Same-day sputum microscopy: The road ahead in tuberculosis diagnosis

Sir,

India accounts for one-fifth of the global tuberculosis (TB) burden, with over 2 million incident cases annually.[1] Having achieved the twin objectives of 70% case detection and 85% cure rate by 2006, Revised National Tuberculosis Control Program’s (RNTCP) vision for the 12th 5 year plan is “universal access: Reaching the unreached.” By 2015, the program aims to achieve early detection and treatment of 90% of the estimated cases including human immunodeficiency virus-associated TB.[1] Improvement in detection rates will be possible only when there is optimal use of sputum microscopy services. The existing standard sputum microscopy procedure requires a TB suspect to give a spot sputum sample and another early morning sample, for which he/she has to return to the health facility the next day. This burdens the TB suspect and results in out of pocket expenditure in the form of transport costs, food and lost wages, pushing the patient below the poverty line. Hence many TB suspects drop out during the diagnostic procedure and remain untreated in the community, providing more opportunities for transmission of the disease.

Before 2007, three sputum smears were used for diagnosis of TB. Systematic reviews showed that the average percentage of all cases detected by the first sputum specimen was 85.8% and the incremental yield of second sputum was 11.9%. The third sputum smear led to an incremental yield of only 3.1% given that the first two were negative. Furthermore, reducing the number of smears decreased the workload of the laboratory technicians.[2] This led to the policy change from three smears to two. However, the issue of the economic burden due to an additional visit to the health center on the subsequent day was not addressed.

Front-loaded microscopy is a new diagnostic strategy in which two smears are prepared from one or more sputum specimens obtained on the 1st day a patient is assessed. When all samples are collected and the results are reported on 1st day, the strategy is termed same-day microscopy. This procedure does not require the patient to visit the health facility multiple times for diagnosis of TB. Thereby, it will reduce the economic burden of an additional visit and thus will lead to lesser drop-out rates during diagnosis and also since the report of the sputum examination is made available on the same-day, it ensures no delay in the initiation of treatment.

An expert group was formed by World Health Organization (WHO) to evaluate same-day microscopy in terms of diagnostic accuracy. The results of the expert group were published recently in “The Lancet Infectious Diseases.”[3] This systematic review and meta-analysis showed that the standard approach of “spot-morning” sputum smears had much the same sensitivity and specificity as that of “same-day microscopy.” Also, one of the large randomized controlled trials included in the review (6068 patients at four geographical sites) included data on patient loss to follow-up and showed that patients assigned to same-day diagnosis were more likely to submit both specimens (drop-out, 2%) than patients screened conventionally (drop-out, 5.8%). Based on this evidence, the WHO issued a policy statement recommending that “countries that have implemented the current WHO policy for two-specimen case-finding consider switching to same-day diagnosis, especially in settings where patients are likely to default from the diagnostic pathway.”[4]

A pilot study performed in New Delhi on 330 TB suspects showed that sensitivity and smear positivity was lower in the same-day diagnosis method as compared to the conventional method.[5] Furthermore, morning specimens have repeatedly shown greater bacillary load and higher sensitivity than spot samples.[6] Therefore, even though same-day diagnosis seems to be a promising technique for the future, large scale multi-centric pragmatic trials have to be done in India to establish diagnostic accuracy and feasibility.

In order to implement same-day sputum microscopy, significant organizational and program changes need to be done first. Since the reports have to be given the same-day, it will require reorientation of the existing manpower in the diagnostic microscopy centers (DMCs). Furthermore, the reports must reach the primary health centers (PHCs) so that treatment can be initiated early. This would require all PHCs and DMCs to have internet based health management information systems for transfer of reports. Quality of same-day sputum microscopy also will have to be rigorously monitored. For this, external quality assurance protocols needs to be devised and tested. Measures need to be taken to rapidly triage TB suspects in the Outpatient departments (OPDs) so that their waiting time is reduced. Once these changes are incorporated in the existing program, this method will go a long way in achieving universal access for TB diagnosis and making our nation TB free.

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