Original Article

Benchmarking Rapid Screening Kits versus Iodometric Titration for Iodine Quantification in Household Salt

Abstract

Background: Iodine deficiency remains a significant public health issue. Despite universal salt iodization efforts in Razavi Khorasan Province, accurate monitoring of iodine content in salt continues to pose challenges. This study evaluates the precision and accuracy of rapid screening kits compared to iodometric titration—the gold standard—for quantifying iodine in household salt, aiming to improve monitoring strategies in the region. **Materials and Methods:** This cross-sectional study was conducted in 2024, collecting 153 household salt samples from areas affiliated with Mashhad University of Medical Sciences. Iodine content was measured using the Waheb iodine test kit, which provides both qualitative and quantitative results. These were compared with iodometric titration. Iodine levels were classified according to WHO/UNICEF/IGN guidelines and Iranian National Standards. Statistical analysis included sensitivity, specificity, positive and negative predictive values, and Cohen's kappa coefficient to assess agreement between methods. **Results:** The mean (SD) iodine concentration measured by the rapid screening kits was 35.75 (13.85) µg/g, while iodometric titration showed 58.38 (31.45) µg/g. The rapid screening kits demonstrated a sensitivity of 84.91% (95% CI: 72.41–93.25%), specificity of 20.00% (95% CI: 12.67–29.18%), positive predictive value of 80.94%, and a negative predictive value of 24.88%. Agreement between methods was poor (Cohen's kappa = 0.037). **Conclusions:** Despite their convenience, rapid screening kits show limited reliability in accurately assessing iodine levels in table salt. The significant discrepancy with iodometric titration highlights the need for improved quality control and development of more accurate rapid testing tools to effectively prevent and control iodine deficiency.

Keywords: *Iodine, rapid diagnostic tests, sensitivity and specificity, sodium chloride, thyroid diseases, titrimetric*

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Introduction

Iodine deficiency remains a significant global public health challenge, as documented by Hatch-McChesney and Lieberman.[1-5] Forty years ago, Iran was one of the counters with most severely affected by iodine deficiency disorders (IDDs), with endemic goiters reported in many regions. The first official reports in 1968 estimated the prevalence of goiters at 10–60%.[3,6] Despite awareness of this issue since 1968, it was formally declared a public health problem in 1980.[7] In the 1990s, the World Health Organization (WHO), UNICEF, and the International Council for the Control of IDDs introduced the Universal Salt Iodization (USI) program to combat IDDs.[1] By monitoring iodine status through urine tests and salt iodine content, countries can effectively track progress towards the elimination of IDDs and ensure optimal health outcomes for their populations.[8] Iran adopted the USI program in 1994, making iodization of household salt mandatory. By 2018, iodized salt consumption reached up to 98% in some regions, contributing to a major reduction in iodine deficiency and hypothyroidism rates globally.[4] However, recent data from Mashhad University of Medical Sciences (MUMS) reveal concerning trends, such as decreased iodized salt consumption and increased neonatal hypothyroidism rates.[9] Neonatal hypothyroidism rates rose from 5.34 to 7.1 per 1,000 live births between 2020 and 2024, surpassing the national average of approximately 4 to 5 per 1000 live births. Additionally, according to self-reported data, iodized salt consumption among

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households covered by MUMS has declined from over 90% to around 80%.[9] To monitor salt iodization programs and evaluate their effectiveness, accurate and efficient methods for assessing iodine levels in salt are essential[10]; however, due to economic sanctions against Iran, these kits were unavailable for several years, leading to heavy reliance on less reliable self-reported data.

This study assesses the accuracy of rapid screening kits for measuring iodine levels in table salt by directly comparing their performance with the gold-standard iodometric titration method. Although these kits are practical for large-scale monitoring, significant discrepancies with the titration results have raised concerns about their accuracy.[10,11] By comparing these methods, this research aims to improve iodine monitoring accuracy, enhance quality control of salt iodization programs, and address gaps in iodine deficiency management.

Beyond the technical aspects, this study also relates closely to nursing practice, especially in public health contexts. Nurses play a crucial role in educating communities about the importance of consuming iodized salt, monitoring iodine status, and addressing nutritional health at individual and population levels. Furthermore, primary healthcare providers are at the forefront of implementing and evaluating public health programs aiming to reduce iodine deficiency, ensuring accurate iodine monitoring, and promoting preventive measures within local communities.

This study is designed to evaluate the precision and accuracy of rapid screening kits for quantifying iodine in household salt, using iodometric titration as the gold standard. The primary aim is to determine the viability of these kits as an alternative method for improving monitoring strategies. The successful validation of a rapid and reliable testing method is crucial for effective public health surveillance. The findings of this research will therefore empower healthcare professionals, including nurses, and policymakers to deliver more effective services and contribute to better health outcomes through improved, evidence-based iodine-related interventions.

Materials and Methods

This cross-sectional study aimed to evaluate the accuracy of rapid screening kits compared to the gold-standard iodometric titration method for assessing iodine levels in table salt. The study was conducted in 2024 in the regions affiliated with MUMS, Iran, including the city of Mashhad and other areas in northeastern Iran near the borders of Afghanistan and Turkmenistan.

The sample size was calculated based on an expected proportion of iodine-sufficient salt (p) of 0.8, derived from a previous study.[4] A 95% confidence level (Z = 1.96) and a 7% margin of error (d = 0.07) were used for this calculation. The initial sample size was then inflated to account for potential non-responses or unusable samples and to ensure adequate power for the diagnostic accuracy analysis, resulting in a final sample size of 153 salt samples.

Accordingly, this number was deemed sufficient for the study. Samples were selected randomly from households within the population covered by MUMS to ensure representativeness.

Iodine was measured using two methods: a rapid screening kit operated by experts involved in the salt iodization program; the gold-standard iodometric titration method conducted at the Food and Drug Administration office of MUMS. Salt iodine levels were categorized according to WHO/UNICEF/IGN standards[12] as either acceptable (30–60 μg/g) or unacceptable (<30 μg/g or > 60 μg/g). The Iranian National Standard (INSO 1195) also specifies this same range of 30–60 μg/g iodine in salt samples.[13] By adhering to the national standard, we contribute to the global effort to eliminate IDDs and improve public health.

After sample collection, each salt sample was immediately placed in an airtight, opaque container to prevent iodine volatilization and degradation. Samples were stored in a cool, dry, and dark environment until analysis. To prevent bias, all samples were labeled with unique codes, and laboratory personnel performing both the rapid test kit and the iodometric titration were blinded to sample identity and to each other's results. Iodine measurement was performed using the Waheb iodine test kit (KIAN, Iran), which provided both qualitative and quantitative assessments. To ensure the accuracy and reliability of the analyses, several quality control measures were implemented. All equipment, such as pipettes, volumetric flasks, and spectrophotometers, was calibrated in accordance with standard operating procedures. Standard iodine solutions were prepared using high-purity chemicals and were standardized against a certified reference material. Background interference was addressed by performing blank determinations, and reproducibility was ensured by analyzing all samples in duplicate. Furthermore, the laboratory participated in proficiency testing to assess the accuracy and precision of its analytical methods. Box plots were used to visually assess the distribution, variability, and presence of outliers in iodine measurements obtained by both the rapid screening kit and the iodometric titration method. The box represents the interquartile range (IQR) from the first (Q1) to third (Q3) quartiles, with the internal line indicating the median (Q2). Whiskers extend to the maximum and minimum values within 1.5 × IQR, and points beyond this range are depicted as individual outliers. Statistical analysis compared the screening kits against the iodometric titration method using several performance parameters.[14,15] Sensitivity measured the proportion of true positive (iodine-sufficient) samples correctly identified by the screening kit, while specificity measured the proportion of true negative (iodine- deficient) samples correctly identified. Positive predictive value (PPV) and negative predictive value (NPV) were calculated to evaluate the clinical utility of the screening process.[14] Accuracy was defined as the proportion of correctly classified samples (both true positives and true negatives).[14] Agreement between the screening kit and titration methods was assessed using Cohen's kappa coefficient.[15]

The Kappa agreement was classified as follows: values less than 0.00 indicated no agreement; 0.00–0.20 indicated slight agreement; 0.21–0.40 indicated fair agreement; 0.41–0.60 indicated moderate agreement; 0.61–0.80 indicated substantial agreement; and 0.81–1.00 indicated almost perfect agreement.

Ethical considerations

This research was approved by the Ethics Committee of MUMS (Ethics ID: IR.MUMS.REC.1402.174). Ethical guidelines were followed, and informed consent was obtained from all participants.

Results

Figure 1 presents iodine level distributions measured by both methods using box plots. The screening kit and iodometric titration methods showed significantly different iodine level results. The screening kit yielded a mean (standard deviation**)** iodine concentration of 35.75 (13.85), µg/g whereas the iodometric titration method indicated a higher mean of 58.38 µg/g with a larger standard deviation of 31.45 µg/g. Additionally, iodometric titration showed a wider range of iodine values (0 to 148.1 µg/g) compared to the screening kit's range (0 to 50 µg/g).

The box plots clearly demonstrate that the IQR—that represents the middle 50% of values—is significantly larger for the iodometric titration method, indicating a wider spread and greater heterogeneity in the measured iodine levels. the IQR—that represents the middle 50% of values—is significantly larger for the iodometric titration method, indicating a wider spread and greater heterogeneity in the measured iodine levels. Moreover, several outliers were observed in the iodometric titration data, suggesting that this method may be more sensitive to extreme values. These outliers likely reflect the inherent variability in iodine concentrations among certain salt samples or technical variations in the titration process.

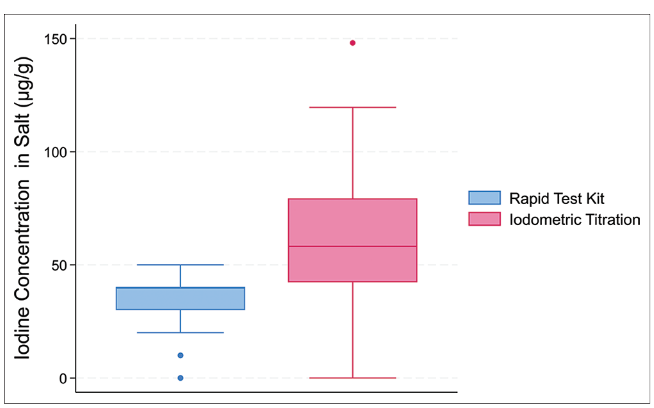

Figure 1: Distribution of iodine concentration in salt: Results from iodometric titration versus rapid test kits (µg/g)

Table 1 summarizes the diagnostic performance of the screening kit compared to the gold standard iodometric titration. The screening kit demonstrated relatively high sensitivity (84.91%) for detecting iodine-deficient salt samples. However, specificity was low (20.00%), resulting in many false positives; that is, the kit frequently misclassified iodine-deficient samples as sufficient, despite correctly identifying many true sufficient cases. The positive likelihood ratio (LR+) of 1.06 indicates that a positive test result only slightly increases the probability of true iodine deficiency. Since this value is close to 1, it suggests limited diagnostic usefulness. Similarly, the negative likelihood ratio (LR−) of 0.75 indicates that a negative result moderately decreases the likelihood of iodine deficiency.

PPV was approximately 80.94%, implying that around 81% of positive test results correctly reflected sufficient iodine levels. In contrast, the NPV was 24.88%, indicating that negative test results are less reliable. Overall, about 72% of samples were correctly classified by the screening kit.

As shown in Table 2, agreement between the screening kit and the iodometric titration method was minimal. The Cohen's kappa value was close to zero and not statistically significant, suggesting that the observed agreement is likely due to chance rather than consistent concordance.

Discussion

IDDs remain a significant public health concern, especially in developing countries where routine monitoring of salt iodine content is essential to ensure effective prevention strategies.[13] Although Iran has made substantial progress in eliminating IDDs through USI programs,[4] recent economic sanctions and domestic financial constraints have severely impinge upon the implementation of the USI program. The inability to conduct routine monitoring of salt iodine content has created a data gap regarding the iodine status of the population.[9] Consequently, recent assessments of iodine intake have primarily on self-reported salt consumption rather than direct measurement. This study aimed to compare the performance of a rapid kit with the gold-standard iodometric titration method for quantifying iodine levels in table salt. Our results revealed a significant discrepancy between iodine concentrations measured by the rapid screening kit and those obtained by iodometric titration. The screening kit reported a significantly lower mean iodine level (35.75 µg/g) compared to the iodometric titration method (58.38 µg/g),

Table 1: Diagnostic performance of the rapid salt iodine test kit compared to the gold standard iodometric titration

Statistic	Value	95% CI
Sensitivity	84.91%	72.41%–93.25%
Specificity	20.00%	12.67%–29.18%
Positive Likelihood Ratio (LR+)	1.06	0.91–1.23
Negative Likelihood Ratio (LR−)	0.75	0.36–1.60
prevalence of insufficient iodine in salt (*)	80.00%	
Positive predictive value (*)	80.94%	78.51%–83.14%
Negative predictive value (*)	24.88%	13.54%–41.20%
Accuracy (*)	71.92%	64.10%–78.88%

*These values are dependent on prevalence of issue.
CI=Confidence interval

Table 2: Agreement between the rapid test kit and the iodometric titration methods

Agreement	Expected agreement	Kappa	Standard error	*Z*	*p*
42.48%	40.26%	0.03	0.04	0.75	0.22

which also exhibited greater variability, a indicated by a larger standard deviation (31.45 μg/g) and broader range (0 to 148.1 μg/g).[11] The screening kit demonstrated high sensitivity (84.91%) but low specificity (20%), leading to a high rate of false positives. Furthermore, the Cohen's kappa coefficient ($\kappa = 0.03$) indicated poor agreement between the two methods, suggesting that rapid screening kits cannot reliably replace iodometric titration for accurate salt iodine assessment.

The elevated false-negative rate poses a significant public health risk, as misclassified iodine-deficient salt as sufficient could delay or omit crucial interventions for iodine deficiency.[16] Vulnerable groups, including pregnant women and children, are at increased risk of IDD-related complications such as goiter, hypothyroidism, and impaired cognitive development.[2,3] Given these concerns, screening kits should be used cautiously in large-scale salt iodization programs. Prior to widespread adoption, they require thorough validation to ensure accuracy and reliability, despite their cost-effectiveness and convenience. Several factors may contribute to the observed discrepancy between screening kits and iodometric titration, including variations in kit sensitivity, iodine loss during storage, and interference from other substances in salt.[17] Inconsistent iodine levels in the salt itself, caused by production processes, storage conditions, and regulatory compliance, may also influence the results of both methods.[11,16,18] Additionally, both methods may be influenced by inconsistent iodine levels due to production processes, storage conditions, and regulatory compliance.[11,16,18] Comparison with similar studies support these findings. For example, a recent study in Ethiopia (Hailu *et al*., 2022) validated a rapid test kit and reported a high sensitivity of 97.5% but a lower specificity of 79.6%,[19] a finding consistent with our observation. Conversely, a comprehensive comparative validation study demonstrated that some modern rapid test kits can achieve excellent performance, reporting sensitivity, and specificity values as high as 97% and 95%, respectively,[20] demonstrating that kit performance can vary depending on regional and methodological factors. Differences in PPV and NPV across studies further suggest that screening kit effectiveness is influenced by specific testing conditions.[19,21]

The low agreement between screening kits and iodometric titration underscores the need for caution when relying on rapid screening methods for salt iodization monitoring. To ensure effective monitoring, accurate iodine assessments, standardized procedures for sample collection and analysis, thorough training for personnel, and regular quality control checks are essential.[16] Moreover, enhanced monitoring and regulation of the salt industry are necessary to address iodine variability.[11,21] Quality control measures, strict adherence to fortification standards, and routine inspections of salt production facilities can help maintain consistent iodine levels. Identifying factors contributing to discrepancies between screening kits and iodometric titration is critical for developing more reliable iodine assessment methodologies.

This study has certain limitations. Although the sample size was sufficient to detect a significant difference between methods, a larger sample could yield more robust results. Additionally, the study was conducted exclusively in one Iranian province, which may limit the external validity of the findings to other regions due to potential regional differences in industrial salt extraction methods and environmental factors. The low agreement observed between iodometric titration and rapid screening kits highlights the need for caution in using these kits for large-scale of salt iodization monitoring.

Conclusion

The findings of this study demonstrate a significant lack of agreement between rapid screening kits and the gold-standard iodometric titration method for quantifying iodine in table salt; the rapid kits not only systematically underestimated iodine concentrations but also exhibited poor specificity, resulting in a high rate of false positives, and consequently their utility for precise public health monitoring is severely limited. Based on these results, we conclude that iodometric titration must remain the primary method for assessment, particularly for confirmatory analysis of borderline or negative results, while concurrently targeted efforts to enhance the accuracy of rapid kits and implement robust quality assurance protocols are essential. This research provides crucial empirical evidence to guide policymakers in refining IDDs prevention strategies, ensuring that monitoring programs are grounded in reliable and accurate data.

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Conflicts of interest

Nothing to declare.

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