

Invasive Procedures with Questionable Indications used in Russia: Recent History

Keywords: Mastectomy; Appendectomy; Cervical ectopy; Diabetes mellitus; Asthma; Bronchoscopy

Abstract

This review summarizes a series of reports on invasive procedures applied with questionable clinical indications. The following topics are discussed: the overuse of the Halsted and Patey mastectomy, relatively high negative appendectomy rate, cauterization of cervical pseudo-erosions regardless of the presence of precancerous lesions, pancreatic blood shunting into the systemic blood flow as a surgical treatment of diabetes mellitus, gastrectomy for peptic ulcers, surgical treatment of bronchial asthma and other respiratory diseases. In this connection, the diagnostic and therapeutic use of bronchoscopy is commented. Some papers containing questionable recommendations have remained without due commentary. Recommendations of invasive procedures without evidence-based indications sometimes reappear in newer publications. Excessive manipulation is unfavorable especially in conditions of suboptimal procedural quality assurance. Applying invasive procedures, the risk-to-benefit ratio should be kept as low as possible, while the principle of informed consent must be observed.

Introduction

This paper summarizes a series of reports on invasive procedures applied in the former Soviet Union (SU) with questionable clinical indications, also for research [1-6]. According to the author's estimates after a practice and clinical attachments abroad, an average size of malignant tumors in surgical specimens was larger in central Moscow clinics compared to hospitals in some countries of Western Europe and Southern Africa, which may reflect efficiency of malignancy detection. Abroad, almost all mastectomy specimens were without muscle. In Moscow hospitals, the modified radical mastectomy (Patey) with the removal of the pectoralis minor muscle has been the standard procedure until recently; but the Halsted operation with the removal of both major and minor pectoralis muscles was applied as well. The Halsted operation prevailed earlier; it was presented as the main treatment modality for breast cancer in some textbooks edited after 2000 [7,8]. In the 1980s and earlier, the Halsted procedure was the predominant method of breast cancer treatment [9-14]. Centrally and medially located breast cancers were treated by a more extensive operation, which included the removal of parasternal and subclavicular lymph nodes [15,16]. The worldwide tendency towards conservation in the treatment of breast cancer remained largely unnoticed in the former SU for a long time. Furthermore, the negative appendectomy rate has been relatively high in Russia favored by the concepts of catarrhal and chronic appendicitis not requiring evidence of acute inflammation in the histological sections. Appendices morphologically indistinguishable from the norm have been habitually reported by pathologists as compatible with appendicitis, surgeons thus receiving no feedback [4]. Another example: thermo-, cryo-, or diathermocoagulation of cervical



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pseudo-erosions (endocervical ectopy), regardless of the presence of precancerous lesions (dysplasia), has been applied routinely. This practice is at variance with the international approach and the evidence that such treatment does not protect against cervical cancer [17]. Cervical ectopies were found at mass examinations and treated by electro- or thermocoagulation [18,19]. It was recommended to start the treatment of pseudo-erosions as early as possible, while large lesions were treated by diathermoconization, a procedure known to be associated with complications [20,21]. Complications of mass cauterizations of cervical ectopies were noticed later. It should be commented that the presence of columnar epithelium on the portio, i.e. endocervical ectropion or cervical ectopy, is considered normal for young women, in particular, if hormonal contraceptives are used [22]. Accordingly, the latter category of females has been at the highest high risk of this overtreatment, reported to be quite unpleasant by some women, who could have made impression to be socially unprotected or immoral. Apparently, an ideation of punishment has played a role in some medical personnel [6]. Furthermore, the cervical conization is a new procedure in Russia; primary hysterectomy has been generally applied instead. Pap-smears have been rare, cervical cancer being diagnosed at a relatively advanced stage [23]. Another procedure, as far as we know, used on a scale unprecedented in other countries, is the therapy with Ultra High Frequency (UHF) electromagnetic fields. The UHF therapy has been officially recommended for children and adults with tonsillitis and other otorhinolaryngological conditions since the early 1960s [24,25]. The UHF therapy is used now as before; last time, the Extremely High Frequency (EHF) waves have also been used for respiratory and allergic conditions in children, while absence of contraindications has been pointed out [26]. At the same time, reports from the former SU on the non-thermal and non-cancer effects of electromagnetic radiation from anthropogenic sources, in particular, functional derangements of the nervous system, have been continued, although some results could not be reproduced [27-29]. However, doses of thermal intensity used in the UHF therapy are higher than those from the environmental anthropogenic sources. Considering anatomical proximity of the tonsils and neural structures especially in children, there have been concerns about such use of microwaves. Note that excessive exposures and imprecise focusing may occur in the therapeutic practice. A case of behavior abnormalities and slight

but persistent dysphagia in a child coinciding with the UHF therapy for tonsillitis and allergic rhinitis has been reported [30]. Experiments on large animals might be helpful to clarify the matter; a search for brain damage using MRI may also be purposive.

Diabetes Mellitus

From 1986 to 1994, 415 procedures of “pancreatic blood shunting into the systemic blood flow” in insulin-dependent diabetics were performed by one research group; besides, the technique was used in several hospitals [31]. Early post-operative complications were reported in 28 (6.8%) patients including 2 cases of sepsis, 1 ileus, 5 exacerbations of pyelonephritis, and 5 cases of pneumonia; two patients died within a week after the surgery. Ketonuria after the surgery was observed in 18 patients agreeing with the known fact that surgical stress can provoke hyperglycemia and ketosis in diabetics [31]. In the paper, somewhat lower figures of complications are given [32]. The patients were subdivided into the groups with a good, satisfactory and no effect, which may be indicative of bias as there was no group with complications or worsening [33]. During this procedure, pancreatic and renal biopsies were collected [34]; more details are in [3]. The same surgery was applied also in type 2 diabetes mellitus [35]. Apart from several reports from Russia and Ukraine [36-44], no analogs of this treatment modality of diabetes mellitus have been found in the literature. The anti-diabetic effect of the shunting was reported to be moderate both in humans [38] and in the preceding experiments in dogs [44]; while thrombosis [37,39], acidosis, peritoneal adhesions and other complications were observed [40,42]. Severe acidosis was pointed out as a typical post-operative phenomenon [40]. It was reported that 27% of the patients developed thrombosis of the splenorenal anastomosis, confirmed by angiography, during the first 8 months after the surgery [37]. In a preceding experimental study, the majority of dogs did not survive the surgical or chemical diabetes induction and subsequent porto-systemic shunting [44], indicating that condition of the animals could have interfered with the evaluation of anti-diabetic effects. The porto-systemic shunting for the treatment of diabetes was recently presented as a valuable achievement [45]. In 2010, it was reported that this method is further in use; and a “high thrombus-related hazard” was pointed out [39].

Peptic ulcer

The surgical treatment of peptic ulcers in the former SU has been partly different from the international practice [46]. According to the author’s observations, the partial gastrectomy for peptic ulcers was performed less frequently abroad, the volume being smaller. In Russia, primary gastrectomy (2/3 - 3/4 of the stomach) or ulcer closure (suturing), depending on the patient’s condition, have been usually applied [47-51]. According to a recent report, the suturing was used in 80% of perforated ulcers despite the tissue damage and inflammation at margins potentially conducive to recurrence [52]. Modern therapy of peptic ulcers has been unavailable on a regular basis for many patients, which is probably one of the causes of the increased incidence of ulcer perforation in Russia in the 21st century [53]. The limited availability of the regular endoscopic screening of gastric ulcers and medical therapy was designated as a “social indication” for gastrectomy [49].

During the 1960-1970s, when the partial or subtotal gastrectomy was nearly the single surgical treatment modality of peptic ulcers [50,51,54], complications had come to the fore [46]. Responsibility for the “hyper-radicalism” was associated with the well-known surgeon Sergei Yudin, who advocated gastrectomy for peptic ulcers, including primary gastrectomy for perforated ulcers [55,56]. Yudin’s article from the late 1940s, recommending gastrectomy for peptic ulcers, was republished 1991 with approving words from the editor [56]; his letters mentioning the same topic were published recently [57]. References to Yudin can be encountered now as before e.g. that he performed the primary gastrectomy in 75% of perforated ulcers [58]. Instructive publications presenting gastrectomy as a main surgical ulcer treatment have been continued [59-63]. In a textbook published 1995, the Billroth’s procedures I and II were listed in the first place among the surgical treatment modalities of peptic ulcers [60]. The partial gastrectomy has been broadly used for the ulcers, in particular, in case of perforation [61-64], explained by the conservatism of surgeons and limited availability of medical therapy [46,49,59]. As mentioned above, gastrectomy has been advocated referring to social indications, “non-compliance” and insufficient availability of modern medical therapy [49,51].

In some publications recommending surgery for peptic ulcers, it was stated that the number of supporters of the conservative ulcer treatment is dwindling [65], “modern medical treatment does not completely solve the problem” [66] and “...does not lead to a complete recovery”, therefore the surgery has been recommended prior to the onset of complications [61]. This approach is at variance with the international literature, according to which medical therapy cures peptic ulcers in a majority of cases [67-69]. Along with gastrectomy, different techniques of vagotomy have been applied for ulcer treatment [70]. Vagotomy was started in the former SU later than in other countries and continues to be used [53,71,72], although abroad vagotomy tends to be abandoned due to the increasingly efficient medical therapy of peptic ulcers [67,73].

Bronchial asthma and other respiratory diseases

Another surgical procedure having no analogs in the international practice is the lung denervation in bronchial asthma [74-80]. Denervation was applied because it supposedly “interrupts pathological impulses from the nervous system” [74]. Such argumentation was frequent in the Soviet-time literature, when the so-called ideas of nervism, associated with the name of Ivan Pavlov, were propagated. In accordance with this concept, non-specific changes of nervous structures e.g. sympathetic ganglia, such as cellular alteration or pigment accumulation, were supposed to justify the denervation surgery for asthma [81]. The surgical treatment of asthma was officially recommended by the Ministry of Health [75]. The open lung denervation via thoracotomy with the “skeletonization” of the pulmonary root was designated as the most recognized surgical procedure for severe asthma [75]. Apart from the root skeletonization, auto-transplantation of lungs was applied for the same purpose [82,83]. Denervation was presented in a textbook as a main surgical treatment modality of asthma [84]. It was recommended for “infectious-allergic asthma”, for severe asthma with glucocorticoid insufficiency, after an unsuccessful carotid sinus denervation and glomectomy [75,80]. Lung denervation, segment-

and lobectomies (discussed below) were advocated even for the cases when a medical treatment “had a temporarily good effect” especially in the presence of inflammatory lung lesions [79]. It was pointed out that the duration of the medical treatment of asthma prior to the surgery should be limited [85].

For example, one research group performed lung denervations in 457 asthma patients [76]. Among these cases, the following numbers of complications were reported: post-operative complications in general - 58, inflammatory complications - 27, pneumonia, empyema, pneumothorax - 11, dysphagia, vocal fold palsy, Horner syndrome - 12, paraplegia or hemiparesis - 2; six patients died within 32 days after the operation [76]. By 2002, the use of the root denervation had been continued [77]. Efficacy of the denervation was designated as moderate, while approximately equal percentages (30-40%) of the patients were found to belong to the groups with a good, satisfactory and no effect [78]. Similarly to the example given in the 2nd section, these data are suggestive of a bias, because no group with complications was among the patients after the thoracic surgery. Furthermore, inflammatory indices (serum immunoglobulins, T- and B-lymphocytes, markers of phagocytosis) were influenced both by the medical and surgical treatment all in the same direction, the surgery being consistently more efficient, which, according to the author’s experience, is suspicious of the data trimming [86,87]. The denervation surgery was often combined with a resection of pathologically altered, from the surgeon’s viewpoint, segments of the lung [75,78]. Morphological images and descriptions of removed pulmonary tissues included emphysema, inflammation and fibrosis without specifying their extension and grade.

Moreover, lung resections were applied as an independent method of asthma treatment, even in the cases when a medical treatment was efficient, whereas indications had initially included bronchiectasis and localized “pneumocirrhosis”, later extended by “bronchitis deformans” [88]. Resections were also performed when the pulmonary lesions were extensive or bilateral i.e. could not be removed completely. It was reported by the same researchers that “no more than 10%” of their asthma patients had been treated by lung resections [88]. The surgical treatment was performed also during remissions deemed necessary for a “radical healing” [89]. According to the concept advocated by Uglov, the main purpose of the asthma surgery was “elimination of the infectious focus”. Chronic pneumonia was declared to be “the basis of bronchial asthma” [89]. Asthmatics were transferred from medical hospitals for the bronchoscopic and surgical treatment [90].

“After a prolonged course of therapeutic bronchoscopies”, Uglov applied resections of lung segments or lobes (deemed irreversibly changed) as a treatment method of asthma, chronic pneumonia and other non-specific pulmonary conditions [89,91]. Apparently, some morphological descriptions of surgical specimens (“penetration by fibrous strands and lymphoid infiltrates, irreversible deformations” etc.) were exaggerated and adjusted to the concept of chronic pneumonia [92,93]. Lobe- and pneumonectomies were applied in non-specific pulmonary conditions (chronic pneumonia, bronchiectasis, and others) in children and adults also by other experts [94], which must have been justified in many cases. Some voluminous morphological descriptions of surgical specimens and

statements that “destructive bronchitis brings about irreversible deformation of the lung”, “severe dystrophic changes”, etc., apparently contributed to this practice [95]. The same approach (bronchoscopy, bronchography, resection) was applied to children with persistent cough and recurrent pneumonias, while malformations alternating with intact pulmonary tissues were described histologically in the surgical specimens [96-99]. The surgery at an early age was deemed favorable in view of supposedly “almost inevitable inflammatory complications” of congenital malformations, which might be true for many cases [96]. However, extensive histological descriptions of supposed malformations partly at variance with the standard editions might have contributed to surgeries beyond clinical indications [100].

It is known that surgery can exert a placebo effect; and that invasive procedures tend to have a stronger placebo effect than non-invasive ones [101,102]. Reported efficiency of the procedures described above could have been caused by the placebo effect exaggerated in some studies by a biased assessment and data trimming, which was known to occur and proven in some studies [87]. Among the mechanisms contributing to the persistence of suboptimal and outdated methods in research and practice has been the limited access to the international literature and authoritative management style [87,103].

Endoscopic methods

The use of endoscopic methods has been discussed previously [2]. The following is added here in connection with the preceding section. Extension of indications for bronchoscopy (Bs) compared to the more conservative earlier approach, was associated with the names of Lev Ioffe and Fedor Uglov [89-93,104-108]. Ioffe wrote in an instructive edition that “Bs must be performed in all pulmonary diseases” [104]. In 1976, Uglov reported on 2477 therapeutic and 5000 diagnostic Bs performed in his institution in patients aged 1.5-78 years predominantly with inflammatory diseases such as bronchitis, chronic pneumonia and asthma, aimed at the “assessment of inflammatory changes in the bronchial tree”. His conclusion was that Bs is important for the detailed diagnosis of practically all pulmonary diseases and can be recommended also at an early stage [107]. “After a prolonged course of therapeutic Bs”, Uglov applied resections of pulmonary segments or lobes deemed irreversibly changed (bronchitis deformans, bronchiectasis, etc.) as a treatment method of asthma, chronic pneumonia and other non-specific pulmonary conditions [107,108]; more details are in the preceding section. Bs was applied and recommended for asthmatic children and adults both during remissions and exacerbations, in mild and severe cases [109-113], including the “pre-asthma” defined as bronchitis with “elements” of bronchospasm and allergy [111,114]. Bs was discussed as a method of early diagnosis for all forms of asthma; it was used repeatedly “for dynamic observation” [109]. Some experts applied up to 15 bronchoscopies (1-2 weekly) in pediatric asthma [115].

Efficiency of therapeutic Bs in moderate bronchitis was pointed out by Uglov, who applied 5-6 bronchoscopies per treatment course [92]. Among others, the “atrophic type” of chronic bronchitis was regarded as an indication for Bs [116]. Laser therapy was applied via bronchoscope in asthma, bronchitis and chronic pneumonia [116-121], also in cases with pronounced atrophy of bronchial mucosa [119], atrophic bronchitis or “primary atrophic bronchopathy” [122-124]. Note that, similarly to other forms of electromagnetic

radiation, laser at lower energies causes warming and at higher - damage of tissues. From the viewpoint of general pathology, atrophy may progress due to the additional damage. Both flexible and rigid bronchoscopes have been used e.g. in chronic bronchitis or asthma [125,126]. For acute pneumonia in children, Bs was aimed to determine the type of inflammation in the bronchi (catarrhal, purulent); in chronic pneumonia it was held necessary for the same purpose, to rule out tuberculosis (Tb) and congenital conditions [127]. In pediatric chronic pneumonia, Bs was recommended by the Ministry of Health for the diagnosis and therapy as one of the main methods [128].

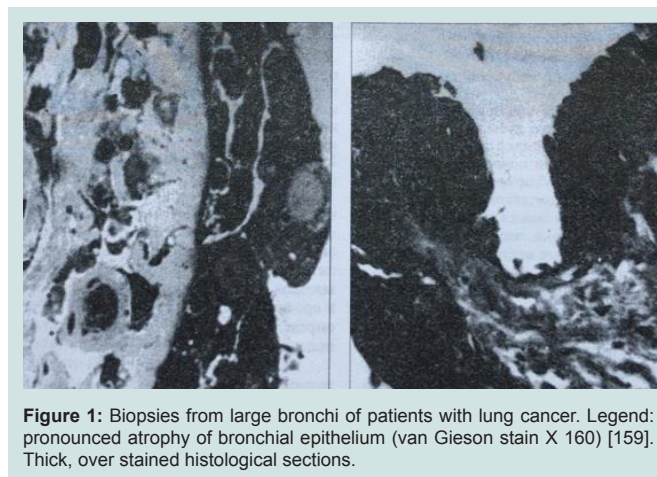
In the book published 1984, Uglov wrote about more than 6000 Bs, 5000 bronchographies plus some angiographies in patients with chronic pneumonia [90], the latter named by him the “basis of bronchial asthma” [107]. “Complete bronchological examination” of asthmatics was presented as necessary [92]. Many thousands Bs often accompanied by bronchography in children and adults with non-specific respiratory diseases were performed also in peripheral institutions and outpatient facilities. At the same time, difficulties with the local anesthesia were pointed out, which necessitated general anesthesia in 20-25 % of the procedures [129]. Later on, Uglov distanced from discussions of Bs, surgical treatment of asthma and chronic pneumonia [130], started campaigning for absolute sobriety, homeopathy, acupuncture, and the use of external painful stimuli in the therapy of asthma [131-134].

Furthermore, broncho- and gastrodoudenoscopy were used as a second step screening procedure e.g. in “chronic non-specific pulmonary diseases” (including asthma and chronic bronchitis) reportedly found in 4.08 % of children residing in industrially contaminated areas of Moscow and the suburbs [135]. Bs was used as a screening method in agricultural workers contacting with dust: both in healthy ones and in those with allergic rhinitis or chronic bronchitis [136], in bronchitis patients professionally contacting with proteolytic enzymes [137], in bronchitis, acute and chronic pneumonia [138-142], in community-acquired pneumonia (1478 bronchoscopies in 977 patients) [143] etc. Some pathologists cooperated in this research, supporting the concept of importance of histological examination of bronchial biopsies in non-specific conditions.

Finally, Bs was applied in all forms of Tb in many institutions and research cohorts [144-150] also when Tb was suspected [141-152], it was recommended for young patients with hyperergic (high degree of hypersensitivity) tuberculin tests [153] or within the diagnostic algorithm for cases of suspected Tb but Mycobacteria-negative sputum [154]. Primary Tb was regarded as an indication for Bs in children [127]. In destructive Tb, therapeutic Bs (1-2 weekly during 2-4 months) was recommended by the Ministry of Health [155] and applied, while the principle of informed consent was insufficiently observed, and complications such as the vocal cord injury were noticed. Bs was used as a screening method for Tb in patients with general malaise, both positive and negative tuberculin tests [156]. Other researchers used Bs as a second step screening method for Tb in children [157]. Endoscopic monitoring of the therapy efficiency has been applied in pulmonary Tb with non-specific bronchial lesions, also recently [147,158].

Bronchial biopsy specimens were used for research, often being

suboptimal quality [2], descriptions sometimes being stereotype, morphometric and other quantitative indices changing according to the concept [2,86,159,160]. Some histological descriptions were doubtful e.g. “atrophic processes” in bronchi of asthmatic children increasing with time: atrophy or “subatrophy” reportedly found in 79.5% of asthmatic children older than 12 years [125]. In some bronchial biopsy studies, scanning electron microscopy was the only morphological method used [139]. Biopsies were taken for research from large bronchi of patients with known lung cancer, whereas quality of histological and ultrastructural images was low (Figure 1) [159], which means additional discomfort with no impact on the therapy. Another example: lavage fluid collected by Bs from patients with lung cancer and from those with Tb (including focal forms, tuberculoma etc.) was examined by infrared spectroscopy without conceivable relation to theory and practice [161].



Conclusion

The principle of informed consent has not been sufficiently known and observed in the former SU, being mentioned only in some recent Bs papers [162-165]. For example, compulsory treatments were applied to alcoholics: prolonged intravenous infusions, sorbent hemoperfusion, endolymphatic and endobronchial delivery of antituberculosis drugs, endoscopic and surgical biopsies etc. [3,166-169]. Note that in conditions of insufficient procedural quality assurance excessive intravenous therapy and Bs can result in complications e.g. thrombosis [170] or, potentially, transmission of viral hepatitis. The use of blood apheresis with questionable indications has been discussed previously [171].

Among the mechanisms contributing to the persistence of suboptimal methods has been the partial isolation from the international community, authoritative management style, lack of criticism, party and military functionaries in leading positions, and shortage of internationally used books even in central medical libraries [103,172,173]. Disregard for the principle of informed consent coupled with the paternalistic attitude towards patients have facilitated the use of invasive methods with questionable indications. Reviewing the Russian-language literature, it can be seen that today it is more aware of foreign publications than it was 10 years ago and earlier. However, some publications containing questionable recommendations have remained without due commentary, so that

relapses of suboptimal practices cannot be excluded. Under these conditions, the purpose of this review was to recollect some invasive methods used with questionable clinical indications in the recent past and to stress that the risk-to-benefit ratio should be kept as low as possible, while the principle of informed consent must be rigorously observed.

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