ORIGINAL ARTICLE

Evaluation of SCINTIGLO™ as a Point-of-care Device for Urinary Protein Estimation

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Abstract

Background and aim: Early detection and serial monitoring of proteinuria are of utmost importance in the management of diseases such as diabetes, hypertension, and pre-eclampsia. Most current screening tools for proteinuria are qualitative or semiquantitative. SCINTIGLO™ is a low-cost, semiautomated point-of-care (POC) device for urinary microprotein quantification, measuring not only albumin but all residual urinary proteins, thereby providing a more reliable and sensitive assessment of microproteinuria. This study aimed to evaluate the diagnostic accuracy of SCINTIGLO™ as compared to automated analyzers.

Materials and methods: The study was conducted on 46 patient samples, 44 samples spiked with albumin, and 636 blind samples. The blind samples were artificially prepared with known albumin concentrations, but the operators were unaware of these values to ensure unbiased assessment. The results obtained from SCINTIGLO™ for these samples were compared with those from two commercially available dipsticks and a fully automated chemistry analyzer, which is also considered the gold-standard method.

Results: SCINTIGLO™ demonstrated an overall agreement of 84.79% with gold-standard results in patient samples and 81.82% in spiked samples, compared to 67.4 and 47.83% for dipsticks A and B, respectively. In the masked study, SCINTIGLO™ matched 93.19% of prepared sample results with expected values, while dipsticks A and B had match rates of 70.08 and 52.28%, respectively. Across all samples, SCINTIGLO™ demonstrated superior diagnostic performance compared to commercially available dipsticks, demonstrating a sensitivity of 94.2%, specificity of 94.5%, precision of 94.4%, and overall accuracy of 94.3%.

Conclusion: SCINTIGLO™ provides a cost-effective, accurate, and accessible method for early detection of proteinuria, making it a promising alternative to existing diagnostic tools.

Clinical significance: The ability to rapidly and accurately detect urinary proteins is crucial for early diagnosis of renal and cardiovascular complications of hypertension and diabetes, as well as pre-eclampsia. SCINTIGLO™ presents a cost-effective POC solution for early diagnosis and monitoring of proteinuria, particularly beneficial in resource-limited settings, where laboratory-based testing is often inaccessible.

Keywords: Autoanalyzer, Diabetic nephropathy, Dipsticks, Pre-eclampsia, Point-of-care, Proteinuria, SCINTIGLO™.

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Introduction

Proteinuria is a broad term used to describe protein in the urine. Persistent proteinuria is a marker of kidney damage and can indicate early renal disease. It marks an increased risk of renal damage secondary to hypertension and cardiovascular disease. The degree of proteinuria correlates with disease progression.[1] Several chronic and progressive diseases benefit significantly from early detection of proteinuria, allowing timely intervention. Proteinuria is a critical marker in diagnosing and staging CKD.

It is one of the early predictors of cardiovascular diseases as well as renal damage in both diabetic and nondiabetic patients.[2,3] First-stage diabetic renal disease and early glomerular lesions can be predicted by measuring urine albumin concentration.[2–4] Pre-eclampsia caused by hypertension during pregnancy is a significant risk factor for maternal mortality and morbidity.[5] It has been proven that high blood pressure could lead to complications in 10% of pregnancies.[5] This condition, if untreated, may lead to macroalbuminuria and end-stage renal disease (ESRD).[6] Studies show that early-stage screening, medical interventions, and lifestyle changes can stop the development of micro- to macroalbuminuria.[2,3] Diabetic nephropathy, hypertension, urinary tract infection, and primary and secondary kidney diseases are the significant causes of microproteinuria. As per the International Diabetes Federation, by the year 2030, 500 million people are expected to live with diabetes all over the world.[7] India has the second-largest diabetic population, with 69.2 million people living with diabetes.[8] Microproteinuria has a prevalence rate of 10–48%.[7] In a national survey of 124,385 women aged 15–49 years (National

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Conflict of interest: NP and MKP are currently employed by Cutting Edge Medical Devices Pvt. Ltd., which funded this research. However, they were not affiliated with the company during the planning, conduct, or analysis of the study. The employment began after the study was completed. The other authors declare no conflicts of interest.

Family Health Survey-3, 2005–2006), it was found that 39,657 women were affected by pre-eclampsia.[9] Rural–urban and marked geographic variation were found with rates of pre-eclampsia ranging from as low as 33% in Haryana to 87.5% in Tripura.[10]

Nephrotic syndrome is one of the known diseases in adults, with an incidence rate of three new cases per 100,000 each year in adults.[11] It is a relatively rare way for kidney disease to manifest as compared to reduced kidney function or microproteinuria as a complication of systemic diseases, such as diabetes and raised blood pressure.[12]

There are several methods available for the estimation of total urine proteins, including the biuret assay,[13] turbid metric methods using trichloroacetic acid (TCA),[14] sulfosalicylic acid (SSA),[15] or benzethonium chloride (BEC),[16] and protein dye-binding methods utilizing Coomassie brilliant blue (CBB),[17] or pyrogallol red molybdate (PRM).[18] Microproteinuria is detected using electrochemical immunosensors, radioimmunoassays, ELISAs, turbidity analysis, high-performance liquid chromatography, and dipstick-based tests such as Albustix® (Siemens) and Micral-Test® (Roche Diagnostics).

The bicinchoninic acid (BCA) method is also used for the determination of proteins. This method combines the reduction of Cu^{2+} to Cu^{1+} by the protein in an alkaline medium with the colorimetric detection of Cu^{1+} using a reagent containing BCA (Pierce™ BCA Protein Assay Kits, Thermo Fisher Scientific).

In practice, there are many clinically accepted methods with many estimation modalities. In the market, there are devices or tools available for measuring urine protein.

- Automated analyzers: These are standardized equipment used in medical laboratories for the quantitative measurement of urine protein, based on a sensitive dye-binding color reagent (Pyrogallol Red), which can be automated. At low pH, Pyrogallol Red is combined with molybdenum acid. The color change is observed to be blue-purple when it combines with protein. The protein concentration in the sample is directly proportional to the increase in absorbance at 600 nm.[19]
- Roche/Hitachi Urinary/CSF protein: This is an automated method used for *in vitro* tests for descriptive quantitative determination of protein in urine and cerebrospinal fluid (Roche/Hitachi Urinary/CSF Protein, Roche Diagnostics Corp.).
- Urine dipstick: This is the semiquantitative method of determining albumin in urine.[20] During the nonavailability of a standard quantitative technique for determining its concentration, dipsticks are used for screening.[20] These test strips consist of a ribbon, around 5 mm wide, made of plastic or paper. Paper strips are used for mass screening for a single reaction. In these, the reactants are absorbed directly onto the paper. Plastic strips change their color when in contact with the compounds present in urine.[21] The test is more sensitive to albumin as it contains more amino groups to accept the hydrogen ions than any other protein. The protein area of the strip can contain different chemicals depending on the manufacturer's choice. Dipsticks are based on the protein error of indicators principle. At a constant pH, the development of any green color indicates the presence of protein. Color ranges between yellow and yellow-green for "negative" and green to green-blue for "positive" reactions. Yet, the diagnostic accuracy of these dipsticks has not been fully established, and this method remains controversial.

Although these are readily available with on-the-spot information to the clinicians and patients, the cost of these dipsticks is relatively high.[22] In a resource-limited setting like India, there is an urgent need for a low-cost point-of-care (POC) device to enable timely disease detection.[23]

Fig. 1: SCINTIGLO™, a portable analyzer providing quantitative readings of microalbuminuria

This study was designed to evaluate a POC device, SCINTIGLO™, developed by Cutting Edge Medical Devices Pvt. Ltd., incubated in the Indian Institute of Technology, Delhi. SCINTIGLO™ is a POC battery-operated device based on the principles of nephelometry, which detects minute quantities of proteins in urine. The device screens albumin in a urine sample and displays quantitative readings.

The objectives of the study are:

- To compare the results obtained on standard laboratory diagnostic equipment for estimating albumin in urine with the non-standard protein dipsticks.
- To compare the results obtained by the new POC device, SCINTIGLO™, with standard laboratory diagnostic equipment for estimating albumin in urine.

Materials and Methods

This study was conducted at the Department of Laboratory Medicine, All India Institute of Medical Sciences (AIIMS), New Delhi, using fresh urine samples received in the department for evaluation of proteinuria over 4 months from June 2017 to October 2017. Ethical and administrative approvals were obtained in accordance with institutional guidelines (Study code: N-1728).

Description of SCINTIGLO™

As shown in Figure 1, SCINTIGLO™ is a POC device for detecting proteinuria. It is portable and works on the principle of nephelometry. The device operates via a microcontroller and is solar-powered, with built-in batteries. The sample is placed in the device using disposable cuvettes (Figs 2 to 4). Five drops of proprietary reagents are added to 3.5 mL of the sample (Fig. 5). Optoelectronics, that is, the interaction between light and the reagents added to the sample, helps detect the amount of protein. The device generates a one- to twelve-digit unique ID for each sample (which can also be the Aadhaar number issued to citizens of India by the Government of India). This device is one of its kind, which offers quantitative readings of the sample in a few seconds with very high accuracy.

The procedure for setting up the device and preparing the samples is shown in the workflow in Figure 6.

Study Population

For this validation study, two types of urine samples were used:

- Patient samples: 10 mL of leftover urine samples that were received in the lab for measurement of urine proteins were used for the study. The lab reference number was used to trace the analyzer reports for comparison after analysis was completed, as a blinded exercise.
- Artificial sample: Fresh morning urine samples were collected (max volume = 500 mL) in a urine collection pot. An equal volume of the sample was divided into different centrifuge tubes. The therapeutic human normal albumin IP. 20% total protein in soluble form was added to the urine sample in various concentrations with serial dilution.

To assess the device's accuracy and precision, a single-blind study was also conducted using artificial samples. The sample concentration ranged from 0 to 450 mg/dL. This concentration range was taken for a blind study. In this, the individuals performing the test were blinded to the sample's concentration range.

The detailed steps for various sample preparations are depicted in Figure 7.

Fig. 2: 100 cuvette boxes for SCITINGLO™

Fig. 3: Cuvette box

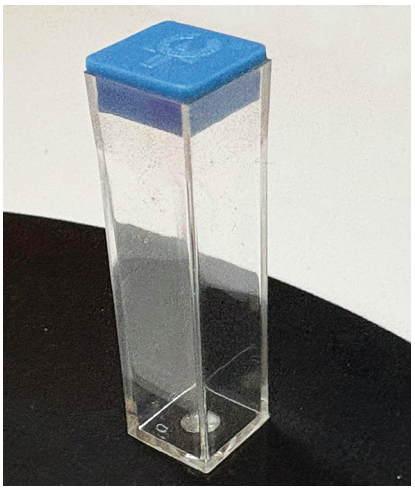

Fig. 4: Proprietary cuvette

Fig. 5: Proprietary reagent

Study Design

A randomized, interventional pilot study was designed to test the accuracy of SCINTIGLO in detecting albumin in urine. The device's results were compared with those of other products on the market, namely dipsticks and an automated analyzer. For this study, two dipsticks were used: URISTIX (manufactured by Siemens, batch no. 012173), marked as dipstick A, and URICHEX [manufactured by Lab Care Diagnostics (India) Pvt. Ltd., batch no. GP-160101], marked as dipstick B. These two dipsticks have been

selected based on randomization and convenience. An automated analyzer with high sensitivity and greater precision was also used for comparison. Its result was considered to be the gold standard and 100% accurate. The automated analyzer was installed in the Department of Laboratory Medicine at AIIMS, New Delhi.

Grading

Urine dipsticks detect microproteinuria qualitatively. They provide a range from 0 to 2,000+ in which the protein could be present. The values in dipsticks are marked as 0, trace, 30+, 100++, 300++, and 2,000+. On the other hand, SCINTIGLO™ provides quantitative analysis. The concentration can range from 2 to 50 mg/dL. To compare the results on the same scale, a grading system was developed for this study, as shown in Table 1. We assigned SCINTIGLO and dipstick grades of I if no protein was present in the sample and 2 if traces were present. We took grade III for SCINTIGLO, while grade II for dipstick, for the sample range between 2 and 5 mg/dL, and so on, as shown in Table 1.

Based on the above grading system, percentages of match and mismatch were calculated by assigning the same results as compared to the automated analyzer with 1 and different with 0 (Table 2).

The sample size was initially calculated using standard formulas for diagnostic studies to reliably estimate sensitivity and specificity. Based on an expected sensitivity of 85% and specificity of 90%, and allowing for a 10% margin for invalid samples, approximately 216 positive and 153 negative samples were required. In the current study, SCINTIGLO™ demonstrated a sensitivity of 94.2%, specificity of 94.5%, precision of 94.4%, and overall accuracy of 94.3%, indicating strong diagnostic performance. The study included 46 patient samples, 44 spiked samples, and 636 blind samples, exceeding the calculated requirements and providing robust statistical power to evaluate the device.

Additional Statistical Measures

Precision-recall (PR) curves were incorporated as an additional statistical measure to illustrate better diagnostic performance,

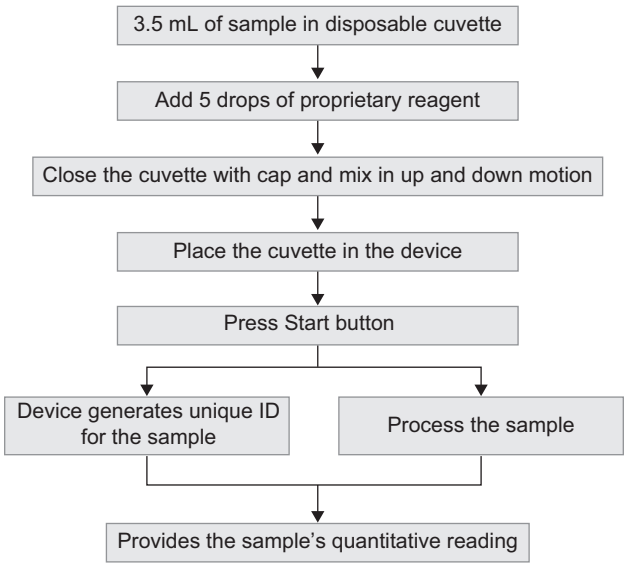

Fig. 6: SCINTIGLO™ workflow

Table 1: SCINTIGLO™ and dipsticks grading system for various ranges of microproteinuria

Ranges (mg/dL)	*SCINTIGLO™*	*Dipsticks A and B*
0 or absent	I	I
Trace	II	II
2 to <5	III	II
5 to <10	IV	II
10 to <20	V	II
20 to <30	VI	II
30 to <50	VII	III
50 to <100	VIII	III
100 to <300	VIII	IV
300 to 2,000	VIII	V
>2,000	VIII	VI

Table 2: Matching and mismatching values

Matching	1
Mismatching	0

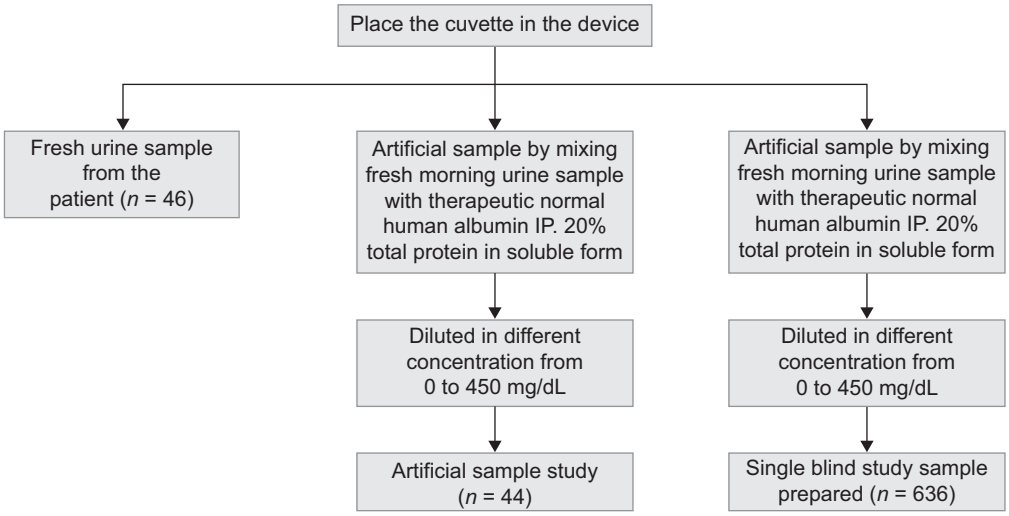

Fig. 7: Sample preparation for SCINTIGLO™

Table 3: Matching percentage of SCINTIGLO™ vs dipstick A and dipstick B with automated analyzer

Sample	*SCINTIGLO™*	*Dipstick A*	*Dipstick B*
Patient sample ($n = 46$)	84.78%	67.39%	47.82%
Prepared sample ($n = 44$)	81.81%	65.90%	38.63%

Table 4: SCINTIGLO™ matching percentage for blind samples

Concentration range (mg/dL)	*Total sample (N = 90)*	*Percentage of match*
0 to <10	46	71.7%
10 to <30	17	94.1%
>30	27	96.3%

especially in datasets with class imbalance. These curves show how precision and recall vary with different decision thresholds, helping to understand how accurately true positive (TP) cases are identified while reducing false positives (FPs).

The Matthews correlation coefficient (MCC) was also included to provide a single, balanced metric that considers all four components of diagnostic classification: TP, true negative (TN), FP, and false negative (FN). This coefficient offers a more reliable evaluation of overall accuracy, even when class sizes are unequal.

Together, PR curves and MCC provide a more comprehensive and robust assessment of diagnostic performance, thereby strengthening the validity of the study's findings beyond simple percentage agreement.

Results

The study was conducted on 46 patient samples, 44 samples spiked with albumin, and 636 blind samples. The results were calculated based on the percentage of match for each of the samples between the automated analyzer (gold-standard values) and all three devices, as depicted in Tables 3 to 5.

The device SCINTIGLO™ demonstrated superior diagnostic performance compared to the two dipsticks, that is, A and B, when compared with the results obtained with the automated analyzer (Table 3). The percentage of match for both the samples was highest with our device. 84.78% of the match was observed with SCINTIGLO™, while 67.39 and 47.82% of matching was obtained for dipsticks A and B, respectively, for the patient sample. For the prepared sample, SCINTIGLO™ achieved an agreement of 81.81% with the expected values, whereas it was 65.90% for dipstick A and 38.63% for dipstick B. The results are also shown in Table 3 and Figure 8.

For the blind sample, SCINTIGLO™ demonstrated superior performance in blind samples relative to dipstick A and dipstick B (Table 4). The matching percentage increases with increasing sample concentration. The percentage is lowest, that is, 71.7% for a concentration range of 0 to <10 mg/dL, while above that it is more than 90%. The highest matching percentage obtained was 96.3% at a concentration range of >30 mg/dL. This result illustrates that SCINTIGLO™ is a much more reliable method to detect the presence of albumin in urine, even in lower concentration ranges, when compared with other methods of detection of microproteinuria.

On a prepared blind sample ($n = 636$), SCINTIGLO achieved an average match of 91.49% when compared with the automated analyzer (Table 5). On varying concentration ranges, the device

Table 5: Matching percentage for SCINTIGLO™ for various concentration ranges for blind sample

S. No.	*Concentration ranges (mg/dL)*	*Number of samples*	*% of match*
1.	Absent	27	0
2.	Trace	84	42.86
3.	2 to <5	119	90.52
4.	5 to <10	83	91.87
5.	10 to <20	83	100
6.	20 to <30	45	100
7.	30 to <50	41	95.13
8.	50 to <100	61	96.73
9.	100 to <300	44	97.73
10.	300–2,000	49	100

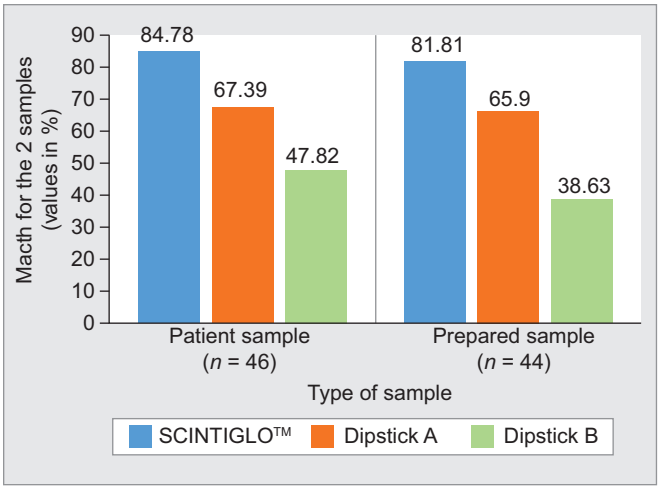

Fig. 8: Comparison of SCINTIGLO™ and the dipsticks with autoanalyzer result

reached the match percentage of 90.52% even at a concentration as low as <5 mg/dL. Accuracy improves with increasing sample concentration. The device shows 100% accuracy at concentrations of 10 to <30 mg/dL and 300–2,000 mg/dL.

From the graph (Fig. 9), it is evident that the device could not detect values below 2 mg/dL, but above that value, the matching percentage is very high. This value is in accordance with Table 4. Values lower than 2 mg/dL are considered negligible and can be ignored.

A PR curve was generated to illustrate the trade-off between precision and recall, with the area under the curve indicating excellent overall performance (Fig. 10).

Discussion

This study aimed to evaluate the effectiveness of a portable device (SCINTIGLO™) for detecting microproteinuria. The device was compared with values obtained from a gold-standard automated analyzer and readily available urine dipsticks.

The presence of protein in urine is the first step in confirming renal disease. Quantitative methods are considered the gold standard in laboratories, and semiquantitative methods are available for detecting microproteinuria. Although the

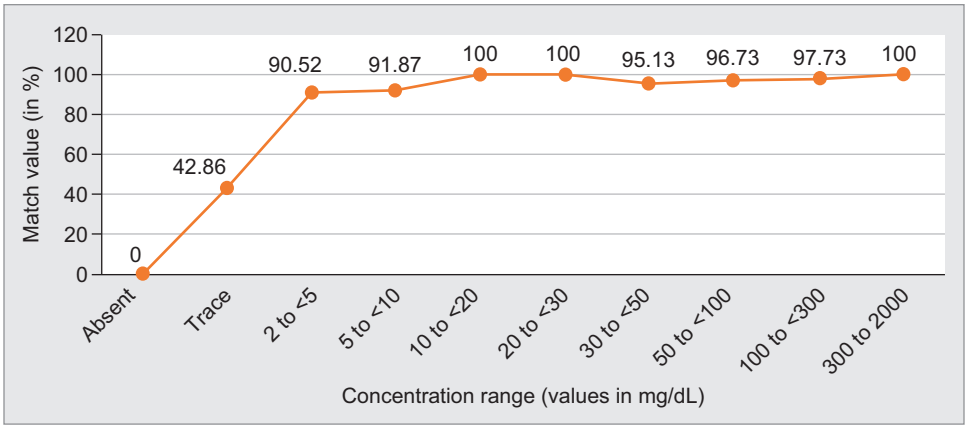

Fig. 9: Percentage of match for different concentration ranges for blind samples for SCINTIGLO

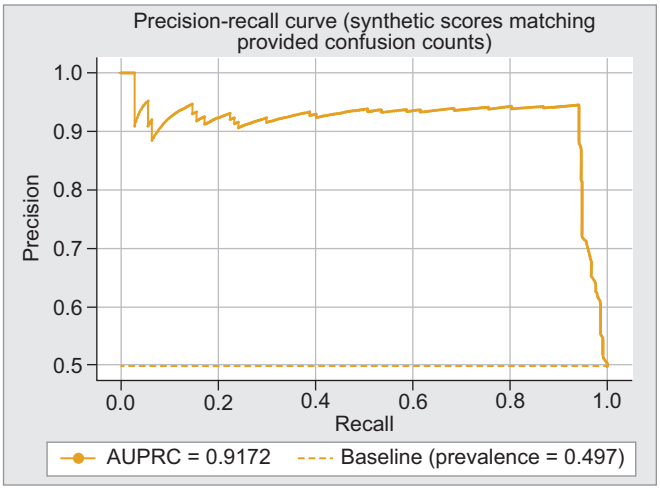

Fig. 10: Precision-recall curve

semiquantitative techniques have been approved by the American Diabetes Association (ADA),[24] several studies have proved their ineffectiveness. There are several limitations to using these dipsticks, given the significant role humans play in interpreting their results. Expiration of the validity period, inadequate storage of strips, exposure to the environment, sample displacement, incorrect interpretation of strip colors, improper insertion of strips into urine, and so on are some of the mistakes that need to be addressed.[25] These dipsticks detect the disease at a very late stage, which could lead to more complications and further increase government healthcare spending. With SCINTIGLO™, these manual issues can be readily avoided. The quantitative results obtained from the device eliminate the need for human interpretation of the test results. Research data show that dipsticks are unable to detect early microproteinuria,[24] whereas SCINTIGLO can detect as low as 2 mg/dL with a matching percentage of 90.52%. The non-efficacy of dipsticks does not make them a reliable source for diagnosis.[24,26] Several studies have shown that the semiquantitative method for detecting microproteinuria is ineffective for accurate identification and discourage its use in primary healthcare settings.[26,27]

In a country like India, the lab tests for microproteinuria cost around Rs. 200–400. In the absence of laboratory tests, patients are advised to use dipsticks due to their easy availability. There is an urgent need for a low-cost POC device to detect microproteinuria and support primary care physicians.

This study is the first of its kind to validate the use of the POC device SCINTIGLO for quantitative measurements. The easy-to-use portable device has achieved an accuracy of above 90% in detecting microproteinuria compared with the gold standard method and dipsticks. The device was observed to quantify urine proteins with high precision over a range from 2 to 50 mg/dL.

With high specificity but low sensitivity, urine dipsticks cannot be considered the sole method for screening renal diseases.[28–31] The positive predictive value of dipsticks reported by Zeller et al. was only 45%.[29] The data from our study also show the same result: The matching percentage of dipsticks for the patient sample and the prepared sample was only 67.39 and 65.90% for A, and 47.82 and 38.63% for B. With our device SCINTIGLO™, the matching percentage was much higher, at 84.78 and 81.81% for patient samples and albumin-spiked samples, respectively, establishing the effectiveness of our device in detecting albumin in urine compared to other available POC methods.

Though dipstick tests have been recommended in some studies as screening tools, urine concentration affects their sensitivity, leaving one in five individuals out. For these reasons, laboratory tests are required to establish the presence of microprotein in urine.[32,33]

Our research data for the device shows an accuracy above 90% across various test methodologies. This portable device gives the quantitative results for microproteinuria detection, eliminating the need for laboratory confirmation. The high accuracy achieved with our device also makes it a suitable option for implementation in a resource-limited setting.

Our study has some limitations, as we tested a few patient samples to diagnose the condition. This was conducted in a tertiary government hospital, but it is required to be validated in primary healthcare settings, especially in rural areas. The comparison was performed with only two dipsticks due to limited time and resources, but such studies can be conducted with a larger number of dipsticks.

Conclusion

The study was conducted in a hospital setting, and SCINTIGLO™ demonstrated reliable diagnostic performance in the

semiquantitative assessment of microproteinuria. Hence, this device may now be evaluated in a rural/community setting. Our results recommend the use of the portable quantitative device SCINTIGLO™ for diagnosing microproteinuria in the absence of laboratory testing. As the dipsticks are not a reliable detection method, the SCINTIGLO device could be successfully implemented, especially in a resource-limited setting. This device enables healthcare workers to make informed decisions for diagnosing and monitoring several prevalent diseases in India, especially at the rural/community levels.

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