Comparative Evaluation of Conventional Culture and Polymerase Chain Reaction for the Diagnosis of Infectious Diseases in a Tertiary Care Hospital in North India

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ABSTRACT

Background: Accurate and timely diagnosis of infectious diseases is critical for effective patient management. Conventional culture methods, though considered the gold standard, have limitations such as longer turnaround time and reduced sensitivity in certain conditions. Molecular techniques like polymerase chain reaction (PCR) offer rapid and sensitive detection but have their own limitations.

Objectives: To compare the diagnostic performance of conventional culture methods and PCR in detecting infectious agents in a tertiary care hospital setting in North India.

Methods: A hospital-based cross-sectional analytical study was conducted from August 2016 to December 2016, including 56 patients with clinically suspected infections. Clinical specimens were processed using both conventional culture techniques and PCR. Data were analyzed using SPSS version 22.0. Diagnostic yield, sensitivity, specificity, and concordance between the two methods were assessed. A p-value <0.05 was considered statistically significant.

Results: PCR demonstrated a higher positivity rate (67.9%) compared to conventional culture (46.4%). The difference in detection rates was statistically significant ($p<0.05$). PCR showed a sensitivity of 84.6% and specificity of 46.7% when culture was used as the reference standard. Concordance analysis revealed moderate agreement between the two methods (kappa $\approx$ 0.31). PCR detected additional cases that were missed by culture, while a small number of culture-positive cases were PCR-negative.

Conclusion: PCR offers superior sensitivity and rapid detection compared to conventional culture methods, making it a valuable adjunct in the diagnosis of infectious diseases. However, due to limitations such as lower specificity and lack of antimicrobial susceptibility data, it should be used in combination with conventional methods. Integrating both approaches can improve diagnostic accuracy and clinical outcomes.

Keywords: PCR; Culture; Infectious diseases; Molecular diagnostics; Diagnostic comparison; Sensitivity; Specificity

INTRODUCTION

Infectious diseases remain a major cause of morbidity and mortality worldwide, accounting for a substantial burden on healthcare systems, particularly in low- and middle-income countries [1]. Accurate and timely diagnosis is critical for effective patient management, appropriate antimicrobial therapy, and containment of disease transmission. Conventional microbiological culture techniques have long been considered the gold standard for pathogen identification; however, these methods are often time-consuming, require viable organisms, and may yield false-negative results in patients already receiving antimicrobial therapy [2,3].

Over the past few decades, advances in molecular diagnostics, particularly polymerase chain reaction (PCR), have revolutionized the field of infectious disease diagnosis. PCR-based methods enable rapid detection of microbial DNA or RNA with high sensitivity and specificity, even in cases where organisms are non-viable or present in low numbers [4,5]. These advantages have led to increasing adoption of molecular techniques in clinical microbiology laboratories, especially for the diagnosis of fastidious, slow-growing, or unculturable organisms [6].

Despite these advantages, molecular diagnostics are not without limitations. PCR assays can be expensive, require specialized infrastructure and trained personnel, and may detect non-viable organisms or colonization rather than true infection, potentially leading to overdiagnosis [7]. Additionally, the lack of antimicrobial susceptibility data from PCR-based methods remains a significant drawback compared to conventional culture techniques, which provide essential information for targeted therapy [8].

In the Indian context, infectious diseases continue to pose a significant public health challenge due to factors such as high population density, limited healthcare resources, and the increasing prevalence of antimicrobial resistance [9]. Tertiary care hospitals often serve as referral centers for complex and severe infections, where rapid and accurate diagnosis is essential for guiding clinical decision-making. While conventional culture methods remain widely used in such settings, the integration of molecular diagnostics is still evolving, and there is limited evidence comparing the effectiveness of these two approaches in routine clinical practice in North India.

Several studies have evaluated the diagnostic performance of PCR in comparison to culture, demonstrating higher sensitivity and faster turnaround times; however, variability exists depending on the type of infection, specimen, and pathogen involved [5,10]. Furthermore, most available studies are conducted in high-resource settings, and their findings may not be directly applicable to resource-constrained environments.

Given this background, there is a need to systematically compare conventional culture methods with molecular techniques such as PCR in a tertiary care setting in North India. Such a comparison would provide valuable insights into their relative diagnostic yield, turnaround time, and clinical utility, thereby aiding in optimizing laboratory workflows and improving patient outcomes.
Therefore, the present study aims to compare the diagnostic performance of conventional culture methods and PCR in the detection of infectious agents among patients in a tertiary care hospital in North India. The specific objectives are to assess the sensitivity and positivity rates of both methods, evaluate their concordance, and determine their practical applicability in routine clinical diagnostics.

METHODOLOGY

Study Design: This study was designed as a hospital-based cross-sectional analytical study comparing the diagnostic performance of conventional culture methods and polymerase chain reaction (PCR) for the detection of infectious agents.

Study Setting: The study was conducted in the Department of Microbiology of a tertiary care hospital in North India, catering to both inpatient and outpatient populations with suspected infectious diseases.

Study Duration: The study was carried out over a period of five months, from August 2016 to December 2016.

Study Population: The study population included patients of all age groups and both sexes who presented with clinical suspicion of infection and from whom appropriate clinical specimens (such as blood, urine, sputum, pus, or other body fluids) were collected for microbiological analysis.

Inclusion Criteria

- Patients with clinical features suggestive of infection
- Patients from whom adequate clinical specimens were obtained for both culture and PCR testing
- Patients who provided informed consent (or assent/guardian consent where applicable)

Exclusion Criteria

- Patients who had received prolonged antimicrobial therapy (>72 hours) prior to sample collection
- Inadequate or improperly collected specimens
- Samples that were contaminated or unsuitable for processing
- Patients who declined to participate in the study

Sample Size: The sample size was calculated based on an expected difference in detection rates between conventional culture and PCR methods. Assuming a culture positivity rate of approximately 50% and PCR positivity of 75%, with a confidence level of 95% and power of 80%, the minimum required sample size was estimated to be 52. To account for potential exclusions and sample losses, a total of 56 samples were included in the study.

Sampling Technique: A consecutive sampling technique was employed, wherein all eligible patients presenting during the study period and meeting the inclusion criteria were enrolled until the required sample size of 56 was achieved.

Data Collection Tools & Procedure: Clinical specimens were collected aseptically following standard protocols depending on the suspected site of infection. Each sample was divided into two aliquots: one for conventional culture and the other for molecular analysis. Culture processing was performed using standard microbiological techniques, including inoculation onto appropriate media, incubation under suitable conditions, and identification of organisms based on colony morphology, staining characteristics, and biochemical tests. For molecular detection, DNA extraction was carried out using standardized kits, followed by PCR amplification targeting pathogen-specific genetic sequences. Appropriate positive and negative controls were included in each PCR run to ensure validity. Patient demographic and clinical data were recorded using a structured proforma.

Study Variables: The independent variable in this study was the diagnostic method used (conventional culture versus PCR). The dependent variables included detection rate (positivity), time to diagnosis, and concordance between the two methods. Additional variables such as patient demographics, type of specimen, and clinical diagnosis were also recorded to assess their potential influence on diagnostic outcomes.

Statistical Analysis: Data were entered into Microsoft Excel and analyzed using Statistical Package for the Social Sciences (SPSS) version 22.0. Descriptive statistics were used to summarize demographic and clinical characteristics. The diagnostic yield of culture and PCR methods was compared using the chi-square test or Fisher's exact test where appropriate. Agreement between the two methods was assessed using Cohen's kappa coefficient. A p-value of less than 0.05 was considered statistically significant.

Ethical Considerations: Written informed consent was obtained from all participants or their legal guardians prior to sample collection. The study adhered to the ethical principles outlined in the Declaration of Helsinki. Confidentiality of patient information was strictly maintained throughout the study, and all data were anonymized prior to analysis.

RESULTS

A total of 56 patients were included in the study, with the majority belonging to the 21–40 years age group (39.3%) and a male predominance (57.1%) (Table 1).

Table 1: Demographic Characteristics of Study Population (n = 56)

Variable	Category	Number (n)	Percentage (%)
Age (years)	<20	10	17.9
	21–40	22	39.3
	41–60	16	28.6
	>60	8	14.2
Gender	Male	32	57.1
	Female	24	42.9

Blood was the most commonly collected specimen (25.0%), followed by urine and pus samples (21.4% each) (Table 2).

Table 2: Distribution of Clinical Specimens (n = 56)

Specimen Type	Number (n)	Percentage (%)
Blood	14	25.0
Urine	12	21.4
Sputum	10	17.9
Pus/Wound swab	12	21.4
Other body fluids	8	14.3

PCR demonstrated a higher positivity rate (67.9%) compared to conventional culture (46.4%) (Table 3).

Table 3: Comparison of Positivity Rates by Culture and PCR (n = 56)

Diagnostic Method	Positive (n)	Negative (n)	Positivity (%)
Conventional Culture	26	30	46.4
PCR	38	18	67.9

Analysis of concordance revealed that 22 samples were positive by both methods, while 14 were negative by both. Notably, 16 samples were PCR positive but culture negative, whereas 4 samples were culture positive but PCR negative (Table 4).

Table 4: Concordance Between Culture and PCR Results (n = 56)

	PCR Positive	PCR Negative	Total
Culture Positive	22	4	26
Culture Negative	16	14	30
Total	38	18	56

When culture was considered the reference standard, PCR showed a sensitivity of 84.6% and a specificity of 46.7%. The positive predictive value and negative predictive value were 57.9% and 77.8%, respectively (Table 5).

Table 5: Diagnostic Performance of PCR (Using Culture as Reference Standard)

Parameter	Value (%)
Sensitivity	84.6
Specificity	46.7
Positive Predictive Value (PPV)	57.9
Negative Predictive Value (NPV)	77.8

DISCUSSION

The present study compared conventional culture methods with polymerase chain reaction (PCR) for the diagnosis of infectious diseases in a tertiary care hospital setting in North India. The key findings indicate that PCR demonstrated a significantly higher positivity rate (67.9%) compared to conventional culture (46.4%), along with high sensitivity but relatively lower specificity when culture was used as the reference standard. Additionally, moderate agreement between the two methods was observed, suggesting that both techniques have distinct yet complementary roles in clinical diagnostics.

The higher detection rate of PCR observed in this study is consistent with earlier reports that highlight the superior sensitivity of molecular methods in identifying pathogens, particularly in cases with low microbial load or prior antibiotic exposure [5,10]. PCR-based techniques can amplify minute quantities of nucleic acids, enabling detection even when viable organisms are not present, which may explain the 16 cases in our study that were PCR-positive but culture-negative. Similar findings have been reported by Mackay et al. and Yang et al., who emphasized the ability of PCR to overcome limitations associated with culture-based methods, including delayed growth and stringent growth requirements [4,5].

Conversely, the lower specificity of PCR in the present study (46.7%) may be attributed to its inability to distinguish between active infection and colonization or residual nucleic acids from non-viable organisms [7]. This limitation has been widely discussed in the literature, where PCR positivity does not always correlate with clinical infection, especially in polymicrobial or commensal-rich sites. In contrast, conventional culture methods, although less sensitive, provide viable isolates that can be further subjected to antimicrobial susceptibility testing, a critical component for guiding targeted therapy [8].

The moderate agreement (kappa ≈ 0.31) between culture and PCR observed in this study aligns with findings from previous comparative studies, which have reported variable concordance depending on the type of specimen and pathogen involved [10]. The discordant results—particularly PCR-positive/culture-negative cases—highlight the potential of PCR as an adjunct tool rather than a replacement for conventional methods. These discrepancies may also reflect pre-analytical factors such as sample quality, timing of collection, and prior antibiotic use, all of which can influence culture yield more significantly than molecular detection.

From a clinical perspective, the rapid turnaround time associated with PCR offers a substantial advantage, particularly in critically ill patients where early diagnosis and prompt initiation of appropriate therapy can significantly impact outcomes. In tertiary care settings with high patient loads and a rising burden of antimicrobial resistance, integrating PCR into routine diagnostics may enhance early pathogen detection and improve antimicrobial stewardship practices [9]. However, the higher cost and requirement for specialized infrastructure may limit its widespread implementation in resource-constrained settings.

The findings of this study have important implications for clinical practice. While PCR demonstrates higher sensitivity and faster detection, it should be interpreted in conjunction with clinical findings and conventional microbiological results. A combined diagnostic approach may provide the most accurate and clinically relevant information, particularly in complex infections.
This study has several strengths, including its prospective design, standardized methodology, and inclusion of a variety of clinical specimens, enhancing the generalizability of findings within similar tertiary care settings. However, certain limitations must be acknowledged. The relatively small sample size (n=56) may limit the statistical power and precision of estimates. Additionally, using

culture as the reference standard may underestimate the true performance of PCR, given the inherent limitations of culture methods. The study also did not include pathogen-specific analysis or assessment of turnaround time quantitatively, which could provide further insights.

Future research with larger sample sizes, pathogen-specific evaluation, and cost-effectiveness analysis is warranted to better define the role of molecular diagnostics in routine clinical practice, particularly in low- and middle-income countries.

CONCLUSION

This study demonstrates that PCR-based molecular methods have a significantly higher detection rate compared to conventional culture techniques in the diagnosis of infectious diseases. PCR exhibited high sensitivity and was particularly useful in identifying pathogens in culture-negative cases, highlighting its value in situations with low microbial load or prior antimicrobial exposure. However, its relatively lower specificity and inability to provide antimicrobial susceptibility data limit its use as a standalone diagnostic modality.Conventional culture methods, despite lower sensitivity, remain indispensable due to their ability to isolate viable organisms and guide targeted antimicrobial therapy. The moderate agreement observed between the two methods underscores the importance of interpreting PCR results in conjunction with culture findings and clinical context.
Incorporating PCR as an adjunct to conventional culture can enhance diagnostic accuracy, enable early detection, and potentially improve patient outcomes, especially in tertiary care settings. Future studies with larger sample sizes and cost-effectiveness analyses are recommended to further define optimal diagnostic strategies in resource-limited settings.

DECLARATIONS

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