modeled as modifiers of effectiveness through improved compliance and achievement of non-lithogenic urinary pH.
Total episodes were calculated by multiplying the probability of lithiasis episode by the simulated cohort size (1,000 patients).
Episodes prevented were calculated as the difference in the expected number of episodes between each preventive strategy and the no-prevention strategy.
NNT represents the number of patients required to prevent one lithiasis episode and was calculated as the inverse of the absolute risk reduction compared with no prevention.
Prophylactic treatment cost (€) corresponds to the annual cost of pharmacological prevention (€ 288 per patient), multiplied by the cohort size.
pH monitoring cost (€) reflects the annualized cost of the monitoring strategy: € 120 per patient for the digital pH meter, € 105.85 for once-daily strips, and € 211.70 for twice-daily strips, multiplied by the cohort size.
Lithiasis treatment cost (€) was calculated by multiplying the expected number of lithiasis episodes by the cost per episode (€ 5,226.39), derived from Lotan et al. (17) and adjusted for inflation.
QALY loss was estimated by multiplying the number of lithiasis episodes by a disutility of -0.08 per episode, based on published SF-6D and EQ-5D data (19).
Incremental cost (€) represents the difference in total costs between each strategy and the comparator (no prevention or drug + pH meter, as specified).
QALYs gained were calculated as the difference in QALY loss between strategies.
Incremental Cost-Utility Ratio was calculated as the ratio of incremental cost to incremental QALYs gained. Strategies that were more effective and less costly were classified as dominant, while those that were less effective and more costly were classified as dominated.

Full pharmacoeconomic estimates

In the analysis of one-year horizon in a cohort of 1.000 recurrent stone formers with no prevention or receiving drug prophylaxis with or without urinary pH monitoring, the pH meter emerged as the only strategy that both reduced total healthcare expenditure below the drug-only benchmark and maximizes health outcomes (Table 8). Total annual costs decreased to near € 601.376 with pH meter monitoring, 15% lower than with once-daily strips, and 18% lower than with twice-daily strips. Moreover, the pH meter achieved the greatest gain QALY (+17.84) and the lowest NNT (4.48) to prevent one recurrence, confirming its status as a dominant strategy, achieving greater effectiveness at a lower total cost than all comparators.

DISCUSSION

This systematic review and economic evaluation demonstrate that digital urinary pH meters, exemplified by the medical device Lit-Control® pH Meter 2.0, provide superior diagnostic accuracy, analytical reliability, and cost-effectiveness compared with traditional reagent dipsticks for urinary pH monitoring in patients with urolithiasis. These findings carry important clinical and policy implications for optimizing individualized prevention strategies, particularly in the long-term management of patients with recurrent urolithiasis receiving pH-modulating therapy.

Among the analytical parameters assessed, measurement resolution emerged as a critical determinant of clinical utility. The portable digital pH meter's fine resolution (0.1 pH units) enables reliable monitoring within the narrow therapeutic range (pH 5.5-6.2) required for effective stone prevention (32). This precision is essential for titrating alkalinizing or acidifying agents to maintain non-lithogenic urine pH values. In contrast, dipsticks – with a resolution typically ≥ 0.5 units – lack the sensitivity to capture clinically relevant fluctuations, limiting their capacity to guide individualized therapy. This shortcoming may perpetuate subtherapeutic urine pH levels, increasing recurrence risk and the need for further medical or surgical interventions (5). Digital pH meters also showed consistently better inter-observer agreement, lower systematic bias associated, and higher reproducibility, supporting their use in both clinical and home settings. Conversely, colorimetric strips are prone to subjective interpretation, and their results can be influenced by multiple factors such as ambient lighting conditions, hydration status, urine concentration and color, immersion time, and variability between brands, or even between batches of the same brand, as previously noted in methodological studies (8). These limitations can reduce patient engagement and self-monitoring adherence, undermining the preventive strategies increasingly recommended in current nephrolithiasis guidelines (3).

From an economic perspective, this analysis revealed that the portable digital pH meter is more effective and less costly than the alternative monitoring strategies. In health economic terms, this represents a dominant result, meaning that the device achieves greater clinical benefit (higher QALYs) while simultaneously reducing overall healthcare expenditure. The portable digital pH meter offers significant economic value, providing substantially higher savings than once- or twice-daily strip testing. As a dominant intervention, formal comparison with commonly accepted willingness-to-pay thresholds in European healthcare systems is not required, thereby representing an unequivocally favorable economic option (20, 33).

This favorable cost-effectiveness profile is particularly relevant given the growing economic burden of stone disease, due to the increasing prevalence, recurrence rates, and treatment costs (34). As reported by *Pietropaolo et al.* (35), the mean procedural costs for managing kidney stone disease can reach € 2.884 for percutaneous nephrolithotomy and € 1.942 for endoscopic laser treatment, with imaging costs (CT scans and ultrasonds) adding several hundred euros per episode. The escalating global incidence of urolithiasis, linked to demographic, dietary, and environmental factors, underscores the urgent need for cost-effective preventive tools capable of alleviating both direct healthcare costs and indirect societal burdens, such as lost productivity and chronic morbidity (36).

The therapeutic efficacy of pH-modulating agents such as potassium citrate and L-methionine is intrinsically dependent on maintaining urine pH within the target range. In a large real-world study, *Galán-Llopis et al.* (5) demonstrated that achieving and sustaining a non-lithogenic urinary pH was independently associated with reduced colic recurrence, with treatment compliance (HR = 0.43) emerging as a decisive predictor of outcome. Reliable and frequent pH monitoring – enabled by digital meters – thus represents a cornerstone of effective prophylaxis. Across all adherence scenarios modeled in this study, the portable digital pH meter consistently achieved the lowest cost per prevented lithiasis episode and generated substantial savings for healthcare systems, exceeding € 4.500 per episode avoided in compliant users.

Beyond economic performance, the integration of connected digital urinary pH meters into mHealth platforms offers a transformative opportunity for remote monitoring, behavioral reinforcement, and adaptive preventive care in urolithiasis management (12). These digital tools enable high-frequency, objective, and real-time pH data capture, allowing clinicians to detect deviations from target values and adjust preventive strategies accordingly (37). This data-driven, personalized approach facilitates early interventions, tailored hydration and dietary recommendations, and optimization of alkalinizing or acidifying regimens before stone-risk thresholds are reached. Digital health tools have already shown improvements in adherence to hydration, diet, and medication routines (9), all of which are critical determinants of recurrence risk. Connected systems such as the Lit-Control® pH Meter 2.0 could thus bridge the gap between patient self-management and clinical oversight, promoting continuous engagement and proactive disease prevention (13, 38).

A key limitation of this analysis concerns the source of the effectiveness estimates used in the economic model. The recurrence rates applied (26 *vs.* 8 episodes per 100 person-years) were derived from studies evaluating pharmacological prevention of recurrent idiopathic calcium nephrolithiasis, primarily using thiazides, citrate, and allopurinol. These pharmacological strategies do not require mandatory urinary pH monitoring, and the reported reduction in recurrence therefore reflects the overall effect of drug therapy rather than the specific impact of urinary pH manipulation. Consequently, the effectiveness parameter used in this study does not quantify the isolated effect of alkalinizing or acidifying treatments on stone recurrence. As a result, the benefits observed in this analysis should be interpreted as those of pharmacological prophylaxis in general, with urinary pH monitoring acting as a supportive tool rather than as a determinant of treatment efficacy. There are additional limitations. First, the included studies displayed heterogeneity in patient populations, device models, and comparator methods. Although random-effects models were applied to account for this variability, residual confounding cannot be excluded. Second, implementation barriers such as patient training, device availability, and the initial investment costs, may limit uptake in low-resource settings. Third, the translation of modeled cost-effectiveness into real-world impact requires structured patient education, clinical training, and health system support. Fourth, the generalizability of our findings to other healthcare systems may be limited, as differences in clinical practice, reimbursement policies, and digital health infrastructure

DECLARATIONS

Ethical approval and consent for participate: *Not applicable. This review used only aggregated data from published studies, no individual patient data were collected.*

Availability of data and material: *This study synthesizes data from publicly available sources. All related data and materials are available from the corresponding author upon reasonable request.*

Competing interests: *B.I. is currently a consultant for Devicare but declares that this relationship started after the completion of the reported work The remaining authors have no relevant financial or non-financial interests to disclose.*

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can significantly influence both feasibility and cost-effectiveness. Finally, pharmacoeconomic estimates were based on the Lit-Control® products pricing, which may differ from alternative digital pH meters and prophylactic treatments in other markets.

Despite these limitations, the evidence presented supports prioritizing digital urinary pH meters as part of modern nephrolithiasis management. Their high analytical resolution, accuracy, precision, sensitivity, specificity, and superior cost-effectiveness position them as the optimal monitoring strategy for both patients and healthcare systems. These findings highlight the potential clinical utility of the portable digital pH meter in the management of urolithiasis. Incorporation of this device into major clinical guidelines could provide clinicians with a reliable, standardized tool for monitoring urinary pH, thereby optimizing patient care. Furthermore, consideration of reimbursement by healthcare systems may facilitate its wider adoption, ensuring that a greater number of patients benefit from evidence-based monitoring strategies. Future studies should explore long-term outcomes and cost-effectiveness to further substantiate its role in routine clinical practice.

CONCLUSIONS

This study suggests the clinical and economic value of digital pH meters in the management of urolithiasis. These devices provide accurate, reliable, and cost-effective urinary pH monitoring, which is critical for implementing evidence-based preventive protocols. Based on the evidence presented, the adoption of advanced digital urinary pH meters may offer meaningful improvements in the secondary prevention of kidney stone disease. Their integration into clinical practice and consideration within guideline recommendations could contribute to enhanced patient outcomes and more efficient use of healthcare resources over the long term. Future research should focus on pragmatic trials assessing long-term clinical outcomes and the integration of these devices with Electronic Health Records, ultimately aiming to optimize individualized care and reduce the global burden of kidney stone disease.

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