



Surgical interventions for pulmonary tuberculosis in Mumbai, India: surgical outcomes and programmatic challenges

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Setting: While surgery for pulmonary tuberculosis (PTB) is considered an important adjunct for specific cases, including drug-resistant tuberculosis, operational evidence on its feasibility and effectiveness is limited.

Objective: To describe surgical outcomes and programmatic challenges of providing surgery for PTB in Mumbai, India.

Design: A descriptive study of routinely collected data of surgical interventions for PTB from 2010 to 2014 in two Mumbai hospitals, one public, one private.

Results: Of 85 patients, 5 (6%) died and 17 (20%) had complications, with wound infection being the most frequent. Repeat operation was required in 12 (14%) patients. Most procedures were performed on an emergency basis, and eligibility was established late in the course of treatment. Median time from admission to surgery was 51 days. Drug susceptibility test (DST) patterns and final treatment outcomes were not systematically collected.

Conclusion: In a high-burden setting such as Mumbai, important data on surgery for PTB were surprisingly limited in both the private and public sectors. Eligibility for surgery was established late, culture and DST were not systematically offered, the interval between admission and surgery was long and TB outcomes were not known. Systematic data collection would allow for proper evaluation of surgery as adjunctive therapy for all forms of TB under programmatic conditions.

The World Health Organization (WHO) reported an estimated 9 million new cases of tuberculosis (TB) worldwide in 2013, of whom 3.5% were multi-drug-resistant (MDR-TB), defined as resistance to at least rifampicin and isoniazid, the two main drugs used in anti-tuberculosis treatment.¹ India has the largest estimated number of MDR-TB cases in the world, responsible for around 20% of the global burden. Treatment of MDR-TB is long and difficult, and globally only half of such cases reach a successful outcome with treatment.¹

In this context of low therapeutic effectiveness, new treatment options are urgently needed. In the pre-antibiotic era, lung surgery was the main therapeutic option for TB.² Today, with increasingly failing treatment regimens, it is again being considered a reasonable approach for some specific cases, notably localised cavitary pulmonary TB (PTB) in patients with treatment failure and sufficient pulmonary reserve to tolerate resection, or in urgent life-threatening situations.³

Despite a renewed interest in this approach, surgery for TB still lacks the support of evidence. Some studies have suggested that surgery is effective for TB cases in specific conditions,^{4,5} and a recent meta-analysis of mostly observational data⁶ showed that surgery may double the odds of a successful treatment outcome for MDR-TB cases.

Data from low- and middle-income countries (LMIC), where the disease is most prevalent, are scarce. Understanding the types of surgical interventions performed as well as their outcomes is a priority for designing effective, feasible approaches for scaling up surgery for PTB in programmatic settings.

This study aims to describe the types, indications, surgical outcomes and programmatic challenges of surgical interventions for patients with PTB in two hospitals in Mumbai, India.

STUDY POPULATION, DESIGN AND METHODS

Study population and design

This is a descriptive study of retrospectively collected data. All patients who underwent surgical interventions for PTB with our surgical team from January 2010 to December 2014 in two Mumbai hospitals—one public (GTB Hospital, the largest TB specialised care hospital in India) and one private (Jupiter Hospital)—were included in the study. Patients who underwent surgery for extra-pulmonary TB were excluded from the analysis.

Complications of surgery, repeat operations and death from any cause up to 3 months after surgery were considered as surgical outcomes. The study also analysed programmatic issues related to TB care such as resistance patterns, surgery types and intervals between starting treatment and surgery and between admission and surgery, among others.

Definitions

WHO definitions were used for patient classification, except for 'treatment failure', as data on sputum examinations were not systematically available. In this case, deterioration of a patient's clinical condition after the fifth month of treatment was used. For the category of surgical intervention, 'elective' was used for any MDR patient with a lung cavity as indication for surgery and a high probability of failure of TB chemotherapy and relapse, defined as persistent sputum positivity at the end of the intensive phase of treatment, while 'emergency' was considered for every other sur-

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gical indication, defined as any TB-related complication considered to be life-threatening or considerably reducing the patient's quality of life. Although the patient could have two or three indications for surgery, only the one stated in the referral request was used to define the 'indication for surgery'. Likewise, only the first complication that could cause permanent disability or death was considered to define 'complication'.

A grading system was used to categorise the severity of the adverse events related to surgical and medical procedures from 1 to 5.⁷ Finally, to define the intervals between treatment start and surgery, whenever the treatment start date was given as a month, it was assumed that the treatment was started on the fifteenth day of that month. Whenever only a year was recorded, 30 June was used.

Statistical analysis

Data from the two different hospitals were pooled into a single database and descriptive statistics were used for data analysis. Frequencies were applied for individual variables and cross-tabulations for comparing different variables. In the case of continuous data, the median was the summary measure for the central tendency, and range was preferred for dispersion. In the case of categorical data, proportions, percentages or ratios were used, depending on the case. Data analysis was conducted using SPSS 18.0 (IBM Corporation, Montauk, NY, USA).

The study was approved by the Institutional Ethics Committee of Jupiter Hospital, Maharashtra, India. As this was a retrospective analysis of routinely collected data, the need for written informed consent from the study participants was waived. Patient information was de-identified and data were analysed anonymously.

RESULTS

The study included 85 patients with a median age of 26 years (range 14–65 years, interquartile range [IQR] 21–34), of whom 19 (22.3%) were women.

Nineteen (22.3%) patients had their drug susceptibility testing (DST) pattern known at the time of indication for surgery. Xpert[®] MTB/RIF (Cepheid, Sunnyvale, CA, USA) was the only method performed for five of the patients (Table 1). Five (6%) patients were enrolled for treatment after loss to follow-up (LTFU). Most patients ($n = 52$) underwent insertion of a chest tube before the surgical procedure, at least half of these in hospitals other than the two study hospitals.

The majority of the surgical interventions were for emergency procedures; only seven (8.2%) were elective surgery. The two main indications for surgery were lung collapse ($n = 36$, 42.4%), followed by pleural thickening ($n = 16$, 18.8%), and the two main types of surgery were decortication and pneumonectomy (Table 2). The main indication for decortication surgery was lung collapse, suggesting extensive pulmonary lesions prior to pleural involvement. During the study period, the complexity of the surgical interventions steadily increased, mainly after 2012, when the number of procedures peaked. Pneumonectomy accounted for nine (27.3%) operations in 2012, rising to 11 (42.3%) in 2014, while there were 16 (48.4%) decortications in 2012, dropping to 9 (34.6%) in 2014.

The median interval from starting anti-tuberculosis drug treatment to the first operation was 227 days (Figure 1), and the median interval from hospital admission to the first operation was 51 days.

Seventeen (20%) surgical interventions resulted in complications, with wound infection the most frequent (five episodes,

TABLE 1 Demographic and clinical characteristics of PTB patients who underwent surgery in Mumbai, India, 2010–2014

Characteristics	Patients with PTB ($N = 85$) n (%)
Age, years, median [IQR]	26 [21–34]
Age group, years	
10–19	15 (17.6)
20–29	35 (41.2)
30–39	21 (24.7)
40–49	11 (12.9)
≥50	3 (3.6)
Sex	
Female	19 (22.4)
Male	66 (77.6)
State of origin	
Maharashtra	59 (69.4)
Uttar Pradesh	21 (24.7)
Others	4 (4.8)
Unknown	1 (1.2)
TB resistance pattern	
Drug-susceptible*	1 (1.2)
RMP-resistant†	5 (5.9)
MDR‡	7 (8.2)
XDR§	6 (7.1)
Unknown	66 (77.6)
TB registration group	
New	39 (45.9)
Relapse	11 (12.9)
Failure	4 (4.7)
Treatment after LTFU	5 (5.9)
No active TB	1 (1.2)
Unknown	25 (29.4)
Previous insertion of chest tube	
Yes	52 (61.2)
No	26 (30.6)
Not available	7 (8.2)

* Susceptible to both RMP and INH.

† Patients who underwent only Xpert testing.

‡ Resistant to at least RMP and INH.

§ MDR-TB with additional resistance to any fluoroquinolone and at least one second-line injectable drug.

PTB = pulmonary tuberculosis; IQR = interquartile range; RMP = rifampicin; MDR = multidrug resistant; XDR = extensively drug resistant; LTFU = loss to follow-up; INH = isoniazid.

29.4%), followed by bronchopleural fistula (four episodes, 23.5%). The type of surgery with the highest number of complications was pneumonectomy, accounting for 9 (53%) episodes (Figure 2). Nine complications were categorised as grade three (severe but not immediately life-threatening), three as grade four (urgent, life-threatening); and five as grade five (resulting in death) (Figure 3).

A repeat operation was needed for 12 (14.1%) patients, of which 10 were for complications, including wound complications ($n = 5$), bronchopleural fistulas ($n = 3$) and haemorrhagic complications ($n = 2$). One repeat operation was a second procedure in a multiple stage approach and another was a procedure for a collapsed lung on the other side of the thorax. Thoracoplasty was the main type of repeat operation, with five (41.7%) episodes. One patient was subjected to four consecutive surgeries for consecutive complications.

TABLE 2 Details of surgical interventions in PTB patients who underwent surgery in Mumbai, India, 2010–2014

Characteristics	Patients (N = 85) n (%)
Side of intervention	
Right	50 (58.8)
Left	34 (40.0)
Not available	1 (1.2)
Surgical intervention	
Elective	7 (8.2)
Emergency	75 (88.2)
Not available	3 (3.5)
Indication for surgery	
Lung collapse	36 (42.4)
Pleural thickening	16 (18.8)
Lung cavity	7 (8.2)
Pyopneumothorax	6 (7.1)
Recurrent haemoptysis	6 (7.1)
Bronchopleural fistula	3 (3.5)
Empyema	3 (3.5)
Aspergilloma	2 (2.4)
Chest abscess	1 (1.2)
Wound complication	1 (1.2)
Not available	4 (4.7)
Type of surgery	
Decortication	34 (40.0)
Pneumonectomy	30 (35.3)
Thoracostomy	10 (11.8)
Lobectomy	6 (7.1)
Wound debridement	1 (1.2)
Thoracoplasty	1 (1.2)
Not available	3 (3.5)
Interval from starting treatment to surgery	
Days, median (range)	227 (10–7588)
Interval from admission to surgery	
Days, median (range)	51 (0–440)

PTB = pulmonary tuberculosis.

Of seven patients submitted for elective procedures, five underwent pneumonectomy and two lobectomy. Two complications were observed in this group: one bronchoaspiration resulting in death and one bronchopleural fistula that needed reoperation.

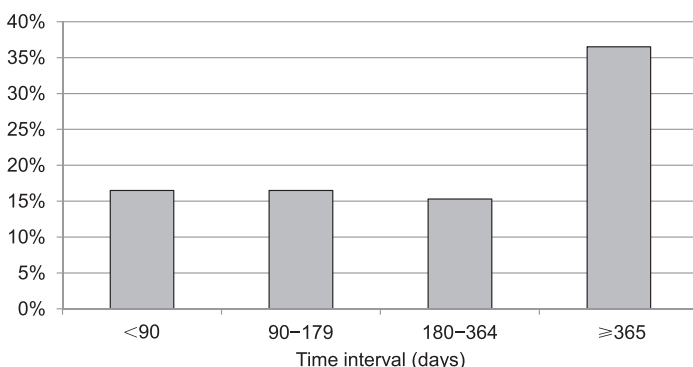


FIGURE 1 Time intervals between treatment initiation and surgical intervention (in days) for PTB patients who underwent surgery in Mumbai, India, 2010–2014. PTB = pulmonary tuberculosis.

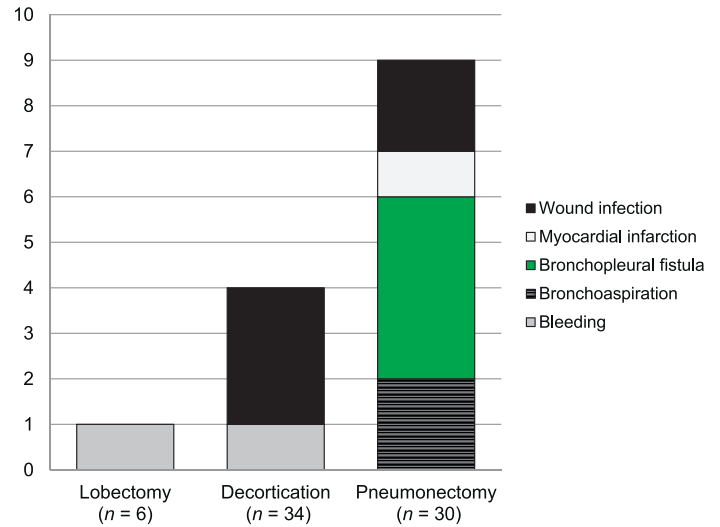


FIGURE 2 Post-surgical complications in PTB patients who underwent selected surgical interventions (lobectomy, decortication and pneumonectomy), Mumbai, India, 2010–2014. PTB = pulmonary tuberculosis.

Among the 52 patients who had previously undergone chest tube insertion, 29 (55.7%) had lung collapse, 11 (21.2%) had pleural thickening and five (9.6%) had pyopneumothorax as the main reason for surgery. All of these patients were admitted for emergency surgical procedures and 11 (21.2%) had complications; wound infection was the most frequent, with four (36.4%) episodes, all of which had good outcomes with repeat operation and antibiotic treatment. There were three (5.8%) deaths in this group, one related to a myocardial infarction and two others with no identified cause.

Five of the 85 patients included in the study died (Table 3). Four had lung collapse and had been on treatment for PTB for >1 year, and all had pulmonary disease that had spread to multiple lobes. None underwent repeat operation. The cause of death for one patient was bronchial aspiration and respiratory failure, and for another it was myocardial infarction. Three patients had no identified cause of death.

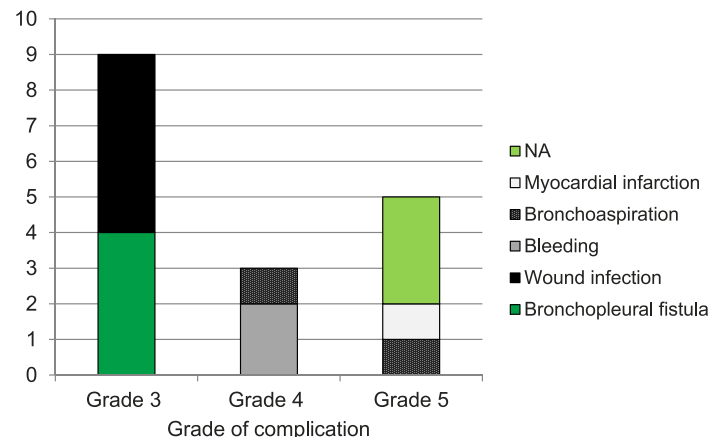


FIGURE 3 Severity of complications with surgical procedures in PTB patients who underwent selected surgical interventions (lobectomy, decortication and pneumonectomy), Mumbai, India, 2010–2014. PTB = pulmonary tuberculosis.

TABLE 3 Outcomes of surgical interventions in PTB patients in Mumbai, India, 2010–2014

Characteristics	Patients (N = 85) n (%)
Surgery complications	17 (20.0)
Wound infection	5 (29.4)
Bronchopleural fistula	4 (23.5)
Bleeding	2 (11.8)
Bronchoaspiration	2 (11.8)
Myocardial infarction	1 (5.9)
Not available	3 (17.6)
Reoperations	12 (14.1)
Thoracoplasty	5 (41.7)
Wound debridement	4 (33.3)
Thoracotomy	3 (25.0)
Death	5 (5.9)

PTB = pulmonary tuberculosis.

DISCUSSION

In our setting, surgery for PTB was mainly indicated at a late, advanced stage of disease as a last resort, often to treat a complication. More than 85% of surgeries were performed on an emergency basis, and only 28% after less than 6 months of anti-tuberculosis treatment. The surgical cases were most likely MDR-TB, but information on DST patterns was largely missing, with data available for only 22.3%. While the adjunctive value of surgery for complications of PTB is less controversial, the value of surgery for improving MDR-TB treatment outcomes has recently been demonstrated in a meta-analysis,⁶ although it is still debatable.

The rationale for recommending surgery for MDR-TB is based on two main arguments.⁸ First, the bacilli may be sequestered inside thick-walled compartments, such as granulomas, abscesses and cavities, where antibiotics cannot easily penetrate. Second, in the course of a long-standing disease with a large number of caseating tissue foci, there is substantial tissue destruction, *Endarteritis obliterans*⁹ and poor vascularisation, reducing drug delivery into the affected tissue. These factors not only impact the survival of the individual patient, they also contribute to the development and transmission of MDR-TB. A recent meta-analysis showed that partial lung resections were associated with better treatment outcomes for MDR-TB compared with no surgical procedure.¹⁰

The timing of the surgical procedure is another point that is still unclear. The WHO currently recommends that resection surgery for MDR-TB should be timed to allow the best chances of cure with the least morbidity.¹¹ This suggests that it makes more sense to perform elective procedures at an earlier stage, when the disease is still confined to one lobe or lung, rather than perform urgent procedures at a later stage with extensively destroyed parenchyma. One study in Peru has suggested that surgery for MDR-TB performed in the first 6 months of treatment increased the probability of a successful treatment outcome with a regimen of shorter duration, with little additional cost to the TB programme, as long as facilities and expertise already exist.¹² Unfortunately, this is not the reality in many LMICs with fragile health systems.¹³

The high burden of MDR-TB in Mumbai, and in the whole of India, and the existence of expertise and facilities, create a clear need and opportunity for early identification of potential candi-

dates for elective resection surgery and enrolment in randomised controlled trials. Patients are usually referred for surgical evaluation on an emergency basis, however, when treatment has been failing for a long time and a large part of the lung parenchyma has already been destroyed. In this sense, physician awareness should be increased to identify and call for surgical evaluation of patients with localised disease, advanced resistant patterns and failing regimens.

Another challenge for the early identification of potential candidates for surgery is the lack of access to DST in the health system. Patients presenting with TB complications seem to be adhering to treatment, with only 5.9% registered as treatment after LTFU. This may suggest that the patients are experiencing complications for other reasons, and MDR-TB could be an important cause. Nevertheless, the resistance pattern of most of the patients was unknown (77.6%). Expanded access to TB culture and conventional DST or molecular DST tests such as Xpert, as recommended by the WHO,¹¹ could potentially reduce complications and the need for urgent TB surgery.

Access to PTB surgery for women could also possibly be a challenge, as in our study it was mainly performed in men, with a sex ratio of 3.4:1. One study in Mumbai has shown that married women may hide their disease for fear of rejection and blame.¹⁴ This could impact timely access to health care and treatment for complications. Health-seeking behaviour could also play a role, as shown in another study,¹⁵ where women, despite suffering greater stigma, were more likely to access health services and adhere to treatment. Better adherence could generate less complications and less need for urgent surgery. More studies are needed to investigate these correlations further.

Another programmatic challenge is the long median interval between admission and surgery, of 51 days. This indicates that the patient may be clinically unstable when admitted, needing management before surgery. The high proportion of patients who underwent insertion of a chest tube (61.2%) before surgery reinforces this argument. This need could again be minimised by early detection of potential patients and enrolment in elective procedures. This also indicates a lack of resources during the pre-operative period or for the surgical procedure itself. Reducing this interval would bring important advantages in clinical outcomes as well as improving the efficiency of the health system by increasing the availability of beds for patients in need in an escalating MDR-TB epidemic.

A very important challenge identified is the lack of information exchange between the TB programme and the surgical team. Documentation of the outcome of anti-tuberculosis treatment was generally absent in the surgical team register, and there was no means of systematically retrieving this information from any source. Without proper communication, it becomes extremely difficult to evaluate the effectiveness of interventions and treatment outcomes, and a fragmented health system is a threat to the safe clinical management of patients. A possible solution could be the systematic use of a unique patient identifier linking surgery data with TB programme data.

The complications and mortality in this study were similar to those in previous reports. In Israel, one cohort of 17 patients showed 5.8% mortality in the early post-operative period, with 35.3% complications.⁴ In Morocco, another study showed 3.44% mortality with 31% complications.¹⁶ In New Delhi, the mortality was 4.2% with 10.1% complications.⁵ In this series, the mortality was 5.9% with 20% complications, indicating that the results of surgery for PTB are consistent in resource-limited settings.

This study had some limitations. It was a retrospective study, based on data collected by the surgical team during hospital admission and follow-up visits. Missing values were significant for some variables, and several assumptions had to be made to ensure completeness of data and analysis. Also, although the hospitals included in the study play an important role in the Mumbai TB programme, our data set may not be representative for the whole city.

CONCLUSIONS

This study shows that morbidity and mortality among PTB patients who underwent surgery in our setting were comparable with other study settings. It also shows, however, that in our experience, most surgery for PTB is indicated at a late, advanced stage of disease, as a last resort.

Further studies should investigate the programmatic challenges of surgery for PTB in a nationally representative sample of patients and the effectiveness of elective PTB surgery in the treatment outcomes of MDR-TB in controlled trials.

To improve access to surgical care for PTB, we need to detect MDR-TB early; expand access to TB culture and conventional or molecular DST, such as Xpert; increase awareness among physicians regarding the possibility of early referral for surgical evaluation for PTB; reduce the interval between hospital admission and surgery; and strengthen referrals and communications between the surgery department and the TB programme, including data sharing.

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Contexte : La chirurgie de la tuberculose pulmonaire (TBP) est considérée comme un adjuvant important dans des cas spécifiques, notamment celui de la TB pharmacorésistante ; les preuves opérationnelles de sa faisabilité et de son efficacité sont cependant limitées.

Objectif : Décrire les résultats de la chirurgie et les défis programmatiques liés à l'offre de chirurgie à Mumbai, Inde.

Schéma : Une étude descriptive de données recueillies en routine relatives aux interventions chirurgicales de TBP de 2010 à 2014 dans deux hôpitaux de Mumbai (un public, un privé).

Résultats : Sur 85 patients, 5 (6%) sont décédés, 17 (20%) ont eu des complications, dont la plus fréquente était une infection de la plaie. Une deuxième intervention a été nécessaire dans 12 cas (14%). La majorité des procédures a été réalisée en urgence et l'éligibilité a

été établie tardivement au cours du traitement. Le délai médian de l'admission à la chirurgie a été de 51 jours. Les profils de résistance de la TB et le résultat final du traitement n'ont pas été recueillis de façon systématique.

Conclusion : Dans un contexte lourdement touché comme Mumbai, des données importantes relatives à la chirurgie de la TBP ont été étonnamment limitées à la fois dans le secteur privé et public. L'éligibilité à la chirurgie a été établie tardivement, la culture et le test de pharmacosensibilité n'ont pas été systématiquement proposés, l'intervalle entre l'admission et la chirurgie a été long et les résultats en matière de TB n'ont pas été notés. Un recueil systématique des données permettrait une évaluation correcte de la chirurgie comme traitement adjuvant de toutes les formes de TB dans des conditions de programme.

Marco de referencia: El tratamiento quirúrgico se considera un complemento importante en el manejo de casos específicos de tuberculosis pulmonar (TBP), como la TB farmacorresistente; sin embargo, las pruebas operativas de su factibilidad y eficacia son escasas.

Objetivo: Describir los desenlaces quirúrgicos y las dificultades programáticas de la prestación de opciones quirúrgicas a los casos de TBP en Bombay, en la India.

Método: Fue este un estudio descriptivo de los datos recogidos de manera sistemática sobre las intervenciones quirúrgicas por TBP, realizadas del 2010 al 2014 en dos hospitales de Bombay (uno del sector público y otro del sector privado).

Resultados: De los 85 pacientes tratados, cinco fallecieron (6%), 17 presentaron complicaciones (20%), de las cuales la infección de la herida fue la más frecuente. Fue necesaria una segunda intervención en 12 pacientes (14%). La mayoría de los procedimientos tuvieron

lugar en un contexto de urgencia y los criterios de selección se analizaron tarde en el curso del tratamiento. La mediana del tiempo entre la hospitalización y la cirugía fue 51 días. El tipo de resistencia de la TB y los desenlaces terapéuticos no se registraron de manera sistemática.

Conclusión: En un entorno con alta carga de morbilidad por TB como Bombay, los datos importantes sobre la cirugía por TBP son sorprendentemente escasos en el sector público y también en el sector privado de atención. Los criterios de selección para la cirugía se analizan tarde, no se ofrece de manera sistemática el cultivo y las pruebas de sensibilidad a los medicamentos, el intervalo entre la hospitalización y el procedimiento es prolongado y se desconocen los desenlaces clínicos de la tuberculosis. La recogida sistemática de datos facilitaría una evaluación adecuada de la cirugía como tratamiento complementario en todas las formas de TB en un contexto programático.