Blinded Rechecking of AFB Smear Microscopy Performance in Selected Private Health Facilities in Tigray, Northern Ethiopia

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Abstract

Background: Direct sputum smear microscopy remains the most cost-effective tool for tuberculosis diagnosis and treatment monitoring in resource constrained settings. Random blinded rechecking is a reliable tool to measure and improve smear microscopy. So, this study was intended to assess random blinded rechecking of AFB smear microscopy performance in selected private health facilities in Tigray region, Northern Ethiopia.

Methods: A cross sectional study was conducted from April 1, 2017 to May 30, 2017. The data was collected using blinded rechecking data collection form. Statistical analysis was done using SPSS version 25 and the reading agreement was done using kappa statistics.

Results: Of the total 269 blinded rechecked smears, 4.8% was found discrepant findings. The major and minor errors were reported by 2.6% (7/269) and 2.2% (6/269) respectively. Likewise, the major error was reported by 50% (5/10) of health facilities with microscopic center. Overall, the sensitivity, specificity, positive predictive value, and negative predictive value of the blinded rechecking smears were 87.5%, 98%, 89.7% and 97.8%, respectively with substantial reading agreement, kappa value= 0.80.

Conclusions: The overall performance of blinded rechecking was satisfactory with good smear reading agreement. But, the major error reported indicated unacceptable performance. To minimize the discrepancy, private health facilities with tuberculosis smear microscopic center should adhere to national tuberculosis guidelines.

Introduction

Tuberculosis (TB) is an infectious disease caused by bacillus *Mycobacterium Tuberculosis* (MTB) members of the genus of mycobacterium [1]. Tuberculosis disease is the top 10 causes of death worldwide [2]. Globally approximately 10.0 million incidence cases, 1.2 million TB death among HIV negative and 251,000 in HIV positive people were reported in 2019 [2]. Moreover, approximately 5-10% of the 1.7 billion people infected with *M. tuberculosis* were developed TB disease during their life time [2]. Individuals untreated smear positive was infected on average between 10 and 15 people every year [3].

Direct sputum smear microscopy is the corner stone method used for diagnosing pulmonary TB which is available in most peripheral health care laboratories [4]. Likewise, it is simple,

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cost effective and provides a preliminary confirmation to the clinicians [5]. But, unreliable acid fast bacilli smear microscopy leads continual transmission of the infection to the community or unnecessary treatment for false positives [6]. On the other hand, misdiagnosis of follow up smears can result patients being placed on prolonged treatment, or treatment discontinue [6,7]. Nationally, of the detected TB cases (64%), only 40% was bacteriological confirmed sputum positive which was relatively low to the expected target (70%) [8]. Likewise, in private health sector, the smear positive detection rate among the pulmonary TB cases was 31.8% which was also below the target (70%) [9]. To ensure the reliability and reproducibility of smear microscopy, quality assurance program is a prominent method [10].

Implementation of quality smear microscopy is essential to improve TB smear microscopy in all public and private health sectors [7,10]. Moreover, case detection using quality assured smear microscopy have a great role for successful end TB strategy [5,7,10]. As per as our knowledge little was known about the performance blind rechecking of AFB smear microscopy in private health facilities in the study region. Moreover, many studies were conducted and limited in public health facilities [11,12]. So, this study was aimed to assess random blinded rechecking of AFB smear microscopy performance in selected private health facilities in Tigray region, Northern Ethiopia.

Materials and methods

Study setting

This study was conducted in Tigray region, Northern part of Ethiopia. Tigray has an estimated total population of 4.8 million people over an area of 50,078.64 square kilometers. Based on the 2007 census projection, majority (80.5%) of the population live in rural areas, while 19.5% are urban dwellers [13]. There were about 57 medium and above private health sectors provided AFB smear microscopy in Tigray region. Of these, 27 health facilities were enrolled and participated in EQA of random blinded rechecking program for AFB smear microscopy. This study was conducted in private health facilities that were enrolled in random blinded rechecking program. But, unfortunately the study was conducted in 10 private health facilities which have proper stored smear slides for blinded rechecking during the study period. The study sites included 2 General hospitals, 4 health centers, 3 specialty clinics and one medium clinic found all over the region.

Study design and period

Facility based cross sectional study was conducted from April 01, 2017 to May 30, 2017 in selected private health facilities in Tigray region, Northern Ethiopia.

Study population

Private health facilities which were enrolled and participated in external quality assessment of random blinded rechecking program for AFB smear microscopy.

Sample size and sampling technique

This study included private health facilities which were enrolled in EQA of random blinded rechecking for AFB smear microscopy. The smear slides for blinded rechecking were collected using LQAS method which is a valid statistical sampling with the assumption a sensitivity of 80%, specificity of 100%, zero acceptance number and 95% confidence interval from routinely collected and stored slides [14].

Data collection techniques

The data was collected using standard blinded rechecking data collection tools. The blinded rechecking smears were collected based on the LQAS method from routine stored smear slides in microscopic center [14]. Once the smear slides were collected at peripheral, and then transported and reread by senior laboratory technology in Tigray health research institute. If discrepant results occurred a second controller was assigned and the final result was generated from this. Finally, all the discordant results were communicated to health facilities.

Definition of terms

Low False Negative (LFN): Scanty or actual number (1 to 9 AFB /100 fields) positive smear misread as negative.

Low False Positive (LFP): A negative smear misread as a scanty (1 to 9 AFB / 100 fields) positive.

Quantification error (QE): Is a positive smear reading when the difference in smear grading report is greater than one between the examinee and controller

High False Negative (HFN): Smear positive with 1+ to 3+ grading or bacilli density misread as negative.

High False Positive (HFP): a negative smear misread as smear positive with bacilli density 1+ to 3+.

Major error: Indicated by HFP and or HFN errors; this type of error is considered the most critical since it has the highest potential impact on patient management, and can result in an incorrect diagnosis or improper management of a patient.

Minor error: Type of errors included LFP, LFN and QE, in clinical practice; these errors may have some impact on patient management. But, for the purpose of evaluating laboratory performance, this type of error is considered less serious, because of the inherent limitations AFB smear microscopy in detecting or few unequally distributed AFB within a smear.

Controller: Supervisory laboratory or technician responsible for rechecking slides.

Statistical analysis

All data was entered into an excel spreadsheet, and then transferred for statistical analysis using SPSS version 25. By considering the reference smear reading results as a gold standard, the sensitivity, specificity, Positive Predictive Value (PPV), and Negative Predictive Value (NPV) of AFB smear reading was determined using 2 x 2 contingency table. The smear reading agreement was also calculated using kappa statistics test.

Ethical approval

Ethical clearance was obtained from Tigray Health Research Institute, Institutional Review Board (THRI, IRB). Official letter was obtained from Tigray health research institute. Permission was also obtained from the study area.

Results

In this study 10 eligible private health facilities which included 2 General hospitals, 4 health centers, 3 specialty clinics and one medium clinic were participated. A total of 269 smear slides were collected and then rechecked in Tigray health research institute. Among the blinded rechecked smears, 4.8% (13/269) were discordant results. The false positive (FP), false

negative (FN) and quantification error (QE) were 1.5% (4/269), 1.9% (5/269) and 1.5% (4/269) respectively. Of the false positives, 1.1% (3) were high false positive (HFP) and 0.4(1) low false positive (LFP). In addition, 1.5% (4) and 0.4% (1) were high false negative (HFN) and low false negative (LFN) respectively. From the total discordant results, 2.6% (7/269) were major and 2.2% (6/269) of minor errors. Majorities of the error were attributed to medium clinics 9% (5) and health center levels 4.7% (2) (Table 1),

The overall sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the blinded rechecking smears were 87.5%, 98%, 89.7% and 97.8% respectively (Table 2). The reading agreement between the microscopic center and the controller was good (Kappa value= 0.80, Percent agreement (94.4%). The major error was reported by 50% (5/10) of the peripheral microscopic center.

Table 1: Error classifications for blinded rechecking of AFB smear microscopy in private microscopic center.

Facility name	Total slides rechecked	Major error		Mino error			Total
		N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
		HFN	HFP	LFP	LFN	QE	Total
General Hospital	62	0	0	0	1(1.6%)	1(1.6%)	2(3.2%)
Health center	43	1(2.3%)	1(2.3%)	0	0	0	2(4.7%)
Specialty clinic	109	1(0.9%)	1(0.9%)	0	0	2(1.8%)	4(3.7%)
Medium clinic	55	2(3.6%)	1(1.8%)	1(1.8%)	0	1(1.8%)	5(9%)
Total	269	4(1.5%)	3(1.1%)	1(0.4%)	1(0.4)	4(1.5)	13(4.8%)

HFN: High False Negative; HFP; High False Positive; LFP: Low False Positive, LFN: Low False Negative; QE: Quantification Error.

Table 2: Blinded rechecking smear reading agreement between microscopic center and reference laboratory.

Microscopic center smear reading * Reference lab smear reading							
		Reference lab smear reading					Total
		Negative	Actual	Positive +1	Positive +2	Positive +3	
Microscopic center smear reading	Negative	229	1	2	1	0	233
	Actual	1	4	0	0	0	5
	Positive +1	3	0	9	0	0	12
	Positive +2	1	2	0	5	0	8
	Positive +3	0	0	2	0	9	11
Total		234	7	13	6	9	269

Discussion

This study was presented performances of random blinded rechecking in selected private health facilities. Of the blinded rechecking smears, 4.8% (13/269) were discrepant results. This is higher than the study indicated 2.1% in private health sectors in Ethiopia, (0.61%) in Addis Abeba and (1.7%) in New delhi [9,15,16]. In contrast, it was lower than a study finding in DRC (10.4%) [17]. The difference was due to sampling variation. Including large volume of blinded rechecking smear increases the performance acceptance. The FP (1.5%) result of this study was lower than study finding revealed a FP of 2.26% [9]. Similarly, the FN (1.9%) of this study was also in line with similar study report (1.99%) in Ethiopia [9]. Moreover, the FP and FN findings of this study were lower than the FP (7.8%) and FN (13%) findings in Argentine and Tanzania respectively [18,19]. The possible reason for FN smear reading is due to poor staining quality, bad microscopy and lack of adherence to internal quality control [14,20]. Moreover, FP results could be due to insufficient decolorization, reagent precipitation and inexperienced microscopist [10,14].

Moreover, the major error was reported by 50% (5/10) of the microscopic center. This was comparable with a study indicated 61.5% (13) in DRC [17]. But, higher than other findings

23.4% in West Amhara, 21% in New delhi and (36.4%) Eastern Ethiopia [12,16,21]. The difference was attributed to methodological difference. A random blinded rechecking smear is the best way to measure the laboratory performance of AFB smear microscopy [7,10,14]. The major error reported with this study was unacceptable results. In line with WHO external quality assessment for AFB smear microscopy, any HFP and one or above HFN is considered as potential source of error for un acceptable performance [10]. Hence, any major error with smear reading is a serious error which indicating misclassification of the diseases and patient management [10,22].

The overall sensitivity (87.5%), specificity (98%), PPV (89.7%) and NPV (97.8%) of the blinded rechecking smears were similar with a study in Addis Abeba showed a sensitivity, specificity, PPV and NPV were 88.4%, 99.3%, 92.4% and 98.9% respectively [23]. But, the sensitivity of this study was lower than study report in Amhara (98.6%) [20]. The difference might be due to variation on the volume of smears collected and rechecked during the study period. Because rechecking large volume of smears gives a large performance acceptance [10,14]. The smear reading agreement was substantial with kappa value 0.80. Similar findings indicated in Eastern part of Ethiopia, K=0.84 [21]. In con-

trast, the agreement was lower than findings in West Amhara, K=0.97 and Addis Abeba, K=0.87 [20,21]. The national guideline for external quality assessment of AFB smear microscopy indicated a sensitivity of 80% and greater is the optimal performance blinded rechecking smear reading [14]. In line with this, the overall sensitivity of blinded rechecking smear in private microscopic center was within an acceptable range.

Conclusion

Overall, private health facilities which were enrolled in blinded rechecking of AFB smear microscopy have shown a good performance. They had also substantial smear reading agreement. But, the HFP and HFN errors found indicated unacceptable performance which was above the cut of value for discrepant errors were defined in WHO for EQA guideline. Any major error may result a significant effect on the patient management and continuous transmission of the infection to the community. To improve this, the selected EQA center should regularly monitored for any discordant results during their random blinded rechecking participation.

Acknowledgments

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