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Invasive procedures with questionable indications and possible placebo effects

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ABSTRACT

This article provides an overview of surgical procedures performed with questionable or excessively radical indications, such as the lung denervation as a treatment of asthma, or the porto-systemic shunting for Type 1 diabetes mellitus. An immediate effect of an invasive procedure including a surgical operation can be influenced by different non-specific factors including a placebo effect. There is an opinion that surgery is associated with a placebo-effect, which can be stronger in case of a more invasive procedure. Reported moderate efficiency of the procedures discussed here could have been caused by placebo effect and/or inexact evaluation. These days, the improvement of Russian economy has enabled the acquisition of modern equipment and supported increasing levels of medical research. Under these circumstances, the purpose of this review is to help to correct the historical problems of surgery in Russia and to remind that, when performing surgical or other invasive procedures, the risk-to-benefit ratio should be minimized.

Key words: *Asthma, denervation, diabetes mellitus, gastroduodenal ulcer, shunting*

Introduction

Partial isolation of Russian medicine and medical research from the international community had consequences for the surgical practice. Several examples are discussed here. In Moscow hospitals, the modified radical mastectomy (Patey) with resection of the pectoralis minor muscle has been the standard procedure during the last decades, but the Halsted operation with the removal of both major and minor pectoralis muscles has been applied as well. The Halsted operation prevailed in earlier times; it was recommended by Russian textbooks of surgery and oncology for all types of breast cancer until the late 1990s [1,2]. The survival after the breast-conserving surgery was found to be not significantly different from the Patey mastectomy as a standard procedure [3]. The shift toward conservation in the treatment of breast cancer in the whole world remained largely unnoticed in the former Soviet Union (SU) for a long time.

Surgical Treatment of Gastric and Duodenal Ulcers

The approach to the surgical treatment of gastric and duodenal ulcers in the former SU has deviated from international practice [4,5]. The use of partial gastrectomy for ulcer treatment remained relatively frequent in many institutions [6] owing to technical problems, conservatism of surgeons [4] and limited availability of the medical therapy [6,7]. During the

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1960-70s, when the partial (2/3-3/4) gastrectomy was almost the single surgical treatment modality for gastroduodenal ulcers [8,9], about 60,000 of such operations were performed yearly in ulcer patients, while significant complications had become obvious [5]. Responsibility for the "hyper-radicalism" in surgery was ascribed, in a veiled form, to the well-known surgeon Yudin (1891-1954), who advocated gastrectomy for ulcer, including the primary gastrectomy for perforated ulcers [10]. One of his arguments was the limited availability of regular medical treatment of ulcer in the SU of the 1940s', while gastrectomy promised good chances of cure [11]. Noticeably, a Yudin's paper from the late 1940s, recommending gastrectomy for gastroduodenal ulcers, was reprinted by the main journal of Russian surgeons Khirurgiia in 1991 with approving words in the preface and free of criticism [11]. Even today, references to the authority of Yudin can be encountered, mentioning e.g. that he had performed the primary gastrectomy in 75% of cases of perforated gastroduodenal ulcers [12]. Instructive publications presenting gastrectomy as a main or single surgical method of ulcer treatment continued to appear [13,14]. In a textbook of surgery printed in 1995, the Billroth's operations I and II were listed in the first place among the surgical treatment methods of gastroduodenal ulcers [14]. Now as before, partial gastrectomy is used as the main surgical treatment for gastrointestinal ulcers, in particular, for perforated ulcers [15-17]. Gastrectomy has also been advocated taking into account the social indications [7,9], while the term "non-compliance" has sometimes been used to indicate insufficient availability of medical treatment [7]. In some publications recommending surgery for the ulcers, it has been stated "the number of supporters of conservative ulcer treatment is decreasing" [18], that "modern medical treatment does not completely solve the problem" [19], and "… does not lead to a complete recovery of patients with gastrointestinal ulcers," and thus the operation has been recommended before the onset of further complications [15]. This view is at variance with the international literature, according to which medical therapy cures peptic ulcer in the vast majority of cases [20-22].

Along with the partial gastrectomy, different types of vagotomy have been used for ulcers, mainly in specialized centers [23]. Vagotomy was started in the former SU later than in other developed countries and continues to be used [24-26], although abroad it tends to be abandoned in connection with the increasingly efficient medical therapy [20,27]. The so-called administrative factor [4] has obviously played a role in the persistence of certain outdated or suboptimal methods in the SU: The support of certain methods by the health care authorities, who sometimes favored less individualized approaches that can be applicable to large categories of patients. This factor must also have contributed to the relatively high negative appendectomy rate in the former SU [28] and the persistence of outdated practices in other fields of medicine, such as the routinely performed diathermocoagulation or cryotherapy of cervical pseudo-erosions (endocervical ectopy or ectropion) regardless of the presence of epithelial dysplasia. Coagulation of an endocervical ectopy with no neoplastic or preneoplastic lesions is at variance with scientific evidence not supporting the hypothesis that the coagulation of an ectopy protects against cervical cancer [29].

Porto-Systemic Shunting for Diabetes Mellitus

It was reported that pancreatic excision biopsies 5 mm × 5 mm in size [30] were collected during the operations of "pancreatic blood shunting into the systemic blood flow in insulin-dependent diabetics [31]." From 1986 to 1994, 409 of such operations in Type 1 diabetic patients were performed by this particular research group [31]. From the same patients, 51 renal core biopsies were collected [30]. Apart from several reports from Russia and Ukraine [32-39], no analogues of this surgical treatment method of Type 1 diabetes mellitus have been found in the literature. This method was also applied in Type 2 diabetic patients with severe hypertension [40]. The anti-diabetic effect of the porto-systemic shunting was reported to be moderate both in humans [31,34] and in preceding experiments in dogs [41]; while thrombosis-related hazards [33,35], post-operative acidosis [36,38], peritoneal adhesions and other complications [38] were observed. Severe acidosis was pointed out as a characteristic post-operative phenomenon [36], which agrees with the known fact that surgical stress can cause hyperglycemia and ketosis in diabetics [42]. It was reported that 27% of

the patients developed thrombosis of the splenorenal anastomosis, confirmed by angiography, during first 8 months after the operation [33]. In the preceding experimental study, the majority of dogs did not survive the surgical or chemical diabetes induction and subsequent porto-systemic shunting [41], signifying that the condition of the surviving animals could have interfered with evaluation of the anti-diabetic effect of the shunting. The collection of biopsies from diabetic patients for research was planned in advance [43]. It should be noted that renal and especially pancreatic biopsy is associated with risks, and is considered too hazardous a procedure for research purposes only [44], which is particularly true if the quality of morphological examination is suboptimal [45,46]. Finally, in the author's opinion, indications to the operations of pancreatic blood shunting into the systemic blood flow in diabetics have not been sufficiently elaborated. This also pertains to angiographic procedures [33] involving catheterization of renal and splenic veins as well as arteriography, as described in [31]. Even today, instead of rethinking the procedure, the porto-systemic shunting in diabetes is presented as a valuable achievement [47]. In 2010, it was reported that this method continues to be used, and the "high thrombus-related hazard" was pointed out [35].

Lung Denervation for Bronchial Asthma

Another surgical procedure without analogs in contemporary international practice is the lung denervation in bronchial asthma [48-53]. This procedure was utilized to treat severe asthma with the substantiation that it "interrupts pathological impulses from the nervous system" [48]. Another reasoning was that morphologic changes of nervous structures such as sympathetic ganglia, which include cellular derangements, pigment accumulation, etc., justified the denervation surgery for asthma [54]. Corresponding articles contained morphological images of poor quality or no images at all. To achieve optimal denervation of the lung, its auto-transplantation for the treatment of asthma was proposed and applied [55,56]. The surgical treatment of asthma was officially approved; recommendations by the ministry of health were issued and recommended for further reprinting by local health care authorities [49]. The method of lung denervation was presented in the main textbook of surgery for students [57]. The open lung denervation via thoracotomy with "skeletonization" of the pulmonary root was designated as the most recognized surgical treatment method for severe asthma [49]. It was recommended for infectious-allergic asthma with a "marked blocking" of beta-adrenergic receptors, for severe asthma with manifest glucocorticoid insufficiency, and after an inefficient carotid sinus denervation with glomectomy [49]. Lung denervation and resection were also advocated for the cases when a medical treatment "had a temporarily good effect", especially in the presence of inflammatory lung lesions [53]. It was pointed out that the duration of medical treatment of asthma before the surgery should be reasonably limited [58]. In 1990, 457 of such operations performed in asthmatic patients were reported by this particular group of researchers [50]. Among those 457 patients, the following absolute complication rates were reported: Post-operative complications in 58 patients, inflammatory complications in 27, broncho-pulmonary (including pneumonia, empyema and pneumothorax)-in 11, neurological complications (including dysphagia, vocal fold palsy, Horner syndrome, etc.) in 12, paraplegia or hemiparesis in 2, whereas 6 patients died within 32 days after the operation [50]. In 2002, it was reported that the use of the surgical lung root denervation had been continued [51]. Reported efficacy of the lung denervation against asthma was generally moderate, while approximately equal percentages (30-40%) of the patients belonged to the groups with a good, satisfactory and no effect [52]. This result gives rise to doubts about the objectivity of the evaluation, because no group with complications or worsening was singled out. Furthermore, immunity- and inflammation-related indices (serum immunoglobulins, T- and B-lymphocyte content, phagocytosis-related indices etc.) were reportedly influenced both by the medical and surgical treatment in the same direction, the surgery being consistently more efficient [59], which is not immediately understandable from the viewpoint of physiology.

The denervation surgery was sometimes accompanied by a resection of pathologically altered segments of pulmonary tissue, or by lobectomy [49,52]. At the same time, the morphological images and descrip-

tions of removed pulmonary tissue were unconvincing, having included emphysematous, inflammatory and sclerotic changes without specifying their extension. Moreover, lung resection was used as a principal method of asthma treatment, also in cases when medical treatment was effective, while the indications had initially included "pneumocirrhosis" and bronchiectasis but were extended to include also "bronchitis deformans" [60]. The resections were also performed in those cases when the pulmonary lesions could not be removed completely (extensive, bilateral lesions). It was reported by the same authors that "no more" than 10% of their asthma patients had been treated by lung resections [60].

Discussion

An outcome of a surgical operation can be influenced by different non-specific factors including a placebo effect [61,62]. It is reasonable to assume that surgery is associated with a placebo effect, and that invasive procedures have a stronger placebo effect than non-invasive ones [62]. Reported moderate efficiency of the procedures described above could have been due to the placebo effect and/or inexact evaluation. Other questionably substantiated or outdated methods used in the former SU were discussed previously [63]. Among the mechanisms contributing to the persistence of suboptimal and outdated methods both in research and in clinical practice has been the authoritative management style, ingrained also in science and medicine, whereas doctors tended to follow instructions of superiors or health care authorities without questioning them on the basis of the international literature. Shortage of internationally used textbooks and manuals should be mentioned here, particularly given the fact that many Some Russian-language editions of that period, and to this day, contain inexact or outdated information and are scarcely illustrated [63]. Furthermore, disregard of the principle of informed consent coupled with the paternalistic attitude towards patients have facilitated the use of invasive methods with questionable clinical indications or for research: The patients were told that it was necessary for treatment or diagnostics, or simply not asked, e.g., in case of intra-operative biopsies [45].

In the context of placebo effect of surgery, costs of invasive procedures should be mentioned, as they can influence the placebo effect. Now as before, all Russian citizens are entitled to free medical insurance that covers a set of diagnostic and therapeutic procedures including surgical operations. However, the patients are often advised to have additional procedures (e.g., computed tomography [CT], magnetic resonance imaging, immunohistochemistry), sometimes with questionable indications, for which they cover the costs [64]. The usual practice is to charge patients through official and unofficial means for treatments and services; unofficial payments are not only accepted, but often demanded from patients or their relatives. Certainly, there are regional differences in this practice. For example, according to the information obtained during the author's visit to the Donetsk regional anticancer center (July 2014), all patients of this governmental institution pay for the diagnostics and treatment, while many payments are under-the-counter or equivalent to bribes. Different kinds of psychological pressure and manipulation can be applied for this purpose. Many physicians, who are employed by the government, practice in private on the part-time basis, often at the same institution. Privately handled cases are usually given more attention, negatively influencing quality of services in the public sector, the border between the state medical institution and a private practice being sometimes effaced. For example, at the Sechenov first Moscow medical university, which is a governmental institution, the following costs for invasive procedures are applied (official course 8 August 2014: 1 united states dollar [USD] = 36.30 Russian ruble): Intramuscular or subcutaneous injection; lymph node biopsy; atheroma removal from the head; laparoscopy; endoscopic gastric polypectomy; mastectomy: Simple, radical; coronary artery bypass surgery [65]. Prices in private clinics vary widely and can be considerably higher than those cited above; for example, ultraviolet irradiation of blood; radio wave treatment of cervical erosion; CT of the abdominal cavity and kidneys [66].

Conclusion

Reviewing Russian-language publications, it appears that today they are more aware of the international literature than they used to be 10 years ago and earlier. However, published questionable recommendations, partly discussed in this review, remain unchallenged

and even approved in some recent publications; therefore, unbiased judgment is needed. The today's upturn in Russian economy enables the acquisition of modern equipment, and medical research is now increasing. Under these circumstances, the purpose of this review was to help to correct the historical problems of surgery in Russia and to remind that, when performing surgical or other invasive procedures, the risk-to-benefit ratio should be kept as low as possible.

Conflict of interest statement

The authors have no conflicts of interest to declare.

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