



## Review

## Retrospective study of clinical and lesion characteristics of patients undergoing surgical treatment for Pulmonary Tuberculosis in Georgia



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## ABSTRACT

**Objectives:** Our aim was to retrospectively compare clinical data and characteristics of removed lesions of the cohort of patients undergoing therapeutical surgery for their tuberculosis.

**Design and methods:** Demographic and epidemiological details, clinical data, data on the surgery performed, macroscopic characteristics of the TB lesions removed, and outcome were recorded retrospectively from the 137 patients who underwent therapeutical surgery for their TB in Tbilisi, Georgia during 2014 and 2015.

**Results:** Men represented 70% of the included patients, presented more comorbidities and underwent operation earlier in terms of days between diagnostic and surgery. Women underwent operation at younger ages, and in MDR/XDR-TB cases, showed higher percentages of sputum conversion at >2 months and of fresh necrosis in the surgical specimens, suggesting a worse evolution. Half of cases were MDR/XDR-TB cases. In spite of being considered microbiologically cured according to WHO, a non despicable percentage of cases showed viable bacilli in the surgical specimen. Even if no causality could be statistically demonstrated, differences could be encountered according to gender and drug susceptibility of the responsible strains.

**Conclusions:** According to our results, host factors such as gender, type of necrosis found in the lesions, size of lesions and presence of viable bacilli in the surgical specimen, should be included in future studies on therapeutical surgery of TB. As most of studies are done in MDR/XDR-TB, more data on DS-TB operated cases are needed. Our results also highlight that, in spite of achieving the microbiologically cured status, sterilization might not occur, and thus new biomarkers and new methods to evaluate the healing process of TB patients are urgently needed and radiological assays should be taken into account.

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### 1. Introduction

According to the World Health Organization (WHO), Georgia has a high incidence of tuberculosis (TB) cases (116/100,000

habitants), with a high Multi-Drug Resistant TB (MDR-TB) burden (51% of all declared cases in 2015).<sup>1</sup> In countries with high incidences, therapeutical surgery is still a good option to cope with TB complications and sequelae, as well as to reduce the bacilli burden<sup>2</sup>; and might be essential as an adjuvant to the appropriate chemotherapy in the MDR-TB cases.<sup>3</sup> In this manuscript, we present a study that aimed to retrospectively compare clinical data and characteristics of removed TB lesions of a cohort of patients undergoing therapeutical surgery for their TB, in the National Center for Tuberculosis and Lung Diseases (NCTLD, Tbilisi, Georgia).

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## 2. Materials and methods

### 2.1. Design

The project was reviewed and approved by the Ethics Committee IRB00007705 NCTLD Georgia #1, IORG0006411 (Tbilisi, Georgia) and the Ethics Committee of Germans Trias i Pujol Hospital (Badalona, Catalonia, Spain) to ensure compliance with all current national and European laws on clinical studies. The study was registered at the clinicaltrials.gov database with the identifier NCT02715271. The results presented here were extracted from a retrospective cohort including all patients operated per clinical routine at the NCTLD.

### 2.2. Data

Data were recorded retrospectively and anonymously from the 2014 and 2015 surgical notebooks in a Spreadsheet created ad-hoc, including different categories on both the patients and the lesions'

characteristics. WHO definitions were used whenever possible.<sup>4</sup> Table 1 includes all data categories recorded, definitions and possible answers. Graph Pad Prism 6 software (La Jolla, CA, USA) was used to draw the figures. Statistical analysis was done using the independent 2 samples t-test to compare continuous variables. The associations with other categorical variables were tested with the Chi-square test or Fisher exact test. All tests were two-tailed, and p-values less than 0.05 were considered statistically significant.

## 3. Results

### 3.1. Demographic and epidemiological features

A total of 137 patients underwent therapeutical surgery for their TB at the NCTLD during the years 2014 and 2015, 96 males (69.8%) and 41 females (30.8%). Men were older (median age = 43.5 years old) than women (28 years old). 25% of men had comorbidities: Hepatitis C Virus Infection (n = 15), Diabetes

**Table 1**  
Data recorded

Group	Category	Variables
Demographic and epidemiological data	Age (years old)	In years old
	Gender	Male/Female
	Smoking habit	on daily or almost daily basis, weekly, monthly, less than monthly, never
	Alcohol intake	on daily or almost daily basis, weekly, monthly, less than monthly, never
General clinical data	Presence of comorbidities	Diabetes mellitus, HIV infection, immunosuppression other than HIV-infection, renal failure, chronic obstructive pulmonary disease (COPD) previous to TB, Hepatitis C Virus infection, hepatic cirrosis, others
Clinical data regarding the TB	history of previous treatment	new patient, relapse patient: treatment after failure, treatment after loss to follow-up patient, other previously treated patient, unknown previous TB treatment
	anatomical site of TB	Pulmonary, extrapulmonary
	drug-sensitivity	Drug Sensitive (DS-TB), Rifampicin Resistant only, Monoresistance to any other drug other than rifampicin, polydrug resistance, MultiDrug Resistant (MDR), extradrug resistance (XDR)
	date of diagnosis of the present TB episode	dd/mm/yy
	date of treatment initiation	dd/mm/yy
	number of lesions found in the chest X-ray assay	n
	bacteriology cured or not at the time of surgery according to WHO's guidelines	Yes/No
Data regarding the surgery performed	time from TB diagnosis and surgery	Recorded in months, and analyzed as always negative, negative at ≤2 months (M) or negative at >2 M
	main indication for surgery	In days Still lesions in X-ray assays, Clinically not cured, Microbiologically not cured, Others (spontaneous pneumothorax, pulmonary haemorrhage, pleural empiema)
	number of operated lesions	n
	type of surgery performed	segmentectomy (for lesion resection or removing lung segment), lobectomy (for lung resection or removing lung lobe), Pulmonectomy (for removal of the whole lung)
	date of surgery	dd/mm/yy
Data on macroscopical characteristics of the TB lesions removed (surgical specimens)	post-surgery complications	Open answer
	lesion size	in cm, considering the maximum lenght
	type of lesion operated	tuberculoma, cavitation
	presence of necrosis	no necrosis, necrosis: moderate growth of connective tissue, alternating with unmodified lung tissue, cirrosis: complete substitution of lung tissue by the connective tissue with damage of vessels and bronchies
	type of necrosis	fresh: necrosis macroscopically looking like of a liquid consistency, dry: necrosis macroscopically looking like of a dry consistency, both: coexistence of fresh and dry necrosis
	Presence of Acid Fast Bacilli (AFB)	Yes/No
Outcome	Positivity of culture of samples in solid medium (Lowenstein-Jensen) for <i>M.tuberculosis</i>	Yes/No
	Official final outcome according to WHO definitions	Treatment completed, Treatment success, Cured, Lost of follow-up, Treatment failed, Still not known, Not evaluated, Death (if death, date of death in dd/mm/yy recorded)

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