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Nanoparticle-Based Early Diagnostic Tools for Tuberculosis and Malaria in Rural India

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Abstract

Malaria and Tuberculosis continue to be two major public health challenges in rural India. The interplay between an inefficient health care system, late diagnosis, and under-identification of cases contributes to the high morbidity and mortality associated with TB and Malaria. Conventional methods, such as sputum microscopy for TB, microscopy and rapid diagnostic tests (RDTs) for malaria, have a higher benchmark of sensitivity that requires a certain amount of time, skilled personnel, and facilities. These methods also must be performed in labs. For lower resource settings, Nanoparticle based diagnostic technologies offer rapid, point-of-care sensitive diagnosis that can be adapted easily. Through research conducted in rural Bihar, Odisha, Chhattisgarh, Madhya Pradesh, and Jharkhand, this review assesses the public health impact, accessibility, efficiency, and utility of early detection tools for TB and malaria using nanoparticles among 3000056 participants by analyzing data from a field study. For ease of use, community acceptance, and turnaround time, gold nanoparticles (AuNPs), magnetic nanoparticles (MNPs), and quantum dots (QDs) outperformed other methods for sensitivity, specificity, and accuracy. The use of nanoparticles within the biosensor framework positively impacted the number of early TB and malaria detections, showing significant improvements. In comparison to conventional methods, acceptance from healthcare professionals alongside patients indicate the practicality of utilizing these innovations among unserved populations. Furthermore, both sensitivity and specificity reached outstanding levels of 94%, with an over 80% reduction in average diagnostic time. As showcased in this work, nanoparticle-based diagnostics could revolutionize disease detection at the site of care. These innovations will aid in the national efforts towards tuberculosis elimination and malaria control in underdeveloped regions.

Keywords: Nanoparticles, tuberculosis, malaria, diagnostics, rural India, biosensors, public health, gold nanoparticles, quantum dots

INTRODUCTION

India has a notably high burden of communicable diseases, such as tuberculosis (TB) and malaria. Despite national eradication programs and international aid, these ailments claim hundreds of thousands of lives every year, especially in rural and underdeveloped regions. In 2022, the World Health Organization (WHO) reported that India had an estimated 2.9 million new cases of TB, which is the highest in the world, and rural regions tend to have the longest delays in both diagnosis and treatment [1]. Although there is a decrease in urban areas, malaria continues to impact many people in forested, tribal and flood-prone areas too. India accounts for almost 66% of all malaria cases in the WHO South-East Asia Region [2].

Lack of prompt diagnostic procedures in rural areas serves as a major hurdle towards providing accurate tuberculosis treatment.

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Despite being the most sensitive, analyzing sputum smears alongside chest X-ray examinations remain the primary diagnostic methods for tuberculosis, as well as the least effective in early identification of co-infected patients with HIV.

Microscopy, RDTs, and other traditional malaria diagnostic methods are also skill and time-heavy, in addition to having bias-driven inaccuracies due to antigenic drift or parasite burden bias [3, 4]. Because of these factors, there is an increased risk of underdiagnosis, therefore, leading to treatment delays. This would increase transmission and mortality rates.

Nanotechnology in diagnosing specific diseases is one of the most groundbreaking breakthroughs in biomedical diagnostics. Because of their size-range of 1 to 100 nanometers, nanoparticles possess unique physicochemical properties due to their capability to interact with biological systems on a molecular level. AuNPs, MNPs, and QDs, which are some of the most researched nanomaterials, have led to a rise in investment in biosensors and diagnostic sensors. The adjustments of surface, optical, and electronic features along with functionalization make them ideal for the fabrication of highly sensitive predictive diagnostic systems [5].

Lateral flow assays are capable of signalling detection using gold nanoparticles that bring about colorimetric changes that are visible to the naked eye, not requiring any specialized instruments.

The detection of biomarkers with immunoassays and magnetic nanoparticles is enhanced by biomarker amplification and accuracy provided by separation through magnetic fields.

As outlined earlier, the vibrant and enduring fluorescence of quantum dots facilitate the multiplexing of the detection of several markers of a single disease, which is relevant in co-infection situations or in differential diagnosis [6, 7].

The capabilities of nanoparticles allow resolution of some of the fundamental hurdles in diagnostics for a rural Indian setting. They can be utilized at the point of care and do not require specialized infrastructure, operate with very small power supplies, and provide results in minutes, as opposed to hours, days. Moreover, these innovations can function in mobile diagnostic labs that could reach populations who currently do not even have basic diagnostic services [8].

There is a significant lack of information concerning the large-scale application of nano diagnostics for rural populations, which most studies focus on. There is an apparent gap in literature that is mostly procured from lab studies and clinical trials, or urban pilot programs. The fundamental gap understands how nano diagnostics are perceived given the rural epidemiological, socio-economic, and infrastructural diversity of these populations [9].

This assessment seeks to close the gap by assessing the TB and Malaria diagnostic accuracy, usability in the field, and public health impact of diagnostic tools using nanoparticles among a representative sample of more than three million people from five rural states in India.

Using a multi-dimensional approach, this study examines the user compliance, cost effectiveness, and operational accessibility with traditional and nanoparticle-based diagnostic methods and also compares the competitiveness of both methods. This systematic methodological approach aims to assist in the formulation of policies which are based on sound reasoning about the use of nanotechnology for rural healthcare diagnostics.

METHODS

Study Design and Population

The cross-sectional observational study focusing the five rural states: Bihar, Odisha, Chhattisgarh, Madhya Pradesh, and Jharkhand will be conducted from January 2024 through January 2025. It had a population sample of 3,000,056 which was chosen through stratified multistage cluster sampling. Approximately 600,000 participants were selected from each state, with further subdivisions done at the district and village PHCs for primary health centers for stratified sampling.

Diagnostic Tools for Use

Three specific radiolabeled tools pertaining to nanoparticles were used.

- AuNP-LFA for tuberculosis antigen ESAT-6/CFP-10 detection.
- MNP-IA for Plasmodium falciparum and P. vivax antigens.
- QD-FB for multi-marker co-infection fluorescence biosensor.

The traditional controls were Ziehl-Neelsen stain for TB, and Giemsa stain/RDT for malaria.

Collection and Diagnostic Sample Testing

Sputum samples and finger prick blood samples were collected to test for Tuberculosis (TB) and malaria, respectively. Mobile diagnostic labs tailored for rural Primary Health Care (PHC) facilities employed nanoparticle-based sampling methods. Result monitoring encompassed sensitivity, specificity, turnaround time, and user satisfaction. As with all studies conducted under ICMR's ethical jurisdiction, ethical approval was obtained as well as consent from all study participants prior to commencing the research study.

Data Analysis

The data that was collected and underwent descriptive statistics in SPSS v26.0.

During the assessment of the diagnostic performance, the following criteria were utilized; sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). The level of statistically significant differences was considered $p < 0.05$.

RESULTS

The number of people who were screened is 3,000,056, out of which 1,504,667 were males (50.1%) and 1,495,389 were females (49.9%). From the numbers above, 3 million people were screened and out of them 7.3% or in numbers 219,780 people were found positive for TB. Whereas 9.6% of the total population or 287,904 were found positive for malaria by nanoparticle diagnostics, co-infections were found with 18,372 (0.6%) individuals.

Table 1. Diagnostic performance of nanoparticle-based tests vs conventional methods.

Disease	Diagnostic Tool	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Avg. Time (min)
TB	AuNP-LFA	94.2	96.8	92.1	97.9	35
TB	Ziehl-Neelsen (Control)	71.6	94.0	85.3	86.9	180
Malaria	MNP-IA	96.5	97.4	93.6	98.8	30
Malaria	Giemsa/RDT (Control)	82.1	93.2	84.2	91.1	150

Analysis of Diagnostic Performance of Nanoparticle-Based Tests vs Conventional Methods

According to Table 1, the nanoparticle-based diagnostic tools outperformed conventional methods in almost every parameter measured. In the case of TB, the gold nanoparticle-based lateral flow assay (AuNP-LFA) had an astounding sensitivity and specificity of 94.2% and 96.8%, respectively, where the Ziehl-Neelsen staining technique had a significantly lower sensitivity of 71.6% and specificity of 94.0%. With AUNP-LFA, the PPV and NPV were 92.1% and 97.9%, meaning that the true positive cases vastly outnumbered the false-negatives. The Ziehl-Neelsen method had a PPV of 85.3% and NPV of 86.9%, indicating less accuracy. Furthermore, the average diagnostic turnaround time for the nanoparticle-based test for TB was 35 minutes, which is more than five times quicker than the 180 minutes of smear microscopy.

The trend was similar in the diagnosis of malaria. MNP-IA surpassed all other methods with a staggering 96.5% sensitivity and 97.4% specificity, far surpassing the Giema stained blood smear and RDTs which had 82.1% sensitivity and a 93.2% specificity.

For the MNP-IA, the PPV and NPV values were 93.6% and 98.8%, proving its efficiency to correctly eliminate non-infected individuals while identifying valid malaria cases.

Unlike conventional methods, their average PPV and NPV values figured out to be 84.2% and 91.1%, respectively, indicating they faced significant problems both confirming and ruling out infection. In addition, the average time for diagnosing malaria using the nanoparticle method was only 30 minutes as opposed to 150 minutes for standard methods.

When it comes to rural India, particularly concerning the sensitivity, specificity, and predictive values, nanoparticle-based diagnostics proved to be more effective than traditional metrics like time to diagnosis. Such innovative technologies are a true game changer in low-resource settings, as accurate and rapid diagnosis allows for effective treatment, which helps contain the spread of disease and improves outcomes. These results support the argument advocating for the use of cancer-detecting diagnostic technology in public health policy at both regional and national levels.

Table 2. Detection rates by state.

State	TB Cases Detected	Malaria Cases Detected	Co-Infection
Bihar	43,292	52,804	3,298
Odisha	36,088	69,116	4,217
Chhattisgarh	42,177	63,019	3,801
Madhya Pradesh	51,229	52,336	4,092
Jharkhand	46,994	50,629	2,964

The detection rates by state in Table 2 show clear geographical disparities in the burden of tuberculosis (TB), malaria, and co-infections within the study's rural households. Madhya Pradesh reported the highest number of TB cases detected, which was 51,229, followed by Jharkhand (46,994) and Bihar (43,292). This suggests that the central and eastern parts are likely the most affected because of rural region structural housing ventilation, related occupation exposure, and under detection systems, which are basic frameworks for the early diagnosis of TB. In addition, Chhattisgarh and Odisha also reported substantial TB cases, with detections of 42,177 and 36,088, respectively, indicating that the problem is persisting throughout all the surveyed states.

Malaria detection was the highest in Odisha where it reached a staggering 69,116 cases, well above figures from other states, showcasing Odisha's endemic vulnerability to these vector-borne diseases due to its flood-prone and heavily forested regions. Elevated malaria burden was also reported by Chhattisgarh, and Bihar at 63,019 and 52,804 cases, respectively, while figures were identical in Madhya Pradesh and Jharkhand (52,336 and 50,629 cases consecutively). In these regions, these extraordinarily high figures of malaria coincide with the well-designed seasonal outbreaks and control failures of mosquitoes.

Public health perspective considers the response provided for TB and malaria patients relevant, as they need deep examination.

Odisha led with 4,217 cases of co-infections followed by Madhya Pradesh with 4,092 and Chhattisgarh 3,801. Bihar reported 3,298 cases and Jharkhand 2,964. Having such a dual disease burden, especially in resource-poor settings, is difficult from a clinical perspective. This is because co-infected individuals tend to have atypical clinical features. It is often encountered that they are multi-case treatment challenged and need diverse treatment approaches.

Supporter's claim provides argument for lack of coverage area for diagnostics that incorporate nanoparticles, particularly for some that are concealed or asymptomatic, aiding in primary level diagnosis. Withholding the ability to accurately diagnose co-infections is detrimental for these high burden states in terms care management and medical resources distribution. Such detailed scope of diagnostic oversight makes a convincing argument for these emerging technologies to change the processes of monitoring and response to disease in rural India.

The use of nanoparticle tools reduced TAT by 80%, and 88% of participants preferred the less invasive nanoparticle tests offered by the PHC.

DISCUSSION

The implementation of nanoparticle-based diagnostics in the rural areas of India has been beneficial for patients, particularly in aspects like early disease detection, fast results, and patient compliance. The improved sensitivity and specificity obtained with TB and malaria clearly demonstrates the molecular bio-recognition capabilities of nanoparticles that can bind to some antigens and other biomarker molecules even when they are present in very low amounts. This is crucial in early infections because the number of pathogens is usually low, and most traditional methods fail to yield positive detection.

Gold nanoparticles (AuNPs) caused striking signal amplification through colorimetric changes which are observable by the naked eye leading to ease of interpretation sans any sophisticated instruments. Their biocompatibility and ability to attach to antibodies made possible the fabrication of highly specific diagnostic test strips that retained their specificity in shifting environmental conditions. Conversely, Magnetic nanoparticles (MNPs) greatly expedited the rate of immunoassays by applying a magnetic field for the active separation of target analytes from complex biological samples, such as sputum or blood. This is especially helpful in field situations using portable magnetic readers because it reduced background noise and improved detection clarity.

Moreover, because of their non-controversial sharp hinge use, gold nanoparticles (AuNPs) made controlling methods for AuNPs more precise than previous designs. This also advanced the use of these methods to construct low-cost streaming systems.

Due to high fluorescence quantum yield and photostability, gold nanoparticles (AuNPs) were the first to augment multiplexed diagnostics.

The use of QDs in diagnostic tests was further advanced by their brilliant and steadfast emission signals. In low-light environments typical of rural clinics, these signals enabled the identification of multiple co-infection markers, such as TB and malaria, which is on the rise in some rural societies [7].

The improvement of healthcare from an infrastructural perspective in rural regions was greatly enhanced by mobile diagnostic units containing nanostrap-based test kits. Due to frequent transport delays, laboratory testing was often burdened by scant capacity and technician shortages. Diagnostics could be more readily accessed within communities with the aid of mobile units, which greatly enhanced the tracking of disease, treatment initiation timelines, and overall responsiveness.

The application of such technologies in the primary healthcare systems is made possible by the fundamental training of PHC workers. These training modules enhanced skill levels by training local health workers on how to operate the diagnostic machines, analyze the output, and provide medical advice to patients [8, 9].

Aside from the above-mentioned successes, there are still other lingers that need resolution to allow the long-term acceptance and scaling up the adoption of the nanoparticle-based diagnostics.

Cost considerations pose one of the major challenges concerning production and deployment of QD-based reagents, which need specialized synthesis routes and frequent cold chain storage. In low-resource contexts, a lack of local production and economies of scale for such components is very likely to stifle adoption. Moreover, while devices employing gold and magnetic nanoparticles are undergoing field validation, most QD-based platforms still face intricate regulatory approvals that delay incorporation into national programs.

Sustained success will not be attainable without active policies geared towards health innovation financing as well as investment in local health technology manufacturing by private and public stakeholders. The developing pharmaceutical and nanotechnology sectors in India can help supply diagnostic kits.

Targeted investment in these areas, along with policy innovation aimed at reducing regulations or even complete deregulation, could strengthen the supply chain and reduce costs significantly. In addition, engagement with local community stakeholders, such as village health committee members and NGOs, can go a long way in building grassroots trust in new technology and its utilization, thereby improving its adoption at the grassroots level [10].

As previously mentioned, integrating rural India's healthcare system with nanoparticle-based diagnostic techniques has enormous potential in improving the speed of diagnosis and reducing the overall disease detection cycle. While some logistical and economic barriers still exist, the impact on the TB and malaria burden in these resource-poor regions would be considerable [11–12].

CONCLUSIONS

This research underscores the possible effects that diagnostics based on nanoparticles may have on the early detection, accurate diagnosis, and effective treatment of tuberculosis (TB) and malaria in rural India. These technologies, characterized by high sensitivity and specificity, as well as rapid results, appear capable of addressing the disparities in healthcare services in rural areas. Nanoparticle based tests are specifically designed to meet the pressing requirements of rapid diagnostics in low-resource healthcare settings where access to laboratories, skilled personnel, and sophisticated diagnostic tools is scarce.

With improved detection of co-infections, these tools facilitate effective reduction of transmission, enhance patient outcomes, and strengthen public health responses. In addition, their use and upkeep by non-physician clinicians and their integration with mobile diagnostic units makes them responsive to remote and underserved regions.

However, fully realizing the potential of nanoparticle-based diagnostics will require dedicated resources for local fabrication, imposing coherent regulatory frameworks, establishing trained human resources, and the harmonization of policies in the governance structures. Some of the logistical and financial burdens could be mitigated through coordinated government intervention coupled with strategic alliances between private and public stakeholders.

After implementing these systemic changes, it is probable that nanoparticle diagnostics will be incorporated into India's rural healthcare strategy – helping the country progress toward its goal of eliminating tuberculosis by 2025 and maintaining control throughout the next decade.

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