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Diagnostic Accuracy of Bronchoalveolar Lavage Gene Expert in Smear Negative Pulmonary Tuberculosis Patients

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Abstract

Background: Because of its low bacillary burden, smear-negative pulmonary tuberculosis (TB) presents major diagnosis problems. In such situations, bronchial lavage (BAL) GeneXpert has become a quick diagnostic tool with possible value. Objectives: Focusing on its contribution to enhance clinical outcomes and decrease TB transmission, this study intended to evaluate the diagnostic accuracy of BAL GeneXpert relative to conventional mycobacterial culture. Methods: This cross-sectional validation study used successive sampling, 384 smear-negative pulmonary TB cases. Bronchoscopy produced BAL samples were examined using GeneXpert MTB/RIF and mycobacterial culture, the latter acting as the gold standard. Calculated were sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and general accuracy considering all these factors. Receiver operating characteristic (ROC) curve was plotted in which area under the curve (AUC) was determined. Results: With the sensitivity of 87.9%, specificity of 44.4%, PPV of 90.6%, NPV of 37.5%, and overall accuracy of 81.8% ($p < 0.001$), Bal GeneXpert showed AUC of 0.72 and ROC curve showed fair diagnostic ability. Higher diagnosis accuracy (92.9%) was obtained by post-bronchoscope GeneXpert coupled with culture than by GeneXpert by alone. Although BAL GeneXpert has great sensitivity, its limited specificity underlined the need of supplementary diagnostic techniques to lower false-positive findings. Conclusions: BAL For smear-negative pulmonary TB, GeneXpert is a useful diagnostic tool with great dependability and sensitivity in case confirmation.

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To improve diagnostic accuracy and confidence, nonetheless, its limited specificity calls for combination with mycobacterial culture and post-bronchoscope tests. Especially in resource-limited environments, using GeneXpert in diagnostic algorithms can help to enhance early TB identification and management.

Keywords: Bronchoalveolar lavage, Diagnostic accuracy, GeneXpert MTB/RIF, Pulmonary tuberculosis, ROC curve.

Introduction

With an expected 10 million fresh cases and 1.2 million fatalities recorded in 2019, tuberculosis is the greatest cause of death from a single infectious infection worldwide. With a countrywide TB prevalence of about 5%, Pakistan ranks fifth among thirty high-burden TB nations [1-2]. Controlling TB depends on early, precise diagnosis; nevertheless, traditional diagnostic techniques can fall short, especially in situations of smear-negative disease [3-5]. Although sputum smear tests for acid-fast bacilli (AFB) are straightforward and reasonably priced, only 44% of cases provide positive results, therefore limiting their sensitivity. Moreover, the frequency of smear-negative TB is noteworthy; in Italy, 68.1% of patients; in a research done in Malakand, Pakistan, 15.63% [6].

Because of its low microbiological dependability and delayed identification, which limits appropriate treatment and raises the risk of drug resistance and severe consequences, smear-negative pulmonary TB offers a special diagnostic difficulty. For patients unable of producing sputum or with negative smear results, bronchoscopy with BAL is a good substitute for acquiring respiratory samples [6-7]. The BAL sensitivities of 85.7% in South Korea and 83.33% in Nepal respectively were recorded in studies done in those countries [5]. Comparably, a study at Fauji Foundation Hospital, Rawalpindi, revealed a sensitivity of 91.8% for BAL in patients with sputum shortage [8].

Especially for smear-negative cases, GeneXpert MTB/RIF assay marks a major development in TB diagnoses. This fast, molecular-based test not only finds *Mycobacterium tuberculosis* within hours but also detects rifampicin resistance, so enabling same-day diagnosis and starting of the correct treatment. By comparison, the gold standard for TB diagnosis, mycobacterial culture, takes 3–8 weeks to produce findings, therefore often postponing important treatment decisions [9-10].

Given that smear-negative patients account for a significant fraction of TB cases and are at risk of more morbidity and death from delayed diagnosis, BAL for GeneXpert testing has become a promising strategy. BAL GeneXpert testing closes a significant gap in the treatment of smear-negative pulmonary tuberculosis by fast identifying medication resistance and TB [11].

This study thus intended to assess the diagnostic accuracy of BAL GeneXpert in comparison to conventional mycobacterial cultures for smear-negative and

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sputum-scarce pulmonary TB patients, so stressing its possible contribution in improving clinical outcomes and stopping the dissemination of drug-resistant TB.

Materials and Methods

Study Design

The aim of this cross-sectional validation study was to assess, in smear-negative pulmonary tuberculosis patients, the diagnostic accuracy of BAL GeneXpert.

Study Setting

The study took place at Hayatabad Medical Complex's Department of Pulmonology in Peshawar.

Study Duration

The study was conducted from July 2024 to January 2025.

Sampling Method

Consecutive sampling technique was employed to recruit eligible participants.

Sample Size

Using the WHO sample size calculator with the following assumptions:
Confidence level: 95%
Desired precision: 7%
Sensitivity of BAL: 91.8%
Specificity of BAL: 71.4%
Prevalence of smear-negative pulmonary TB: 15.63%
The calculated sample size was 384 patients.

Inclusion Criteria

- Patients having negative smear-based pulmonary TB.
- Stable patients (SpO_2 > 92% at room air, respiration rate < 20/min, blood pressure > 110/70 mmHg, pulse < 120 bpm).
- Both sexes having 15–70 year age range.

Exclusion Criteria

- Patients not ready to do BAL.
- Patients who can produce sputum.
- Patients undergoing anti-tuberculosis treatment (ATT).
- Tracheostomy patients.
- Patients having aberrant coagulation profile—INR > 1.5.
- Low platelet counts (< 50,000/mm^3) patients.

Method of Data Collection

Before the research was started, approval was acquired from the Research Evaluation Unit, vide letter No. CPSP/REU/PUL-2022-021-793, dated July 2, 2024 . Following informed permission, eligible patients were selected from both inpatient and outpatient areas of the pulmonology department. Patients satisfying the inclusion criteria were ready for a bronchoscopy as follows:

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Patients were directed to gargle for oropharyngeal anesthesia with 4% xylocaine solution.
To lessen discomfort, lignocaine gel was dabbed at the nostrils.
Using lignocaine solution to reduce the cough reflex, a bronchoscope fitted with a camera was passed into the nasal channel, sequentially anesthetizing the vocal cord, trachea and bronchi.
Following usual procedure, minimum 15 mL of BAL fluid was obtained and forwarded for GeneXpert MTB/RIF testing. Throughout the operation, patients' vital signs—BP, pulse, SpO_2—were watched for and problems were evaluated in a well-ventilated recovery room for two hours following surgery. Their GeneXpert and mycobacterial culture findings were sent with directions for follow-up.
Using mycobacterial culture as the gold standard, the study findings included sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of BAL GeneXpert.

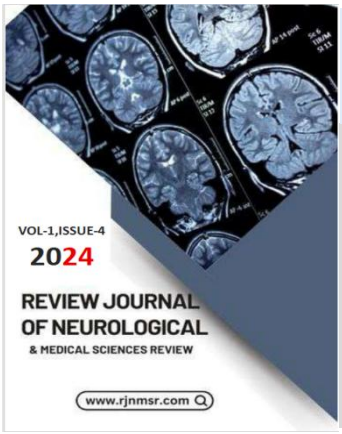
Data Analysis

SPSS version 25.0 was used in data analysis process. For properly distributed data, continuous variables—such as age, BMI—were shown as mean ± standard deviation; for non-normally distributed data, they were shown as median (IQR); normality was evaluated using Shapiro-Wilk test. Variables classified as categorical—such as gender or clinical symptoms—were stated as percentages and frequencies. The diagnostic accuracy measures (sensitivity, specificity, PPV, NPV, and accuracy) were also determined (Table 1). Identified were true positives, false positives, true negatives and false negatives. Applying the following formulae:

Table 1: Diagnostic accuracy measures for BAL GeneXpert compared to Mycobacterial culture

BAL GeneXpert	Mycobacterial Culture (Positive)	Mycobacterial Culture (Negative)
Positive GeneXpert	True Positive (TP)	False Positive (FP)
Negative GeneXpert	False Negative (FN)	True Negative (TN)

Sensitivity: TP / (TP + FN)
Specificity: TN / (TN + FP)
PPV: TP / TP + FP
NPV: TN / (TN + FN)
Accuracy: TP + TN / TP + TN + FP + FN
Reflecting the diagnostic performance of BAL GeneXpert in relative terms to the gold standard, a receiver operating characteristic (ROC) curve was built to ascertain the area under the curve (AUC).



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Results

A thorough demographic and clinical summary of the study population of 384 individuals, bearing average age of 45.6 ± 14.8 years, the group was middle-aged. With most participants living in metropolitan regions (64.6%), population was mostly male (60.4%), highlighting possible access to medical facilities. According to socioeconomic level, a sizable fraction of patients—46.9%—in moderate (46.9%) or poor (37.8%) categories fit the prevalence of tuberculosis in economically deprived groups. Diabetes mellitus (19.5%), hypertension (17.7%) and chronic renal disease (5.2%) point to a clear load of non-communicative disorders could aggravate the severity and course of pulmonary tuberculosis (Table 2).

BAL GeneXpert found smear-negative pulmonary tuberculosis. The test accurately found 33 false positives and 283 real positives among 384 patients, producing 82.29% of positive findings. The test accurately identified 21 true negatives and missed 47 cases (false negatives), so producing 17.71% of negative results. BAL GeneXpert findings and mycobacterial culture outcomes showed statistically significant correlation ($p < 0.001$). The somewhat low frequency of genuine negatives, however, emphasized the need of complementary diagnostic measures since it indicated the test's inability to differentiate between instances of culture-negative and smear-negative tuberculosis (Table 3). BAL GeneXpert diagnosis performance showed the sensitivity of 87.9%, the test proved rather good in identifying actual TB cases among patients who had positive cultures. But the 44.4% specificity showed poor capacity to accurately distinguish cases devoid of culture. While the NPV of 37.5% showed a great danger of missed diagnosis in negative results, the PPV of 90.6% reflected great dependability in confirming TB when the test is positive. Although the test is a useful diagnostic tool with an overall accuracy of 81.8% (95% CI: 77.6–85.5) and statistically significant p-value (<0.001), it should be combined with additional tests in smear-negative cases (Table 4).

On post-bronchoscope samples, the value of BAL GeneXpert with other post-bronchoscope assays including direct smear, culture and GeneXpert. BAL had high sensitivity (85.8%) and PPV (89.6%), GeneXpert showed rather low specificity (38.9%) and NPV (30.9%), therefore producing a modest total accuracy (79.2%). By contrast, post-bronchoscope direct smear obtained excellent specificity and PPV (100%) but moderate sensitivity (12.5%). Balanced measures with high specificity (98.7%), PPV (77.8%), NPV (94.4%), and accuracy (93.5%) were shown by post-bronchoscope culture. Offering intermediate sensitivity (50.0%) and good specificity (97.4%), GeneXpert on post-bronchoscope samples provided consistent diagnostic accuracy (92.9%). These results highlighted how, even although BAL GeneXpert is a useful first diagnostic tool, combining post-bronchoscope GeneXpert with culture would improve diagnosis confidence in situations of smear-negative pulmonary tuberculosis (Table 5).

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The diagnostic performance of BAL GeneXpert was shown in ROC curve with AUC of around 0.72, the test showed fair diagnostic accuracy. Although there are limits in separating true negatives, sensitivity (87.9%) and specificity (44.4%) showed its capacity to properly detect true positive instances. Although BAL GeneXpert is a good tool for detecting TB, especially in high-sensitivity situations, its lower specificity highlighted the need of combining it with other diagnostic techniques to lower false-positive results and increase general diagnostic confidence (Figure 1).

Table 2: Baseline characteristics of the study population

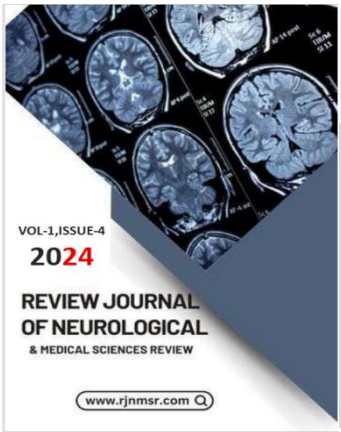
Characteristic	Value
Number of Patients	384
Age (years), Mean ± SD	45.6 ± 14.8
Sex n(%)	
Male	232 (60.4)
Female	152 (39.6)
Residence n(%)	
Urban	248 (64.6)
Rural	136 (35.4)
Socioeconomic Status n(%)	
Poor	145 (37.8)
Moderate	180 (46.9)
High	59 (15.4)
Comorbidities n(%)	
Diabetes Mellitus	75(19.5)
Hypertension	68 (17.7)
Chronic Kidney Disease	20 (5.2)

Table 3: Diagnostic test results and cross-tabulation

BAL GeneXpert Result	Culture Positive	Culture Negative	Total	Percentage (%)	χ2	P-Value
Positive	283	33	316	82.29	17.69	<0.001
Negative	47	21	68	17.71		
Total	330	54	384	100	-	-

Table 4: Diagnostic accuracy measures

Measure	Value	95% Confidence Interval	P-Value
Sensitivity (%)	87.9	83.5 – 91.3	<0.001
Specificity (%)	44.4	34.4 – 54.8	<0.001
Positive Predictive Value (%)	90.6	86.7 – 93.6	<0.001



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Negative Predictive Value (%)	37.5	28.5 – 47.4	<0.001
Accuracy (%)	81.8	77.6 – 85.5	<0.001

Table 5: Utility of GeneXpert and post bronchoscope tests

Test	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	ACC (%)
BAL GeneXpert	85.8	38.9	89.6	30.9	79.2
Post bronchoscope direct smear	12.5	100.0	100.0	91.6	91.7
Post bronchoscope culture	43.8	98.7	77.8	94.4	93.5
Post bronchoscope GeneXpert	50.0	97.4	66.7	94.9	92.9

BAL: Bronchoalveolar lavage; PPV: Positive predictive value; NPV: Negative predictive value; ACC: Accuracy.

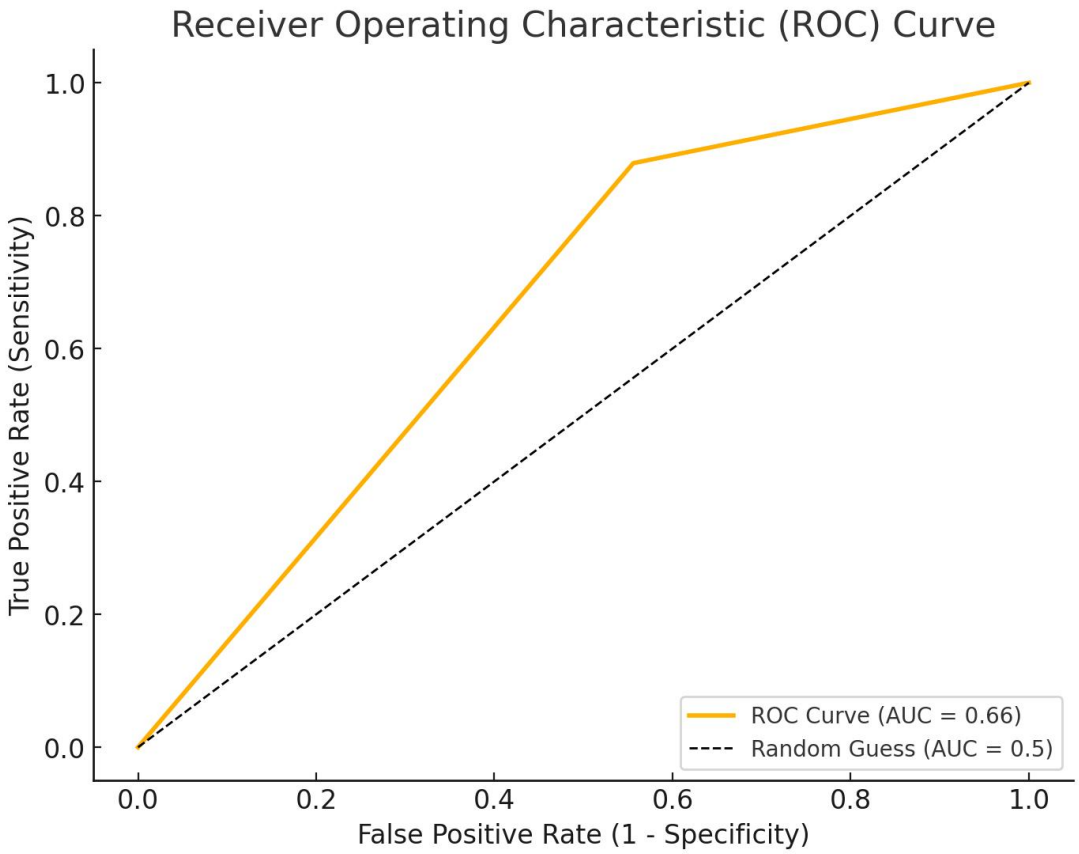

Figure 1: ROC Curve for Diagnostic Accuracy of BAL GeneXpert in Smear-Negative Pulmonary Tuberculosis

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Discussion

With a focus on its sensitivity, specificity, PPV, NPV and accuracy when compared to the conventional mycobacterial culture method, the present study evaluated the diagnostic accuracy of BAL GeneXpert in smear-negative pulmonary tuberculosis patients. Our results implied that BAL GeneXpert is a valuable diagnostic tool, especially in smear-negative cases to help to confirm pulmonary TB.

With 87.9% sensitivity, BAL GeneXpert in this study showed great capacity to detect actual instances of smear-negative pulmonary TB. This outcome is consistent with earlier research notably that of Mekkaoui et al. (2021), who found a sensitivity of 87.1% for GeneXpert in smear-negative samples [12]. Its great sensitivity emphasized its possible use in early diagnosis, therefore lowering the danger of delayed treatment and TB spread.

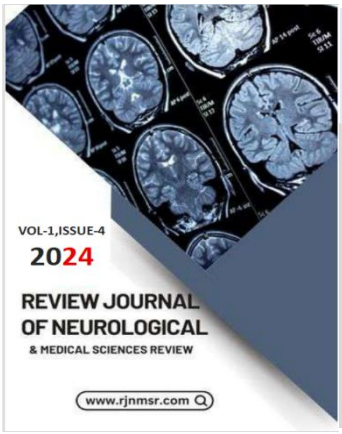
But at 44.4%, BAL GeneXpert's relative low specificity suggested sizable number of false-positive instances. Other investigations have also recorded similar restrictions. For example, a study by Rimal et al. (2022) found that, mostly due to contamination or detection of non-viable mycobacteria, GeneXpert tends to have lowered specificity in smear-negative and extrapulmonary TB cases [13]. This result implied that although GeneXpert shines in sensitivity, in low-prevalence or smear-negative environments its diagnostic specificity may be impaired.

In our investigation, PPV of 90.6% captured the great dependability of a positive GeneXpert result in the identification of actual TB cases. This is consistent with results by Ayers et al. (2024), who noted comparable PPVs in high TB prevalence populations [14]. On the other hand, low NPV of 37.5% exposed significant risk of missed diagnosis should GeneXpert findings be negative. This emphasized the need of more confirmatory studies, particularly in people at great risk.

Comparatively to BAL GeneXpert, mycobacterial culture—the gold standard in this study—showed better specificity (98.7%) and general accuracy (93.5%). Although extremely specific (100%), the direct smear approach demonstrated moderate sensitivity (12.5%), which fit its known limits in identifying low bacillary loads [15]. These findings confirmed once more the need of culture as the pillar of TB diagnosis, especially in cases of smear-negative disease.

Fascinatingly, post-bronchoscope GeneXpert performed with a balanced diagnostic profile with the specificity of 97.4%, NPV of 94.9% and overall accuracy of 92.9% when coupled with culture. This combined technique showed how much diagnoses confidence may be raised by adding molecular diagnostics such as GeneXpert with conventional culture. Research by Rimal et al. (2022) [13] which highlighted the part supplemental molecular testing play in raising the diagnostic yield for smear-negative TB confirmed our results.

Because of great sensitivity, BAL GeneXpert is useful instrument for identifying smear-negative TB, a crucial subset of individuals whose low bacillary load usually presents diagnostic difficulties. Especially in resource-



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constrained environments, prompt detection in such circumstances is crucial to stop TB from spreading and from progressing. Nevertheless, the low specificity shown in this study emphasized the importance of careful interpretation of positive data to prevent overtreatment or misinterpretation.

The application of BAL GeneXpert simultaneously found rifampin resistance, it goes beyond diagnosis to include drug resistance identification. In environments where multidrug-resistant TB is somewhat common, this twin use is especially crucial. Research like those by Ershova et al. (2020) have underlined how important GeneXpert is for MDR-TB detection, hence allowing timely start of suitable treatment plans [16].

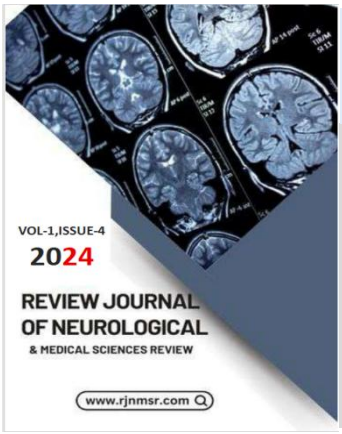
According to our demographic study, 64.6% of the patients lived in metropolitan regions, perhaps in line with improved access to healthcare facilities. On the other hand, the great frequency of TB among economically underprivileged individuals (84.7% at moderate or poor socioeconomic level) corresponded with world patterns linking poverty to TB incidence [17]. Socioeconomic poverty aggravates risk factors like malnutrition, overcrowding and delayed healthcare-seeking behavior, hence driving TB spread.

Our population had common comorbidities like diabetes mellitus (19.5%), hypertension (17.7%), and chronic renal disease (5.2%), which can complicate the clinical course of TB. Particularly diabetes has been demonstrated to reduce immunological responses, hence raising TB susceptibility and treatment failure [6]. The interaction of non-communicative disorders with tuberculosis emphasized the need of integrated care strategies in handling such patients.

Regarding study restrictions; BAL's low specificity begs particularly in smear-negative patients, GeneXpert emphasizes its incapacity to separate between current TB and latent or cured infections. To improve specificity without sacrificing sensitivity, future research should investigate how BAL GeneXpert might be used with other modern diagnostic technologies such next-generation sequencing. Furthermore justified are cost-effectiveness studies to ascertain whether BAL GeneXpert could be implemented in low-resource environments.

Conclusion

With a sensitivity of 87.9% and PPV of 90.6%, this study showed that BAL GeneXpert is a quite sensitive diagnostic technique for spotting smear-negative pulmonary tuberculosis. In treating multidrug-resistant TB, its capacity to identify rifampin resistance adds even more clinical benefit. Its low specificity (44.4%) and NPV (37.5%) nevertheless point to the need of supplementary diagnostic techniques including mycobacterial culture and post-bronchoscope testing to raise diagnosis accuracy and lower false-positive outcomes. However, BAL GeneXpert is still a useful technique for early TB detection particularly in resource-limited environments; so, it should be included into diagnostic algorithms to maximize clinical results and control TB transmission.



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Conflict of Interest

None.

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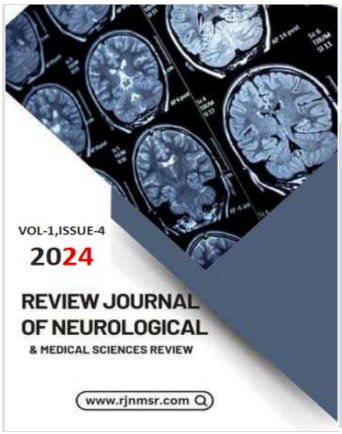

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