

## Invasive Procedures with Questionable Indications: Prevention of a Negligent Custom

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### Abstract

This is an update and continuation of preceding reports on invasive methods used with questionable indications in the former Soviet Union. Among others, the following is discussed: the surgical treatment of diabetes mellitus, of bronchial asthma and some other respiratory conditions, the overuse of gastrectomy for peptic ulcers, of Halsted and Patey mastectomy, coagulation of cervical pseudo-erosions without epithelial dysplasia, enhanced negative appendectomy rate. The use of endoscopy with diagnostic, therapeutic and scientific purposes is discussed. The purpose of this review was to comment on some reports from the recent past with questionable recommendation for the practice, to stress that the risk-to-benefit ratio should be kept possibly low, and informed consent obtained.

**Keywords:** Medical ethics; Informed consent; Surgery; Endoscopy

### The Background

This review summarizes several preceding papers on invasive procedures applied with questionable clinical indications in Russia and the former Soviet Union (SU) [1-3]. According to the author's estimates following practice and clinical attachments in several European countries, an average size of malignant tumors in surgical specimens was larger in Moscow than abroad. This probably reflects greater efficiency of cancer diagnostics. Outside of the former SU, almost all mastectomy specimens were without muscle. In Moscow, the modified radical mastectomy of Patey with the removal of the pectoralis minor muscle has been the standard procedure until recently; but the Halsted procedure with the removal of both pectoralis muscles was applied as well. In the 1980s and decreasingly during the 1990s, the Halsted procedure was the widespread method of breast cancer management [4]; it was presented as the main treatment modality for breast cancer in some textbooks edited in the 21<sup>st</sup> century [5]. The worldwide tendency towards conservation in the treatment of breast tumors remained largely unnoticed in Russia for many years. Furthermore, the negative appendectomy rate was comparatively high in the former SU thanks to the widely used histopathological diagnoses of "simple", catarrhal and chronic appendicitis not requiring acute inflammation for diagnosis. Appendices histologically indistinguishable from the norm or surgery-related artefacts have been habitually reported as compatible with appendicitis, surgeons thus receiving no feedback from pathologists. Moreover, cauterization or cryodestruction of endocervical ectopies (pseudo-erosions) without epithelial dysplasia were applied routinely. The pseudo-erosions were detected at mass examinations and treated by coagulation. Note that this practice does not protect from cervical cancer and disagrees with the international approach [6]. In particular, the recommended treatment of large ectropions by diathermoconization was noticed to be associated with complications [7]. At the same time, Pap-smears have been rare and technically suboptimal; cervical cancer being detected averagely late. It should be commented that the occurrence of single-layered columnar epithelium (which usually covers the cervical canal) beyond the external cervical orifice, i.e. endocervical ectopy, is

generally considered normal for women during their reproductive years, particularly if hormonal contraceptives are used.

The use of parabolbar and subconjunctival injections of carbinine, taurine and mildronate, applied in age-related vascular ophthalmic conditions [8,9], seen to be complicated by hematomas, has been commented upon previously [10]. The effect of mildronate - if any - could have been adverse due to the diminished availability of adenosine triphosphate as the energy carrier [11]. A benefit from temporary increase in the concentration of these substances in orbital tissues can hardly be understood [10], while parabolbar injections are associated with a risk of complications. Intracoronary injections of cell suspensions obtained from abortion material and named "allogenic multipotent stromal cells" in patients with dilated cardiomyopathy [12] were commented upon with an illustration [13]. Excessive endoscopic and endovascular manipulations with injections of proteinaceous material, especially in conditions of suboptimal procedural quality assurance, can lead to inflammatory, infectious and thrombotic complications. Another questionable procedure is the therapy by ultra high frequency electromagnetic waves (UHF) of thermal intensity in children for rhinitis, sinusitis, tonsillitis etc. Risks from radio-frequency fields of subthermal intensity have been discussed but remain unproven [14]. An overexposure, especially for eye lenses and the brain can occur in patients receiving shortwave diathermy if certain output power levels are exceeded. In routine practice excessive exposures and imprecise focusing may occur. A singular case of transitory strabismus and dysphagia in a child, started at the time of the UHF-therapy for allergic rhinitis and tonsillitis at the age of 4-6 years, is known [15]. Since the early 1960s, the UHF treatment has been recommended for use in the pediatric otorhinolaryngology by the guidelines issued by the Health Ministry. Currently, UHF therapy is further in use; besides, extremely high frequency (EHF) waves have been used for respiratory and allergic conditions in children, while the absence of contraindications was pointed out [16]. Considering the anatomical proximity of tonsils and neural structures especially in young children, there are concerns about such use of the UHF waves [14].

## Diabetes Mellitus

The “pancreatic blood shunting into the systemic blood flow” was recommended and applied as a surgical treatment method for moderate to severe insulin-dependent diabetes mellitus (DM) [17]. For example, from a total amount of 415 cases, early post-operative complications were noticed in 28 patients including 2 cases of sepsis, ileus (one case), exacerbated pyelonephritis (5 cases), pneumonia (5 cases); 2 patients died during a week of the surgery. Ketonuria developed in 18 cases [17] agreeing with the knowledge that surgical stress can provoke hyperglycemia and ketosis in diabetics. Comparable percentages were reported in [18]. The patients were subdivided into groups with a good, satisfactory and no effect [19]. As there was no group with complications or deterioration, objectivity of the data appears questionable.

Excepting several papers from the former SU [17-21], no reports on this treatment of DM were found in the literature. The same operation was applied also in type 2 DM with arterial hypertension [22]. The anti-diabetic effect of the shunting was reported to be moderate in both humans and the preceding experiments with dogs [23]; thrombosis, peritoneal adhesions and other complications were encountered, severe acidosis designated as typical [20,21]. Using angiography, thrombosis of the splenorenal anastomosis was detected in 27% of patients in the first 8 months post-surgery [20]. In a preceding experiment, the majority of dogs did not survive the DM induction by pancreas resection or streptozocin with the subsequent shunting [23], indicating that poor condition of the animals was a confounding factor. The porto-systemic shunting in DM was recently presented as a valuable achievement [24]. In 2010, it was reported that this method continues to be applied, while a “high thrombus-related hazard” was acknowledged [21].

During the surgery, pancreatic and renal biopsies were taken. The histological descriptions were partly in disagreement with the generally accepted knowledge: glomerulitis with mesangial interposition, displacement of mesangial cells to the periphery of capillary loops, double-contoured glomerular basement membranes and mesangiolytic changes were presented as typical features and consecutive stages of diabetic glomerulosclerosis; more details and references are in [3]. These changes are in fact morphological signs of membranoproliferative glomerulonephritis which, if found in a diabetic patient, is usually interpreted as a superimposed condition. It should be commented that renal biopsy is generally indicated for diabetics only if a renal condition other than diabetic nephropathy, potentially requiring a special treatment, is suspected. The interpretation of the morphological features of glomerulonephritis as typical phenomena or stages of diabetic nephropathy can therefore be misleading. As for the descriptions of pancreatic islets with destruction and necrosis of B-cells [25], it may have been autolysis. Note that renal and pancreatic biopsies are associated with risks. The same is true for renal and splenic venography, celiac arteriography etc. performed in parallel with the surgical treatment of DM [18].

## Peptic Ulcers

The surgical treatment of peptic ulcers in the former SU has been different from the international practice [26]. According to the author's observations, the partial gastrectomy for peptic ulcers was performed less frequently abroad, and the volume was smaller, usually corresponding to antrectomy. For perforations, ulcer excision was performed abroad more frequently than in Russia, where a primary gastrectomy (2/3 - 3/4 of the stomach) or simple suture (depending on the patient's condition) usually occurred [27-29]. It was reported in 2014 that a simple closure was performed in Russia in 80% cases of perforated ulcers [30]. The limited availability of the modern medical therapy and endoscopic monitoring of gastric ulcers were named social indications for gastrectomy [29].

During the 1960-1970s, when gastrectomy was practically the only available surgical treatment of chronic ulcers [31], complications were noticed [26]. The hyper-radicalism in gastric surgery originates from the famous surgeon Sergei Sergeevich Iudin; his works recommending gastrectomy have been reprinted with supportive comments and are referenced up to now [32-34]. The partial gastrectomy continues to be applied and advocated for ulcer perforation [26,29,35-39], which was explained by doctors' conservatism, patients' non-compliance, social indications, and limited availability of modern medical therapy [26,29]. In some publications advocating surgery for peptic ulcers, it was stated that support for the drug therapy is declining: “Modern medical treatment does not completely solve the problem” [39] and “...does not lead to a complete recovery”, so an operation should be performed before to complications develop [36]. This approach disagrees with the modern knowledge that most peptic ulcers are cured by medical therapy [40]. Along with gastrectomy, various modalities of vagotomy have been applied [29,30,36-38]. Iudin was against vagotomy; this method was started in the former SU later than in other countries and continues to be used, although it is largely obsolete abroad due to the improving efficiency of drug therapy [40].

## Pulmonary Disorders

A surgical procedure with no analogy in international practice is thoracotomy with lung denervation in bronchial asthma (BA) [41-44]. Closed denervation by thoracoscopy was also applied; but the first modality was named “the most recognized method” in the guidelines by the Health Ministry [42]. Denervation was applied because it supposedly “interrupts pathological impulses from the nervous system” [41]. This argumentation was usual in literature from the Soviet period, where the concept of nervism was propagated. In accordance with this concept, histological descriptions of “degeneration” in nervous structures such as ganglia of the autonomic nervous system were presented as a reason for the denervation surgery [41]. The surgical denervation was recommended by the guidelines of the Health Ministry for the treatment of BA [42]. The thoracotomy with open lung denervation and “skeletonization” of the pulmonary root was designated the most recognized surgical procedure for severe BA in both textbooks and the Ministry of Health's guidelines [42]. In particular, it was recommended for “infectious-allergic” and severe steroid-dependent BA and after an unsuccessful glomectomy [42]. Lung denervation, segment- and lobectomies (more details in the next section) were advocated even for cases when drug treatment “had a temporary effect”, especially in the presence of inflammatory pulmonary lesions. It was suggested that medical treatment prior to surgery should be of limited duration. For example, one group of experts performed lung denervations in 457 BA patients; among them, the following complications were encountered: inflammatory complications (27 cases), pneumonia, empyema, pneumothorax (11 cases), dysphagia, vocal fold palsy, Horner syndrome (12), paraplegia, hemiparesis (2); post-operative complications in general (58 cases), six patients died within 32 days of the operation [44]. By 2002, the method was further in use [43]. Denervation surgery was sometimes combined with a resection of pathologically altered, from the surgeons' viewpoint, pulmonary segments or lobes [42]. Histological descriptions of surgical specimens were often non-specific (inflammation, sclerosis etc.), sometimes being apparently adjusted to the concept.

Moreover, lung resections were applied as an independent method of BA management, even in the cases when a medical therapy was effective. Indications included local pulmonary lesions such as bronchiectasis, pneumocirrhosis and bronchitis deformans [45]. Resections were also performed when the lesions were extensive or bilateral, thus being not completely removable. The surgery was performed also in remissions of BA, deemed necessary for a radical healing. This concept was advocated primarily by Uglov [45,46], whereas the main purpose of asthma

surgery was claimed to be the “removal of the infectious focus”. Chronic pneumonia was claimed to be “the basis of BA” [45]. For the bronchoscopic and surgical treatment, asthmatics were transferred to the surgery from medical hospitals [46].

“After a prolonged course of therapeutic bronchoscopies”, Fedor Uglov and co-workers [45] performed segment- and lobectomies, removing pulmonary tissue regarded by them to be irreversibly changed, as a treatment method of BA, chronic pneumonia and other non-specific conditions. The same methods (bronchoscopy, segment- or lobectomy) was applied in different institutions also to children with persistent cough and recurrent pneumonias, whereas malformations alternating with intact pulmonary tissues were described microscopically [47,48]. Morphological descriptions of supposed malformations partly different from internationally used handbooks could have apparently contributed to the surgical treatment beyond clinical indications.

### Endoscopic Methods

The use of endoscopy with questionable clinical indications and for research has been discussed elsewhere [2]. Extension of indications for bronchoscopy was associated with the names of Fedor Grigorievich Uglov [45,46] and Lev Tsodikovich Ioffe [49,50]. The latter wrote that “bronchoscopy must be performed in all diseases of the lung” [50]. Uglov [46] informed on approximately 6000 bronchoscopies performed in children and adults with inflammatory conditions such as chronic pneumonia, bronchitis and BA with the purpose of the “evaluation of inflammatory changes in the bronchial tree”. According to his opinion, bronchoscopy was essential for the detailed diagnosis of almost all respiratory conditions also during the early stages. The “complete bronchological examination” of asthmatics was regarded as necessary. Many thousands of bronchoscopies in children and adults with the above-named conditions were performed also in provincial hospitals and outpatient centers. At the same time, difficulties with local anesthesia were noticed, which made general anesthesia necessary in 20-25 % of the cases [51].

After a course of therapeutic bronchoscopies, resections of pulmonary segments or lobes deemed irreversibly changed were performed [45,46]. Bronchoscopy was used and recommended for BA patients in both remission and exacerbation phases, including pre-asthma defined as bronchitis with “elements” of bronchospasm and allergy [52,53]. Bronchoscopy was discussed as a method of early diagnostics for all forms of BA; it was applied repeatedly for monitoring [52]. Bronchoscopy and bronchial biopsy in asthmatics were also used for research, sometimes repeatedly, in mild and moderate cases, in children and the elderly [53-58]. At the same time, it was reported on the enhanced complication rate of bronchoscopy in BA; nonetheless, the same experts performed 388 bronchoscopies in 216 asthmatics, with no resultant change in diagnosis [59].

Furthermore, bronchoscopic laser therapy was applied in BA and bronchitis, also with atrophy of bronchial mucosa, atrophic bronchitis or primary atrophic bronchopathy [60,61]. Note that similarly to other electromagnetic waves, laser causes warming at lower levels of absorbed energy and the damage of tissues at higher levels. Both flexible and rigid bronchoscopes were used [62]. It is known that additional damage is unfavorable for atrophic tissues. In pediatric acute pneumonia, bronchoscopy was performed to determine the type of inflammation in the bronchi: catarrhal or purulent. In patients with chronic pneumonia it was also used to exclude tuberculosis and congenital malformations [63]. Bronchoscopy was applied in bronchitis, acute and chronic pneumonia, also for research [64-67], including community-acquired pneumonia: 1478 procedures in 977 young patients [68]. The broncho- and gastroduodenoscopy was used as a second stage screening method

in chronic non-specific respiratory conditions, including BA and bronchitis, found in over 4 % of children “from ecologically disadvantaged areas” [69]. Endoscopic monitoring with multiple procedures has been applied in tuberculosis also with non-specific bronchial lesions [70]. Bronchoscopy has been used as a second step screening method for pulmonary tuberculosis in children [71]. Indications for bronchoscopy are beyond the scope of this review; however, one citation seems to be appropriate: “As it is an invasive procedure, the following should be asked: what question am I trying to answer by bronchoscopy? Will the answer justify the risks of the procedure?” [72].

Although sometimes of suboptimal quality [2,73], bronchial biopsy specimens were used for research. Histological descriptions were often stereotype, morphometric and other quantitative indices sometimes changing according to the concept; more details and images are in [2]. Some histological descriptions were doubtful e.g. “atrophic processes” in bronchi of children with BA increasing with time: atrophy or subatrophy reportedly found in about 80% of asthmatic children over 12 years old [62]. In some bronchial biopsy studies, scanning electron microscopy was the only morphological method [64], hardly contributing to diagnosis. Biopsies were taken for research from the large bronchi of patients with confirmed lung cancer, while the quality of histological and ultrastructural specimens was poor [2,73], which means discomfort for the patients with no consequences for the treatment. Another example: lavage fluid from patients with lung cancer or tuberculosis (including focal forms, tuberculoma etc.) was used for research by infrared spectroscopy with no impact on the therapy [74]. Finally, gastroduodenoscopy with biopsies for research was applied in children with rheumatoid arthritis, dermatomyositis, scleroderma, systemic lupus erythematosus, various respiratory and hepatobiliary conditions, for the screening of children born to mothers with BA, as well as in patients with uremia [49,69,75-79].

### Conclusion

It is known that the concept of informed consent has not been uniformly accepted in Russia. Today, patients are sometimes requested to sign in advance a form confirming that they agree to all required diagnostic and therapeutic procedures. In regard to endoscopy, informed consent is mentioned only in some recent papers. For asthmatic children aged 5-15 years, the consent of parents was regarded to be sufficient in a bronchoscopic study [80]. Note that principles of informed consent or assent are applicable also to children and adolescents, especially in case of research [81,82]. Compulsory treatments were applied to alcoholics, including prolonged intravenous infusions, pyrotherapy with sulfozine (oil solution of sulphur for intramuscular injections) and pyrogenal, sorbent hemoperfusion, endolymphatic and endobronchial drug delivery, endoscopic and surgical biopsies of internal organs, endoscopic cholangiopancreatography and angiography without clear indications also for research [83,84]; more details and references are in [3,85]. It should be commented that excessive endovascular and endoscopic manipulations can lead to the transmission of viral hepatitis [86], which occurred in treated alcoholic patients. A combination of the viral and alcoholic liver injury is known to be unfavorable.

Factors contributing to the persistence of suboptimal methods included the partial isolation from the international scientific community, former party, military and law enforcement functionaries or their protégées in leading positions, lack of criticism, insufficient use of the foreign literature and unavailability of some internationally used handbooks even in central medical libraries [87,88]. Disregard for the principle of informed consent together with authoritative attitudes towards patients contributed to the use of invasive methods with questionable indications. Today, there are grounds for optimism: the Russian-language literature is increasingly aware of foreign publications, diagnostics and treatments being adjusted

to international standards. Some publications containing questionable recommendations have remained without due commentary however, so that the possibility of reversion to suboptimal practices is not excluded today. Therefore, the purpose of this paper has been to overview some invasive methods used with questionable clinical indications and to emphasize that the risk-to-benefit ratio should be kept as low as possible, with the requirement for informed consent rigorously observed.

### Conflict of Interest

The author declares no conflict of interests.

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