

Invasive Procedures Used in Tuberculosis with Questionable Indications: Report from Russia

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Abstract

Surgical treatment of tuberculosis has been applied in the former Soviet Union more frequently than in other countries. On the contrary to the international practice, tuberculoma cases have been often operated on. There was a decreasing tendency since the last decades; but the surgery rate is still comparatively high. Surgeries were sometimes performed without preceding chemotherapy. Among others, an argument in favor of the early surgery was non-compliance increasing with time. Compulsory treatments of patients with Tb and/or alcoholism are discussed here. The factors predisposing to the use of invasive procedures with questionable indications included the partial isolation from international scientific community, insufficient consideration of the principles of informed consent, professional autonomy and scientific polemics, as well as paternalistic attitude to patients. The message of this review is that patients should not undergo operations to comply with doctrines. Evidence-based clinical indications must be determined individually.

Keywords: tuberculosis; surgery; bronchoscopy; alcoholism; Russia

Introduction

After the successful development of medical treatment of tuberculosis (Tbc), the use of surgery has declined in many countries. However, over the last few decades, the development of drug-resistant *M. tuberculosis* strains has lowered success rates for drug therapy alone and has led to an increase in numbers of patients needing surgery [1]. Priority of Russia in this field was claimed [2,3]. The surgery of Tbc has been performed not only in specialized centers but also in peripheral hospitals [4,5]. This development was associated with the names of Lev Bogush (1905-1994) and Mikhail Perelman (1924-2013), who propagated the surgical treatment of Tbc [6]. In particular, Perelman (the Chief specialist for Tbc at the Health Ministry of RF until 2010) advocated early surgery in patients with comorbidity of Tbc and alcohol-related conditions.

Methods

This is a narrative review based predominantly on Russian-language and partly on the international literature. The search of literature was performed mainly on PubMed, on the Internet, in libraries and the electronic database eLibrary.ru. It should be mentioned in this connection that, unlike other countries, public libraries are rarely used in Russia and usually contain no professional literature.

Medical libraries are hindered from using by the general public, including even retired doctors, by technical difficulties [7]. The data from the literature have been reviewed and synthesized on the basis of the author's observations since the 1970s. Clinical recommendations are generally avoided here. This gave to the author a possibility to limit the citation of international literature as the number of references supporting the narration is quite large.

Results

The incidence of Tbc in Russia increased from 34.0 in 1991 to 90.4 per 100,000 in the year 2000 and declined to 48.3 by 2017 [8]. Similarly, to other diseases [9,10], these drastic oscillations could have been partly explained by artifacts, in particular, underestimation during the Soviet era. In the period 1973-1987, 285,000 patients with pulmonary Tbc were operated in the former Soviet Union, in 1987 - 26,000, while 85% of the surgeries were lung resections. In 1986-1988, ~17,500 operations for pulmonary Tbc were performed annually in the Russian Federation (RF) only in specialized institutions [3,11]. More than 29% of newly diagnosed Tbc cases were operated on at that time. In 1989, Perelman claimed that the surgery rate in Tbc must be increased by a factor of three [11]. Nonetheless, the quantity of surgeries declined to 10,479 (~9% of newly diagnosed cases) by 2003 along

with post-Soviet social perturbations [12]. The same surgery rate (9%) was reported in children in adolescents [13]. In the international literature, corresponding figures are usually below 5% [14-16]. The forms of Tbc most frequently treated by resections and pneumonectomies were cavitary Tbc (52.2%) and tuberculoma (43.9%) [17]. For example, a series of 578 surgeries in 502 patients included operations for fibro-cavernous Tbc (196 cases) and tuberculomas (161 cases), while the most frequent procedures were lung resection (280 cases) and pneumonectomy (80 cases). Perelman concluded that “indications for surgical management of pulmonary Tbc should be generally expanded” [18]. A study from Sechenov Medical University, the leading institution in this field, reported 771 lung operations, including 168 pneumonectomies, 181 lobectomies, 180 other resections, performed in 700 Tbc patients, up to 4 operations per patient. Postoperative complications were recorded in 100 (12.9%) and lethal outcomes in 12 (1.5%) of the cases [19]. Another example from the same institution: a series of 60 operated Tbc patients, whereas the complication rate was 37%, mortality 5%; 18.3% of the patients were released from the hospital with persisting complications [20].

Resections were recommended also for patients with inactive post-tuberculous fibrosis including oligosymptomatic cases [21]. At the same time, operations were performed in florid disseminated disease [22]. In some provinces of the Urals, Siberia and Volga regions, 25-40% of patients with destructive Tbc were operated on [23]. At the time of initial diagnosis, surgery has been considered indicated in 15-20% of patients [24, 25]. According to another paper, indications for surgery were found in 20-30% of patients at the time of diagnosis and/or in those with active Tbc [26]. In Yekaterinburg and surrounding province (years 2006-2008), indications for surgery were found in 1784 from 4402 (40.5%) patients with pulmonary Tbc, while 1079 (24.5%) were operated on. Among reasons of the allegedly low surgery rate were the non-compliance and unavailability of patients [27]. According to the recent handbook, ~6.4% of Tbc patients are operated on in RF; but “in some provinces, which cooperated with the Perelman’s Institute... the surgery rate has been much higher” [28]. It was stated in a seminal article dated 2009 that a half of lung surgeries in RF were performed for Tbc [2].

The recommendation to perform lung resections for tuberculoma originated from Lev Bogush [29].

Tuberculoma larger than 2 cm has been regarded as indication for surgery [28,30,31]; in children and adolescents even 1.5 cm [13]. Tuberculomas >1 cm was routinely operated on [32-34]. Those located in the pulmonary segment 6 were to be removed independently of size [31]. Tuberculoma has been among the forms of the disease most frequently operated on [24]. Reportedly, every third surgery for Tbc in RF has been performed for tuberculoma [35]. It has been the most frequent indication for the lung surgery in pulmonary Tbc at the I.M. Sechenov Medical University (44.2% of the cases in general; in children - 40.7%) [2,36]; while at some pathobiological hospitals the share reached 50-80% [35]. Tuberculoma was the form of Tbc most often operated on by Giller and co-workers: 81 from 179 cases in one series [37]. The surgical treatment of tuberculoma was recommended also for cases with extensive lesions in remaining pulmonary tissues [38]. Bilateral resections were performed in various forms of Tbc including tuberculomas on both sides [39-41]. Apropos, the term “Tuberculoma” in the titles of the articles [42,43] was replaced in the PubMed by “Tuberculosis”. Those who sent the wrong titles to the PubMed probably understood what they were doing, as tuberculoma is not uniformly regarded to be indication for thoracic surgery. As mentioned above, recommendations are avoided in this review.

Tuberculoma was the most common indication, and lobectomy - the most frequent operation in elderly Tbc patients, whereas potential contagiosity was an argument in favor of the thoracic surgery [44,45]. According to Giller and co-workers, a reduction of Tbc incidence and mortality can be achieved only through a “radical sanitation” of contagious patients including those without destructive pulmonary lesions [37]; and that surgery is important because it prevents infection of other people [2]. “Reduction of *M. tuberculosis* circulation in the society” has been declared to be one of the goals of the surgical treatment [24]. For that reason, early compulsory hospitalization has been recommended [46,47]. One more citation: “Active surgical sanitation of infectiously dangerous patients with pulmonary Tbc contributes to the rapid improvement of epidemiological statistics” [48]. No mentions of informed consent have been found in the context.

Out of 1,311 Tbc cases operated at the Phthisio pulmonology Institute in St. Petersburg, 241 had recurrences and 203 underwent repeated interventions [49]. Postoperative recurrences were

regarded as indications for repeated surgeries up to a concluding pneumonectomy [41] and resections of the remaining sole lung [50]. For example, resections on both sides ending with a pneumonectomy, along with 52 bronchoscopies, were performed in one case [51]. Bilateral lobectomies or pneumonectomy plus contralateral “sparing” resection were regarded to be indicated for patients with a Tbc lesion on one side and non-specific inflammatory or fibrotic lesions in the contralateral lung [52]. Bilateral resections and bilobectomies were performed for different lesions including tuberculomas [39-41,50,52,53]. According to a recent monograph, among 420 patients operated for tuberculoma, bilateral operations were performed in 130 (31%) [54]. Resections were regarded to be applicable also in cases with severe respiratory insufficiency [4,50,55,56].

Another indication, also in children and adolescents, has been the “absence of positive dynamics” after 4-6 months of medical therapy or earlier in case of drug resistance [13,30,43]. The resistance per se and irreversibility of morphological changes were declared to be indications for surgery [24]. Resections for Tbc were performed by some experts without preceding attempt of medical treatment or within one month after the diagnosis [32,57]. One of the arguments in favor of the early surgery was the non-compliance increasing with time [32] as the patients collected knowledge and advice. Cherkasov and co-workers stressed advantages of surgery without preceding medical therapy as it shortened the treatment duration [42].

Lung operations were performed and recommended also for aged patients with comorbidities [44,58-60]. Sokolov found indications for surgery in 210 from 289 (72.6%) of Tbc patients 50-73 years old and operated 180 (62.2%) of them, 144 operations being lung resections. Among the latter 144 patients, 93 (66.4%) had cavitating lesions and 43 (30.8%) tuberculoma. A post-surgery reactivation of Tbc was recorded in 8.6% of the cases, fistula - in 27.2%, atelectasis - 20%, pneumonia - 5.7%, pleural empyema - 3.6%, other complications - 12.9%; 8 (5.7%) patients died after the operations [60]. The frequency of adverse effects has probably been underestimated due to the limited follow-up. In the monograph based on 233 lung resections in Tbc patients older than 50 years (mortality - 5.4%), Gorovenko et al. reasonably concluded: “It is important that a surgery does not provoke an unfavorable outcome” [58].

The overuse of bronchoscopy in RF has been discussed elsewhere [61]. Bronchoscopy has been applied in all forms of Tbc in many institutions and cohorts, also within a diagnostic algorithm for suspected Tbc with the sputum negative for *M. tuberculosis* [62]. Primary Tbc was regarded as an indication for bronchoscopy in children [63], although it is reportedly no more sensitive for the culture than gastric aspirations [64]. Bronchoscopy was used as a screening method for Tbc in patients with general malaise, having both negative and “hyperergic” (high degree of hypersensitivity) tuberculin tests [65,66]; or as a second step of screening in children [67]. In the recent handbook of pediatric pulmonology, suspected Tbc is listed among indications [68]. Therapeutic bronchoscopy and endoscopic monitoring has been applied in Tbc also with non-specific bronchial lesions [69-71]. In destructive Tbc, therapeutic bronchoscopies (1-2 weekly during 2-4 months) were recommended by the Ministry of Health [72]. An example: 22,469 procedures performed in 5195 patients from 1994 through 2013 (1123 yearly on average), including 1766 (34%) patients older than 65 years, at a pathobiological hospital in Moscow (705-1225 beds at different times; 368 surgeries performed in 2013) [73,74]. Of note, viruses can be transmitted by endoscopy [75]. Not surprisingly, the incidence of hepatitis B was found to be five times higher in Tbc patients than in the general population of Russia [76]. The enhanced frequency of viral hepatitis or of its markers in Tbc patients including children was reported [77].

Pulmonary resections and pneumonectomies for Tbc were performed also in the former GDR. Of note, amongst 502 surgical cases (81 pneumonectomies, 266 lobectomies, 155 segmental resections), there were only 3 tuberculomas [78]. Indications for surgery were more limited than discussed above, being evaluated after chemotherapy and stabilization of the disease. Contralateral foci were considered to be contraindications. In 1965, results of a study were published indicating a decline in the vital capacity of the lungs after resections [79]. Mainly small case series were reported [80-82]. A tendency of a decrease in the surgery rate for Tbc was noticed [78,83,84]. Today, surgeries for pulmonary Tbc in Germany are highly selective [85].

Surgical and other treatment of tuberculosis and alcoholism

A particular ethical problem has been the overuse of surgery in Tbc patients diagnosed with an alcohol use disorder. According to official instructions, indications for surgery have been broader in alcohol-dependent than in other patients [47,86]. In case of alcoholism, the surgical treatment was recommended to be applied earlier, after a shorter period of medical therapy. The Chief phthisiologist of the Health Ministry (until 2010) Mikhail Perelman insisted on early surgery in Tbc patients with alcohol dependence, and operated them also in the absence of demonstrable *M. tuberculosis*. The same expert noticed that alcoholics have more frequent post-surgery complications [87]. Epshtein and Palei recommended reducing the pre-operative therapy of alcoholics to 1.5-2 months; they also recorded complications in 67 from 178 operated patients with Tbc and alcoholism [88]. Ogirenko and co-workers designated the indications for surgery in destructive Tbc combined with alcoholism as “urgent”, mentioning at the same time potentially grave consequences of thoracic surgery in such patients [89]. One study reported that 53.2% of *M. tuberculosis* excretors with concomitant chronic alcoholism underwent surgery [90].

The overuse of bronchoscopy in children and adults with Tbc and other diseases had been discussed above and elsewhere [61]. Bronchoscopy has been used in Tbc patients diagnosed with alcoholism also in non-specific bronchial conditions [91]. Bronchitis is frequent among alcoholics in the former SU due to smoking and heavy binge drinking with a risk to sleep down at a cold place. Along with other complications, vocal cord injuries were observed after repeated bronchoscopies. Endoscopic procedures are associated with transmission of viral infections [75], in particular, under conditions of suboptimal procedural quality, as it is sometimes the case in supposed alcoholics. Infection with viral hepatitis by endoscopic and endovascular manipulations is known to occur among these patients. Of note, a combination of viral and toxic liver injury is harmful. The endobronchial, endotracheal (through microtracheostoma) and other parenteral drug delivery routes were preferred in Tbc patients diagnosed with alcoholism [92-94]. Certain anti-tuberculosis drugs (cycloserine, rifampicin and other) exacerbated alcohol-related hepatic and neural derangements [47]. Nevertheless, rifampicin was officially recommended for patients with comorbidity of Tbc and alcoholism, and administered also intravenously [86,92,95]. Furthermore, it should be

mentioned that vigorous vomiting triggered by apomorphine as aversive therapy of alcohol dependence provoked hemoptysis and pneumothorax in Tbc [47,91]. Many treatments in patients diagnosed with alcoholism have been in fact compulsory (discussed below). Of note, the presence of Tbc and/or alcohol use disorder does not interfere with a person's right to refuse a treatment. The principle of informed consent for invasive procedures is of particular importance in conditions where overtreatment may occur [96].

Compulsory treatments and detainment

According to the governmental Regulation No. 378 of June 16, 2006, patients with contagious Tbc are not permitted to reside in one apartment with other people. The outpatient treatment is supposed to be hardly applicable [97]. As per the Federal Law 77-FZ “Prevention of tuberculosis spread” of June 18, 2001 (amended 2013), “patients with contagious Tbc, repeatedly violating the anti-epidemic regime, those evading examinations or [emphasis added] therapy, are hospitalized for obligatory examination and treatment.” It is specified by the same law that the principle of informed consent is not applicable under these circumstances, and that patients must undergo prescribed examination and therapy. The non-observance of this law may lead to a criminal prosecution. It was reported that over 6000 legal proceedings in the period 2004-2008 resulted in compulsory hospitalizations of 3163 Tb patients [98]. In one series, 463 judicial cases resulted in 421 court decisions to hospitalize Tb patients [99]. Almost all claims of that kind from authorities are currently satisfied by courts in the Moscow province (oblast). The police are obliged to help at hospitalizations and search of evading individuals [100].

Reportedly, over of 60% patients broke out from a “phthisio-narcological” institution for compulsory treatment of Tbc combined with alcoholism; ~50% of them were brought back by the police [101]. The duration of stay in such institutions was around a year or longer [91]. The phthisio-narcological institutions were fenced by barbed wire and guarded by the police. The regime was like in prison. The personnel were entitled to punish patients. As mentioned above, parenteral drug delivery routes were preferred [94]. The compulsory treatment has been endorsed by laws and regulations [91,102]. In 1974, chronic alcoholism was declared to be a ground for compulsory treatment; the regulations were made stricter in 1985, making compulsory hospitalization and therapy of

chronic alcoholics independent on their anti-social behavior. This was found in the 1990s to be contradictory to human rights and the system of compulsory treatment has been partly dismantled; but experts recommended its restoration and further development [98]. According to a survey, 62.6% of specialists in addiction medicine supported enforced treatment of alcoholism [103]. The compulsory therapy of socially dangerous alcoholics is stipulated by Articles 97 and 98 of the Criminal Code of RF. The implementation of compulsory examinations and treatments is increasingly efficient these days. Reportedly, 100% of *M. tuberculosis* excretors in Moscow province have been hospitalized since 2019 [100]. Besides, there is a legal mechanism permitting compulsory treatment of prison inmates diagnosed with an "open form of Tbc" (Article 18 of the Criminal Executive Code of RF) and/or alcoholism [104]. In one study, 29.5% of prisoners having Tbc were operated on; thereafter 22.6% of them developed exacerbations. The treatment results were inferior to those in the general population [105]. Suboptimal procedural quality and post-surgery nursing probably played a role.

Compulsory treatments are generally at variance with the international practice and regulations. According to The World Medical Association, neither statutory exceptions to the principle of informed consent nor conditions of required care allow legally binding measures against patients refusing a treatment or hospitalization [106]. In a case of incapacity to give consent because of unconsciousness or mental confusion, doctors proceed on the basis of the patient's best interests or implied consent. As mentioned above, the presence of Tbc or alcohol use disorder does not interfere with a person's right to refuse a treatment.

Overtreatment of patients diagnosed with alcoholism

This section is an updated summary of the article [107]; all references can be found there. The problem of excessive alcohol consumption in Russia is well known; but there is a tendency to exaggerate it. In this way, responsibility for the relatively low life expectancy is shifted onto the people, that is, self-inflicted diseases caused by excessive alcohol consumption. Among others, the following treatments were applied to patients diagnosed with alcoholism: prolonged intravenous infusions, sorbent hemoperfusion, endobronchial and endolymphatic drug delivery, pyrotherapy with sulfozine (oil solution

of Sulphur), endoscopic cholangiopancreatography and angiography sometimes without clear indications. The intravenous detoxification was regarded to be indicated to nearly all alcohol-dependent patients: 7-10 infusions daily, combined with intramuscular injections. The recommended duration of the intravenous detoxification therapy was 5-25 days in different instructions. Intravenous infusions of sodium chloride, magnesium (Mg) and glucose have been recommended for patients diagnosed with alcoholism including withdrawal syndrome. Of note, intravenous glucose and Mg are generally not indicated in the settings of withdrawal syndrome. Excessive infusions of Mg-containing solutions are associated with adverse effects. Lengthy drip infusions are uncomfortable; some patients regarded them as torture. Apparently, an ideation of punishment has played a role. In conditions of suboptimal procedural quality assurance, endovascular manipulations lead to transmission of viral hepatitis and other infections, which is known to occur in treated alcohol-dependent patients.

Recommendations of intravenous infusion therapy of alcohol intoxication and withdrawal syndrome with both crystalloid and colloid solutions can be found also in recent instructive publications. This is at variance with the international practice. Alcohol and its metabolites are eliminated spontaneously while rehydration can be usually achieved per os. Many cases with symptoms of excessive infusion, fluid overload, pulmonary or generalized edema have been reported. Besides, various intramuscular injections were recommended: Mg sulphate, sodium bromide and thiosulphate, subcutaneous infusions of saline and insufflations of oxygen (300-500 ml); Unithiol, Dimercaprol, cranio-cerebral hypothermia (1-1.5 hours); extracorporeal ultraviolet irradiation of blood, etc. [107].

Furthermore, antipsychotic drugs (phenothiazines, haloperidol) have been applied in adults and adolescents diagnosed with alcohol dependence in the absence of psychosis. Neuroleptics have been recommended by most authoritative handbooks. Apart from other potential side effects, the synergism between some antipsychotics and alcohol, aggravating liver injury, should be considered. With regard to alcohol-related dementia (and other dementia in alcohol consumers) it should be stressed that antipsychotic use was associated with increased risks of stroke, venous thromboembolism, myocardial infarction, heart failure, fracture, pneumonia and

acute kidney injury [108]. Unfounded psychopathological interpretations of alcohol dependence and overextended diagnostic criteria of alcoholism, used in RF, have been pointed out [109]. In fact, many individuals classified as alcohol-dependent are socially adapted and well-functioning. Not all alcohol consumers become dependent and not all dependent people progress to unfavorable outcomes [109].

Moreover, biopsies from kidneys, pancreas, liver, lung, salivary glands, stomach and skin were collected from patients diagnosed with alcoholism, also for research. Other invasive procedures (celiacography, endoscopic cholangiopancreatography etc.) were applied in persons diagnosed with alcoholism without clear indications; details and reference are in [107]. Finally, the “ultra-rapid” (one session) psychotherapy of alcohol dependence, popular in the former Soviet Union and known as coding, should be mentioned. This method was started during the anti-alcohol campaign (1985-1989); it was criticized as unethical because of mystification, intimidation, spraying of the throat with ethyl chloride, massage of trigeminal nerve branches, forceful backwards movements of the patient’s head etc. The latter may be dangerous for patients with vertebral abnormalities. Nevertheless, the method continues to be used [107].

Discussion

Surgery without sufficient indications has been discussed previously: the overuse of gastrectomy for peptic ulcers, of thoracic operations in bronchial asthma and other respiratory diseases, spleno-renal anastomosis for diabetes mellitus. Endocervical ectopies (named pseudo-erosions in RF) have been routinely cauterized without cytological tests; Pap-smears for early detection of cervical cancer have been infrequent and below the international standards, cervical cancer being diagnosed relatively late. Considering the breast cancer incidence, millions of women in the former Soviet Union underwent Halsted and Patey mastectomy with removal of pectoral muscles without evidence-based indications, often without informed consent [96,110]. Unfavorable consequences of the *Pectoralis* muscle resection are known. Predisposing factors included autocratic management style, insufficient consideration of professional autonomy and informed consent as well as partial isolation from the international scientific community. The isolation was

conducive to parallelism in research with repetition of studies, unnecessary experimentation, and application of invasive procedures without sufficient indications. Under conditions of paternalism, misinformation of patients and compulsory treatments are deemed permissible [111]. The mentioning of informed consent started in papers from Russia not long ago. For example, it has been recommended in the recent monograph titled “Pulmonary tuberculoma” to “explain to the patients in popular form that surgery is necessary” [54] instead of objective depiction of potential benefits and risks. Justifications of surgical hyper-radicalism could be heard in private conversations among medics, for example: “The hopelessly ill are dangerous”, that is, may commit reckless acts undesirable by the state. For example, glioblastoma patients have been routinely operated on, while it was believed by some staff that the treatment was generally useless, just forcing many patients to spend the rest of their lives in bed [112]. The training of medical personnel under the imperative of readiness for war has been another motive. Persons with alcohol use disorders are convenient objects for that purpose [107]. Some invasive methods with questionable indications were advocated by first generation military surgeons [96,110]. The ethical and legal basis of medical practice and research has not been sufficiently known and observed in the former SU. The term “deontology” is often used for medical ethics in this country. Textbooks and monographs on deontology explained the matter somewhat vaguely, with truisms and generalities but not much practical guidance. Considering shortcomings of medical practice, research and education, governmental directives and increase in funding are unlikely to be sufficient for a solution. Measures for improvement of the healthcare in RF must include participation of authorized foreign advisors.

Conclusion

Factors contributing to the use of invasive procedures with questionable indications have included the partial isolation from international scientific community, insufficient consideration of the principles of professional autonomy and scientific polemics, as well as paternalistic attitude to patients. Ethical and legal basis of medical practice and research has not been sufficiently known and observed in RF. Insufficient coordination of medical

studies and partial isolation from the international community can result in parallelism in research, unnecessary experimentation, and application of invasive procedures without sufficient indications. In regard to Tbc, the role of surgery remains controversial. The message of this review is that patients should not undergo operations merely to comply with doctrines. Evidence-based clinical indications must be determined individually, the patients being objectively informed on potential benefits and risks.

Conflicts of Interest

The author declares that he has no conflict of interest.

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