Let's Talk TB

A Series on Tuberculosis, A Disease That Affects Over 2 Million Indians Every Year

Management of Tuberculosis: 10 Common Pitfalls to Avoid

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Abstract

Indian TB patients get diagnosed after a delay of nearly two months, and are seen by 3 different providers before a diagnosis is made. At the primary care level, patients rarely get investigated for TB, even when they present with classic TB symptoms. Instead, providers give broad-spectrum antibiotics (e.g., fluoroquinolones) and remedies such as cough syrups and steroids. Even when TB is considered likely, private physicians tend to order tests that are non-specific, such as complete blood count, ESR, Mantoux test, and chest X-rays. They rarely seek microbiological confirmation via sputum smear microscopy, culture or polymerase chain reaction tests. Even if the diagnostic hurdle is overcome, TB treatment in the private sector is far from standard. When private practitioners initiate anti-TB treatment, they tend to use drug regimens that are not recommended by WHO or the International Standards of TB Care. Furthermore, private practitioners often fail to ensure treatment completion, and provide adherence support to their patients. This article discusses the 10 most common pitfalls that doctors should avoid. Addressing these pitfalls should great improve the quality of TB care in India.

Key words: tuberculosis, common pitfalls, management errors

PITFALL 1: NOT RECOGNIZING AND SUSPECTING TB

Doctors in India often miss TB, because they do not suspect TB in patients presenting with cough for 2 weeks or longer.[1] Multiple rounds of broad-spectrum antibiotics are tried, but tests for TB are rarely ordered at the primary care level.[2] Even when TB is suspected, history taking is often incomplete – family history of TB is rarely elicited, and previous treatment for TB is also missed.[2]

PITFALL 2: INADEQUATE DIAGNOSTIC WORK-UP

When doctors in India think of TB, they often order non-specific tests such as total and differential blood counts (TC/DC), erythrocyte sedimentation rate (ESR), and chest X-ray.[1,2] While these tests can be helpful, they do not confirm tuberculosis. Abnormal X-rays, for example, do suggest TB, but other lung conditions can also produce abnormalities on radiography. So, only relying on chest x-ray can result in over-diagnosis. Tuberculosis can only be confirmed by microbiological tests such as sputum smear microscopy, GeneXpert, and cultures. So, it is very important to order sputum tests that can directly detect *Mycobacterium tuberculosis*.

PITFALL 3: USE OF INAPPROPRIATE DIAGNOSTIC TESTS

Active tuberculosis is a microbiological diagnosis. Serological, antibody-based tests (e.g., TB ELISA) are inaccurate and banned by the Indian government.[3] They should not be used for TB diagnosis. In India, there is growing concern that tests such as Mantoux (tuberculin skin test) and IGRAs (e.g., TB Gold, TB Platinum) are being misused for active TB diagnosis. These tests were designed to detect latent infection, and cannot separate latency from active disease.

The Standards for TB Care in India (STCI) clearly states that both TST and IGRAs should not be used for the diagnosis of active TB in high endemic settings like India.[3] If Man-

toux and IGRAs are used for active TB diagnosis, this will result in significant over-diagnosis of TB, because of the high background prevalence of latent TB infection in India. In children, STCI suggests that the Mantoux test may have some value as a test for infection, in addition to chest x-rays, symptoms, history of contact, and other microbiological investigations (e.g., gastric juice acid fast bacilli and Xpert MTB/RIF).[3]

PITFALL 4: NOT CONSIDERING THE POSSIBILITY OF DRUG-RESISTANT TB (DR-TB)

DR-TB occurs when patients fail to complete first-line drug therapy, have relapse, or newly acquire it from another person with DR-TB. All persons who have previously received TB therapy must be considered to have suspected DR-TB. If patients have any risk factors for drug-resistance, or live in a high MDR-TB prevalence area (e.g., Mumbai city), or do not respond to standard drug therapy, they must be investigated for MDR-TB using drug-susceptibility tests (DST) like GeneXpert, line probe assays, and liquid cultures. Indian physicians under-use DST and this can result in mismanagement.

PITFALL 5: EMPIRICAL MANAGEMENT OF SUSPECTED TB WITH QUINOLONES AND STEROIDS

When doctors suspect TB or other lower respiratory tract infections, they frequently use broad-spectrum fluoroquinolones (e.g., levofloxacin, moxifloxacin) for short periods. However, such empirical management with fluoroquinolones will mask and delay the diagnosis of TB. Fluoroquinolones, in particular, are bactericidal for *M. tuberculosis* complex. Empiric fluoroquinolone monotherapy for respiratory tract infections has been associated with delays in initiation of appropriate anti-tuberculosis therapy and acquired resistance to the fluoroquinolones.[4] Doctors also tend to use steroids in individuals with history of chronic cough. Steroids, again, can result in temporary clinical improvement, but delay the diagnosis and treatment of underlying tuberculosis.

PITFALL 6: ONCE TB IS DIAGNOSED, NOT ADDRESSING CO-MORBIDITIES AND CONTACTS

Once TB is diagnosed, it is important to make sure the patient is not suffering from co-morbid conditions such as HIV and diabetes. It is also important to check if the patient is a smoker/alcoholic and provide them advice on smoking/alcohol cessation. It is also necessary to ask about TB symptoms among family members. In particular, small children living in the same family as the adult case must be tested for TB.

PITFALL 7: USE OF IRRATIONAL TB DRUG REGIMENS

Even if the diagnostic hurdle is overcome, TB treatment in the private sector is far from standard.[1] When private practitioners initiate anti-TB treatment (ATT), they tend to use drug regimens that are not recommended by WHO or the Standards of TB Care in India (STCI). All patients who have not been treated previously and do not have other risk factors for drug resistance should receive a WHO-approved first-line treatment regimen for a total of 6 months.[4] The initial phase should consist of two months of isoniazid, rifampicin, pyrazinamide and ethambutol. The continuation phase should consist of isoniazid and rifampicin given for 4 months.

There is no need to add additional drugs such as quinolones to the standard drug regimen.[4] Also, there is no need to extend the duration of treatment beyond 6 months, unless there is evidence of treatment failure, or there are complications (e.g., bone & joint TB, spinal TB with neurological involvement and neuro-tuberculosis). Drug dosages should be based on body weight, and daily dosing is preferable.[4] Some physicians have the mistaken perception that second-line medication are more potent than first-line medication. In fact they are less effective (and more toxic) medications, and should be reserved only for patients with drug-resistant TB, or first-line drug intolerance.

PITFALL 8: NOT ENSURING TREATMENT ADHERENCE

Adherence to the full course of ATT is critically important to ensure high cure rates and to prevent the emergence of drug-resistance. But private practitioners struggle to ensure adherence. Most do not maintain any medical records, and this makes it very difficult to follow-up patients. Patients often do not receive sufficient counseling about the importance of completing the full course of ATT. Drug-related side effects (if not adequately counselled on at the outset) is another common reason for non-adherence, and possible treatment default.

Every TB patient should receive counseling at the start of TB treatment. By notifying all TB cases to the local health authorities, private practitioners can seek help from the public sector to help follow-up patients who default. Physicians can also work with community-based organizations, and enlist community health workers to supervise treatment.

PITFALL 9: NOT MONITORING RESPONSE TO THERAPY AND CHANGING REGIMENS WITHOUT DST

Once ATT is started, doctors have the responsibility

of monitoring the patients to check whether therapy is working. This requires follow-up smear and culture testing. Negative smears at the end of therapy is important to ensure cure. If a patient is not responding to ATT, it important to investigate why. Addition of a single drug to a failing regimen is a big concern. Many physicians add a quinolone to the 4 first-line drugs (HRZE) when the standard therapy does not result in improvement. This is wrong, and can result in MDR-TB.

Sometimes, patients end up moving from one doctor to another, and each time the drug regimen gets modified without adequate drug-susceptibility testing (DST) to guide the choice of drug combinations. This creates a perfect environment for drug-resistance to emerge or worsen.

PITFALL 10: NOT NOTIFYING ALL CASES AND USING FREE PUBLIC SECTOR SERVICES FOR VULNERABLE PATIENTS

TB treatment is available free of cost to all patients in India via the Revised National TB Control Programme (RNTCP).[5] So, private practitioners can refer all TB patients for treatment through the RNTCP, unless patients insist on being treated in the private sector. RNTCP provides a range of services such as contact investigation, linkage to free TB drug programs, adherence support, and linkage to PMDT services for patients with MDR-TB.[5] By availing these free services, patients can protect themselves from catastrophic health expenditures. Irrespective of where the patients are diagnosed and treated, it is mandatory for private practitioners to notify all TB cases to their respective District or Corporation TB Officers.

REFERENCES:

1. Satyanarayana S, Subbaraman R, Shete P, et al. Quality of tuberculosis care in India: a systematic review. *Int J Tuberc Lung Dis.* 2015;19(7):751-63.
2. Das J, Kwan A, Daniels B, et al. Use of standardised patients to assess quality of tuberculosis care: a pilot, cross-sectional study. *Lancet Infect Dis.* 2015 (published ahead of print).
3. World Health Organization Country Office for India. Standards for TB Care in India. URL: http://www.tbcindia.nic.in/pdfs/STCI%20Book_Final%20%20060514.pdf (date accessed 7 April 2015), 2014.
4. TB CARE I. International Standards for Tuberculosis Care, 3rd Edition. URL: www.istcweb.org (date accessed 7 April 2015) 2014.
5. Sachdeva KS, Kumar A, Dewan P, Kumar A, Satyanarayana S. New Vision for Revised National Tuberculosis Control Programme (RNTCP): Universal access - "Reaching the un-reached". *Indian J Med Res.* 2012; 135(5): 690-4.