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Surgical Procedures with Questionable Indications: A Letter from Russia

Keywords: Peptic ulcer; Gastrectomy; Diabetes; Portosystemic shunting; Asthma; Denervation

Introduction

Partial isolation of Russian medicine and medical research from the international community had consequences for the healthcare. Obviously, it is one of the causes of the relatively low life expectancy [1]. According to the author's estimates after a practice abroad, an average size of malignant tumors in surgical specimens was considerably larger in central Moscow clinics compared to hospitals in some countries of Western Europe, which means that early detection of malignancies is less efficient in Russia. 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 in the last decades; 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 recommended by Soviet-time textbooks for all types of breast cancer. The Halsted operation was presented as a main treatment modality for breast cancer even in some handbooks edited after the year 2000 [2,3]. The worldwide tendency towards conservation in the treatment of breast cancer remained largely unnoticed in the former Soviet Union (SU) for a long time. Today admittedly, mastectomy without muscle removal is becoming increasingly prevalent. Furthermore, the negative appendectomy rate has been relatively high in Russia probably favored by the outdated concepts of catarrhal and chronic appendicitis not requiring histological signs of acute inflammation for the diagnosis [4]. Appendices morphologically indistinguishable from the norm have been habitually reported as compatible with appendicitis, surgeons thus receiving no feedback from pathologists. Thermo-, diathermo- or cryo-coagulation of cervical pseudo-erosions (endocervical ectopy) regardless of the presence of epithelial dysplasia, has been routinely applied in the former SU. Coagulation of an endocervical ectopy without neoplastic or preneoplastic lesions is at variance with scientific evidence not supporting the hypothesis that it protects against cervical cancer [5]. Cervical ectopies were found at mass examinations and treated by electro- or thermocauterization [6,7]. The complications of such approach were noticed later [8-10]. It was recommended to start the treatment of the pseudo-erosions possibly early, while large lesions were to be treated by diathermoconization i.e. conization by means of an electrocautery device [11], a procedure known to be associated with complications [12]. It should be noted that according to the international literature, "in most women during the reproductive period, the mucin-secreting columnar epithelium of the endocervix is present on the cervical portio, forming the endocervical ectropion or cervical ectopy" [13], in particular, if hormonal contraceptives are

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Letter to the Editor

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taken in. Cervical conization is a new procedure in Russia; primary hysterectomy has been generally applied. Pap-smears have been rare, cervical cancer being diagnosed at a relatively advanced stage [14]. In this letter are discussed several invasive procedures deviating from the international practice.

Surgical Treatment of Diabetes Mellitus with Pancreatic and Renal Biopsies

In a series of studies from Russia, pancreatic and renal biopsies around 5 mm in size were collected during the operations of "pancreatic blood shunting into the systemic blood flow in insulindependent diabetics" [15]. From 1986 to 1994, 409 of such operations in type 1 diabetic patients were performed by this particular research group [15]. From the same patients, 51 renal core biopsies were taken [16]. Apart from several reports from Russia and Ukraine, no analogs of this surgical treatment of type 1 diabetes mellitus have been found in the literature [17-24]. The method was applied also in type 2 diabetic patients with severe hypertension [25]. The anti-diabetic effect of the porto-systemic shunting was reported to be moderate both in humans [15,19] and in preceding experiments in dogs [26]; while thrombosis [18,20], acidosis [21,23], peritoneal adhesions and other complications [23] were observed. Severe acidosis was stressed as a typical post-operative phenomenon [21], which agrees with the known fact that surgical stress can provoke hyperglycemia and ketosis in diabetics [27]. It was reported that 27% of the patients developed thrombosis of the splenorenal anastomosis, confirmed by angiography, during first 8 months after the operation [18].

In the preceding experimental study, the majority of dogs did not survive the surgical or chemical diabetes induction and subsequent porto-systemic shunting [26], indicating that poor condition of the animals could have interfered with assessment of anti-diabetic effects of the shunting. Nonetheless the method was applied in humans. The collection of biopsies from diabetic patients for research was planned in advance [28]. It should be commented that renal and especially pancreatic biopsy is a hazardous procedure to be performed solely for research purposes [29] especially in conditions of suboptimal quality of histological examination [30,31]. Morphological descriptions of pancreatic and renal biopsies taken from diabetic patients [28,32,33], discussed in [30,31], were partly at variance with usual morphological

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descriptions [34-36]. Histological evaluation of the renal and pancreatic biopsies in the above-cited studies was performed with participation of the same researchers, who developed the concept of hypoplastic renal dysplasia [37-39], unknown in the international literature and potentially interfering with the diagnosis of Alport syndrome. Some histological images in [37-39] had apparently been artifacts or tangential sections of renal glomeruli (e.g. an image from [37] republished 25 years later in [40]), partly reproduced and commented in [30,31]. In the author's opinion, indications to the organ biopsies used for research in the studies [28,32,33,37-43] have not been uniformly adequate. This pertains also to angiographic procedures [18] involving catheterization of renal and splenic veins as well as arteriography, described in [15]. The porto-systemic shunting for the treatment of diabetes has been presented in a recent paper as a valuable achievement [44]. In 2010, it was reported that this method continues to be used; and a "high thrombus-related hazard" was pointed out [20]. Other studies, where biopsies had been used for research, were discussed in [45,46].

Treatment of Peptic Ulcer

The approach to the surgical treatment of the peptic ulcer disease in the former SU has been different from the international practice [47,48]. According to the author's observations, the partial gastrectomy for peptic ulcers was performed less frequently outside Russia, the volume being smaller, mostly corresponding to antrectomy. For perforating ulcers, excision was a routine procedure abroad; the excision specimen was sent for histological examination. In Russia, primary gastrectomy (2/3 - 3/4 of the stomach) or ulcer closure (suturing), depending on the patient's condition, have been predominantly applied [49-53]. According to a recent communication, the suturing has been applied in 80% of perforated ulcers despite tissue damage and inflammation at the margin potentially conductive to recurrence [54]. Gastrectomy remained relatively frequent in many institutions [55] owing to conservatism of surgeons [47] and limited availability of the medical ulcer therapy [51,55]. Medication costs for outpatient treatment are not covered by medical insurance in Russia. Modern therapy of chronic diseases e.g. peptic ulcer is hardly available on a regular basis for a majority of patients, which is apparently one of the causes of the increased incidence of ulcer perforation in Russia in the 21st century [56]. Limited availability of the regular endoscopic screening of gastric ulcers and especially of medical therapy of ulcer disease was designated as a "social indication" for gastrectomy [51].

During the 1960-1970s, when the partial or subtotal gastrectomy was almost the single surgical treatment modality of peptic ulcers [52,53,57], about 60,000 of such procedures were performed yearly in ulcer patients, while significant complications had come to the fore [48]. Responsibility for the "hyper-radicalism" was associated with the famous surgeon S.S. Yudin, who advocated gastrectomy for peptic ulcers, including primary gastrectomy for perforated ulcers [57,58]. Yudin's article from the late 1940s, recommending gastrectomy for peptic ulcers, was republished by the main journal of Russian surgeons "Khirurgiia" in 1991 with approving words from the editor [59]; his letters mentioning the same topic were published recently [60]. References to Yudin can be encountered now as before [51] e.g. that he performed the primary gastrectomy in 75% of perforated ulcers [61].

Instructive publications presenting gastrectomy as a main surgical method of ulcer treatment have been continued [62-66]. In a textbook of surgery published in 1995, the Billroth's procedures I and II were listed in the first place among the surgical treatment methods of peptic ulcers [63]. Now as before, partial gastrectomy is applied for peptic ulcers, in particular, in case of perforation [64-66]. As mentioned above, gastrectomy has been advocated referring to social indications [51,53], while the term "non-compliance" was used in an unusual sense to designate insufficient availability of medical treatment [51]. In some publications recommending surgery for the ulcers, it was stated that "the number of supporters of conservative ulcer treatment is decreasing" [67], "modern medical treatment does not completely solve the problem" [68] and "... does not lead to a complete recovery of patients with gastrointestinal ulcers," therefore the operation has been recommended before the onset of further complications [64]. This view is at variance with the international literature, according to which medical therapy cures peptic ulcer in a vast majority of cases [69-71]. Along with gastrectomy, different techniques of vagotomy have been applied for ulcer treatment, mainly in specialized centers [72]. S.S. Yudin opposed vagotomy [57]; it was started in the former SU later than in other countries and continues to be used [56,73,74], although abroad vagotomy tends to be abandoned in connection with the increasingly efficient medical treatment of peptic ulcers [69,75].

Lung Denervation in Bronchial Asthma

Another surgical procedure having no analogs in the contemporary international practice is the lung denervation for bronchial asthma [76-82]. This procedure was applied because it supposedly "interrupts pathological impulses from the nervous system" [76]. Such argumentation was typical for the earlier Soviet period, when so called nervism ideas, associated with the name of I.P. Pavlov, were propagated [83]. Along these lines, morphologic changes of nervous structures e.g. sympathetic ganglia, such as cellular alteration, pigment accumulation, etc. were supposed to justify the denervation surgery for asthma [84]. To achieve a complete denervation of the lung, its auto-transplantation for the treatment of asthma was applied [85,86]. The surgical treatment of asthma was officially approved; recommendations by the Health Ministry were issued [77]. The open lung denervation via thoracotomy with "skeletonization" of the pulmonary root was designated as the most recognized surgical procedure for severe asthma [77]. The method was presented in the students' textbook of surgery as a main surgical treatment modality of asthma [87]. It was recommended for "infectious-allergic asthma", for severe asthma with manifest steroid insufficiency, after an unsuccessful carotid sinus denervation and glomectomy [77,82]. Lung denervation and resections of parts of the lungs were advocated even for the cases when a medical treatment "had a temporarily good effect" especially in the presence of inflammatory lung lesions [81]. It was pointed out that the duration of medical treatment of asthma prior to the surgery should be reasonably restricted [88]. By 1990, 457 of denervation procedures were performed in asthma patients by this particular group of researchers [78]. Among these cases, the following absolute numbers of complications were reported: post-operative complications in general - 58 patients, 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 [78]. In 2002, it was stated that the use of the lung root denervation had been continued [79]. Efficacy of the denervation procedure was generally designated to be moderate, while approximately equal percentages (30-40%) of the patients belonged to the groups with a good, satisfactory and no effect [80]. These data are suggestive of a bias, because there was no group with worsening or complications, which should have been present in patients after a 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 constantly more efficient [89], which, according to the author's experience, is suspicious of data trimming [46,90]. The denervation surgery was often combined with a resection of pathologically altered, from the surgeon's viewpoint, segments of pulmonary tissue, or by lobectomy [77,80]. Morphological images and descriptions of removed pulmonary tissues included emphysema, inflammation and fibrosis without specifying their extension and grade. According to experience [46], cliché descriptions of that kind can relate to mild or moderate changes hardly distinguishable from the norm. Moreover, lung resection was applied as an independent method of asthma treatment, even in the cases when medical treatment was efficient, whereas the indications had initially included "pneumo cirrhosis" and bronchiectasis but were later extended by "bronchitis deformans" [91]. 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 authors that "no more than 10%" of their asthma patients had been treated by lung resections [91].

The use of bronchoscopy in asthmatics should be commented briefly. Bronchoscopy was recommended as a standard procedure for patients with severe asthma [92,93]. For example, it was reported on 756 bronchoscopies in 472 cases of asthma [93]. There is an opinion, however, that it has no benefits for asthmatics [94]. Bronchoscopy was broadly used for asthma research [95-97], sometimes repeatedly [98], also in mild [99,100] and moderately severe [101,102] cases, in children [103] and elderly [104]. It was reported on enhanced complication rate after bronchoscopy in asthmatics, including severe complications [105]. In some studies, simplistic morphological descriptions of bronchial biopsies, statistically significant differences between average morphometric indices in different patient groups e.g. with severe and moderate asthma, or morphometric indices uniformly increasing with the therapy duration, might be suspicious of data trimming. Informed consent has been mentioned only in a few recent papers [101,106].

Discussion

It is known that surgery can exert a placebo effect; and that invasive procedures tend to have a stronger placebo effect than noninvasive ones [107,108]. Reported efficiency of the procedures described above could have been caused by the placebo effect enhanced in some studies by a biased evaluation and data trimming. Other invasive procedures possibly applied without evidence-based indications were discussed in [4,30,31,45,46]. 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. Some invasive methods with questionable indications were fostered by first generation military surgeons (Babichev, Kovanov, Kuzin, Meshalkin, Yudin) [2,59,63,76,77,84,85,87,88,93,109]. Absence of internationally used textbooks and manuals of surgery even in central medical libraries [110] should be mentioned as well. Some Russianlanguage textbooks (e.g. [2,63,87]) contained outdated information. The recently started series of so-called National Manuals is partly represented by compilations from foreign sources without references, whereas the quality of translation is questionable in places, and terminological confusion can be encountered [111]. National manuals may exist in addition to internationally used handbooks, if the latter are available in libraries and are acquired by medical institutions in sufficient quantities, which is generally not the case in Russia [110]. Finally, disregard for the principle of informed consent coupled with the authoritative attitude towards patients have obviously facilitated the use of invasive methods with questionable indications and for research.

Conclusion

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. In spite of unsatisfactory conditions of medical libraries [110], the foreign literature is increasingly available via the Internet. However, publications containing questionable recommendations, including those discussed in this review, have remained without due commentary. Recommendations of invasive procedures without evidence-based indications sometimes reappear in newer papers. Excessive manipulation is especially undesirable in conditions of insufficient procedural quality assurance [112,113]. The today's upturn in Russian economy enables the acquisition of modern equipment, medical research being intensified. Under these conditions, the purpose of this letter was to overview some surgical modalities with questionable indications and to remind that, performing invasive procedures, 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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