

Overdiagnosis and Overtreatment of Radiation-Related Malignancy in Belarus, Kazakhstan and Ukraine

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Introduction

The main topic of this commentary is the cancer treatment, used in some countries of the former Soviet Union (SU), which is not entirely in agreement with the international practice. The topic is developing rapidly these days. Many clinical guidelines are adjusted to the international standards thanks to the PubMed and other gratis Internet databases. However, certain human factors are persisting. This topic is interconnected with some features of ex-Soviet healthcare: paternalism, authoritative management style, disregard for the principles of informed consent, professional autonomy and scientific polemics. For example, the worldwide tendency towards a more sparing breast cancer management was not followed in the former SU for decades. According to the most recent National Manual of breast diseases, the Halsted procedure with the removal of both Pectoralis muscles predominated during the whole 20th century [1]. In the 1980s and decreasingly in the 1990s, it was a predominant method of the breast cancer management, presented as the main treatment modality of in some textbooks and monographs published after the year 2000 [2-5]. The newest textbook of oncology lists the Halstead and Patey procedures with the muscle resection in the first and second places among surgical treatments without further comment [6]. The Halsted operation has been used and recommended both for ductal carcinoma in situ (CIS) and for disseminated carcinoma as a palliative procedure, which is hard to understand physiologically [7-10]. Old age was not regarded as contraindication for the excessive radicalism; more details and references are in the book [1,11].

The recommendations are currently adjusted to international patterns. Another extreme is observed: mastectomy without removal of pectoral muscles is called "mutilation" allegedly causing "severe moral injury" [12]. Such statements are accompanied by images of patients after reconstructive surgery, where breasts look (almost) as if not operated. Apparently, the motive is economic as the costs of plastic surgery are borne by patients. Another quote from the most recent handbook of breast diseases: "The importance of preserving the mammary gland for the social, professional and family rehabilitation of a woman is paramount" [1]. In fact, esthetic demands can be met in many cases by external prostheses. Risk-reducing bilateral mastectomy in cancer patients is a potentially life-extending intervention facilitating prosthetics. Clinical recommendations are avoided here [13].

Radiation-Related Thyroid Nodules

An increase in the detection rate of thyroid cancer (TC) in contaminated regions started four years after the Chernobyl accident (hereafter accident) [14]. While iodine-131 therapy of Graves' disease in adults was known to cause hypothyroidism, it was not linked to TC. However, studies of children exposed to therapeutic radiation reported increased TC incidence, typically after latencies of ten years or more [15]. In contaminated regions, the rise in incidence coincided with the start of the screening around 1989.

The mass screenings uncovered not only small nodules but also previously neglected late-stage TCs. Moreover, there was a tendency among non-exposed individuals to register as Chernobyl victims to access state-provided benefits [16]. In 1990, the year when regulations on Chernobyl-related social protection had been issued, a rapid increase in the registered incidence of conditions eligible for such benefits was observed. International observers noticed that many claims of supposedly radiogenic diseases lacked sufficient validation [16]. TC cases brought from other regions must have been averagely at a later stage than those identified through local screening. This agrees with the data that the first wave of post-accident TCs were larger and less differentiated than those diagnosed ten years later [17,18].

The following claim is potentially misleading: "With regard to the size of the primary tumor, 77% were greater than 1 cm, suggesting that these were not incidental thyroid cancers detected by aggressive screening" [19]. In fact, the screening detected both incidental and advanced, previously neglected malignancies. It has been argued that the screening cannot explain the age-related differences in incidence, as increases in Chernobyl-related TCs were most notable among children and adolescents. There is an explanation: the minors received special attention, were accessible at schools and kindergartens, being often examined under time pressure, in the atmosphere of radiophobia and anticipation of thyroid tumors [14].

TCs have been rarely diagnosed in children and adolescents in the former SU prior to the accident. In Russia, thyroid cancer began to be recorded as a separate entity in 1989 [14]. In Belarus between 1981 and 1985 only three cases were detected in minors under 15 years old, corresponding to the incidence of 0.3 cases/million/year. In Ukraine during the same period, 25 cases were recorded (0.5/million/year), while in the northern, subsequently contaminated

regions of Ukraine only one TC case was diagnosed [20,21]. According to the International Agency for Research on Cancer, “In the whole of Belarus, by 1995, the incidence of childhood thyroid cancer had increased to 4 cases per 100000 per year compared to 0.03-0.05 cases per 100000 per year before the accident” [22]. According to the American Thyroid Association (ATA), the TC incidence increases with age, from below 1 case/million/year in children younger than ten years, to 3.5 in 10-14, and 15.4 in adolescents aged 15-19 [23].

Despite the unexpectedly short latency, there is generally no doubt that radiogenic TCs did occur after the accident, although other factors contributed to the incidence increase: false-positivity, diagnosis of latent or dormant cases as TC, registration of unexposed patients as radiation-exposed. It had been known prior to the accident that mass screening can significantly increase the TC detection rate [24]. Finally, iodine-deficient areas, like those affected by the Chernobyl fallout, are associated with increased thyroid nodule prevalence and malignancy risk [25,26].

It has been claimed that TC incidence in Belarus and Ukraine had been comparable with that in other countries, that is, much higher than the figures cited above [20,21,27-29]. For example, Fridman claimed this with the reference, where no such statements were found. The misquoting suggests an effort to camouflage the low pre-accident TC detection rate [29,30]. The screening after the accident resulted in the detection of numerous latent or previously neglected TCs [31,32].

Considering the above, the statement that “in children born a year after the Chernobyl disaster, the age-specific incidence rates were comparable to those expected based on the incidence trend of 1978-1986” is pointless [33]. Pre-accident TC incidence was low, and there was no recognizable upward trend. Despite the return to the background radiation levels, TC detection rates in Belarus have remained elevated, likely due to increased awareness among both physicians and the general public [28,33]. The graph in the article demonstrates elevation of the registered TC incidence [33]. Of note, after 2003, the highest detection rate was observed among subjects older than 45 years, probably due to the screening discontinuation among younger people and increased health-seeking behavior in older persons [33].

The lack of a comparable increase in TC incidence among children born after the accident has explanations unrelated to radiation. This population segment did not undergo mass screening. The diagnostic quality has improved, the pool of undetected cases depleted, and there were no longer any incentives to inflate the figures. Exaggeration of the Chernobyl topic facilitated many scientific careers, secured foreign sponsorship and international cooperation. Moreover, the accident has been exploited to strangle the nuclear energy production in many countries, maintaining high prices for fossil fuels [24]. According to interviews with local practitioners and researchers, manipulation with numerical data and specimens has taken place, which was not unusual for the Soviet medical science [34,35].

Another quote reads as follows: “It is also important to note that the increase in morbidity was primarily noted in the southern regions of Belarus, which were most contaminated with radioactive iodine” [33]. This can be explained by the disproportionately intense screening in most contaminated areas. An insightful example appears in (commented in [37]), which stressed that “the overall cancer morbidity rate in all organs including colon, urinary bladder, and thyroid, was significantly higher in the Gomel

region” (the most contaminated oblast of Belarus) than in the least contaminated Vitebsk province [36,37]. In fact, the difference was insignificant: 225/100,000 in Gomel vs. 219/100,000 in Vitebsk oblast. Of note, many patients migrated to the capital city of Minsk. As a result, the cancer incidence in Minsk was significantly higher than in the most contaminated Gomel oblast (263.7 ± 1.76 vs. 224.6 ± 6.3 ; $p < 0.001$) and in the surrounding Minsk province (263.7 ± 1.76 vs. 216.6 ± 3.9 ; $p < 0.001$) [36].

Mechanisms of false positivity have been discussed [32,37]. When a thyroid nodule was found by the screening, a fine-needle aspiration biopsy usually followed. Data on its diagnostic sensitivity for detecting post-Chernobyl pediatric TC are presented in the thesis [38]. Out of 238 cases, the diagnosis of TC was confirmed in 161. Papillary carcinoma was correctly identified in 69.5% of cases, and its follicular variety in 36.5%. Suspicious cytological findings required surgical clarification. The specimens were sent to a pathologist, who sometimes confirmed malignancy of a totally removed nodule in case of uncertainty. Histological verification confirmed the cancer diagnosis in 78 % of surgical specimens [38]. The actual percentage was probably lower, given the tendency to conceal false-positivity. Low quality of histological sections, impeding the evaluation of cell nuclei, contributed to false-positivity [39]. In the 1990s, cyto- and histopathological criteria of TC were not sufficiently known. Foreign cytology and histopathology manuals were used rarely in the 1990s. Misleading histological images from widely used manuals were reproduced and commented [32,35,37,40,41]. Some cases were diagnosed as TC based on cellular atypia, which can occur in adenoma and other benign nodules. Illogical diagnostic formulations, suggestive of false-positivity, have been used: “non-invasive follicular carcinoma” or “follicular CIS” [40]. It is known that follicular nodules without invasive growth are generally regarded as benign. Papillary hyperplastic and other benign thyroid nodules were sometimes misclassified as malignancy after the accident.

Misunderstanding can arise from the paper titled “The Chernobyl Forum: major findings and recommendations”, containing the following phrase in the abstract: “Apart from the dramatic increase in thyroid cancer incidence among those exposed at a young age and some increase of leukemia and solid cancer in most exposed workers, there is no clearly demonstrated increase in the somatic diseases due to radiation” [42]. However, in the Chernobyl Forum publication cited in, leukemia and solid cancers (other than TC) are not discussed [42,43]. In the Report of the UN Chernobyl Forum Expert Group “Health”, it was commented that “there is currently no evidence to evaluate whether a measurable risk of leukemia exists among the exposed as adults in the general population. With regard to liquidators, there is clearly a need to clarify the existing observations” and further “there is no evidence of increased risk of non-thyroid solid cancers resulting from Chernobyl” [44]. The same, in principle, is said in the text of the article [42]. The above-cited statement about an “increase of leukemia and solid cancer” in the open access abstract is substantiated neither in the article text nor by the literature cited in [42].

The following quotes are thought-provoking: “Practically all thyroid nodules, independently of their size, were regarded at that time in children as potentially malignant tumors, requiring an urgent surgery” and “Aggressiveness of surgeons contributed to the shortening of the latent period” [14]. In some institutions, thyroid surgery became more aggressive, while a “maximally radical approach” was recommended [45-47]. The treatment protocols included: “the total thyroidectomy combined with neck dissection followed by radioiodine ablation” and external irradiation with

40 Gy [48,49]. Completion thyroidectomy was performed in previously operated children and adolescents [50,51]. Well-known experts recommended total thyroidectomy with neck dissection for supposedly radiogenic TC independently of the tumor size [51-53]. The last edition of the National Manual of pediatric surgery recommends organ-saving operations only for T1aN0M0 (according to the TNM-classification), while for all other TCs “thyroidectomy with subsequent radioablation” and central neck dissection is recommended [54]. This approach is generally at variance with that applied in other countries, including Japan after the Fukushima Daiichi accident [55]. The publications were cited incorrectly to endorse the recommendation: “The most prevailing opinion calls for total thyroidectomy regardless of tumor size and histopathology” [46,56-58]. In fact, the cited articles discuss not total but near-total thyroidectomy. Analogously, the articles were misquoted in [51,58-60].

The problem of false-positivity and “excessive activity in thyroid surgery” was pointed out by the Russian Health Ministry, but the overtreatment went on in Belarus and Ukraine [61]. The Minister ordered a revision of thyroidectomy specimens from pediatric patients residing in the contaminated Bryansk province of Russia [61]. The revision confirmed the false-positivity: “Diagnosis of TC was confirmed in 79,1 % of cases (national level: 354 cases) and 77,9 % (with international participation: 280 cases)” [38]. A monograph published 2009 compared the proportion of thyroidectomies, in which some functioning thyroid tissue was retained in children and adolescents. The percentages of thyroid parenchyma preservation were as follows: 87.2% in Chelyabinsk, 64.3% St. Petersburg, 35.0% Minsk, and 13.9% in Kiev [62]. After the Fukushima Daiichi accident in Japan the figure was 92% [63]. Pediatric papillary TCs in Japan were different from those detected after the Chernobyl accident, rarely displaying de-differentiated solid and/or trabecular patterns [64,65]. In contrast to Chernobyl-related cases, most TCs detected after the Fukushima accident were of well-differentiated papillary type, confirming the more efficient and averagely earlier cancer detection in Japan [66,67].

A study led by E.D. Williams reported that “The exposed and unexposed tumors from the same geographical area are essentially identical morphologically and in their degree of aggressiveness... childhood papillary TCs from Japan were much more highly differentiated ($p < 0.001$), showed more papillary differentiation and were less invasive than Chernobyl tumors” [64]. In later papers by the same team but without Prof. Williams the description was quite different: Childhood Japanese papillary TCs differed from Ukrainian cases by more pronounced invasive properties suggesting higher aggressiveness of TCs in young Japanese patients [65]. The latter statement is unfounded and contradictory to [64]. In a more recent paper, the authors acknowledged that Ukrainian “radiogenic” or “radiation-related” TCs “had a solid-trabecular growth pattern and displayed morphological features of aggressive biological behavior” [68].

In another report, “given the presence of radiation exposure in the patients’ histories”, total thyroidectomy was performed in 405 out of 465 (87.1%) patients with papillary microcarcinoma [69]. Of these, 76.1% received postoperative radioiodine therapy; neck dissection was performed in ~50% of the cases. Recurrence of cancer was recorded in 1.3% of patients (median follow-up 5.2 years). The authors pointed out that microcarcinomas were indolent [69]. Nevertheless, some experts have recommended radioiodine therapy for papillary microcarcinoma or for TC in general, which is generally not in agreement with the international literature [51,70]. Given the potential adverse effects of radioiodine, the

ATA Guidelines recommended selective rather than blanket administration of iodine-131 [71]. The selective approach is generally recommended for papillary TC with the intermediate risk [72].

Another study from Belarus encompassing the period 1990-2005 with the average follow-up of 12.4 years included 936 young TC patients. During the observation period, 17 deaths were recorded - seven from suicide and five from external trauma. Only two patients died from cancer progression [29]. In young females, postoperative scarring and cancer stigma may contribute to depression [16,73]. Suicide is often underreported with official rates possibly 2-3 times lower than factual figures [74]. Along with overestimation of medico-biological consequences of CA, a tendency to downplay its psychological impact has been noticed [75].

Given the generally good long-term prognosis of papillary TC, it is unlikely that the screening reduces cancer-specific mortality. Furthermore, it remains unclear whether early detection significantly improves the quality of life. The harm resulting from false-positivity and overtreatment of TC is precarious in young patients as the diagnosis may cause stigmatization [76]. Finally, total thyroidectomy is contraindicated in conditions where the access to lifelong levothyroxine replacement cannot be guaranteed due to armed conflicts or other reasons. Epidemiologists warned against the overdiagnosis of TC from mass screening using modern imaging technologies [77].

Bladder Lesions

The diagnostic reliability depends on the quality of histological specimens. This is a probable explanation for the fact that in different groups of males with benign prostatic hyperplasia and women with chronic cystitis, from the radioactively contaminated regions and the city of Kiev, severe urothelial dysplasia and CIS were diagnosed by bladder biopsy in different groups of patients as frequently as in 56-92 % of random cases [78-81]. The random selection mode was stressed: “The Institute of Urology in Kiev during 1994-2006 collected all prostatic hyperplasia patients who underwent suprapubic prostatectomy, and all these patients were included in our study in different years without exception” [80]. The frequency of neoplastic and preneoplastic lesions cited above is obviously overrated. Some patients must have undergone invasive treatments based on questionable histological diagnoses of urothelial CIS and microinvasion. Some images are reproduced and commented in [82].

It can be reasonably assumed that so-called Chernobyl cystitis [80,83], reportedly characterized not only by urothelial dysplasia or CIS but also by “reactive epithelial proliferation associated with hemorrhage, fibrin deposits, fibrinoid vascular changes, and multinuclear stromal cells”, was partly caused by repeated cystoscopies, “mapping” biopsies, and cauterization [83]. If left untreated, a considerable percentage of CIS are expected to progress to invasive carcinoma. The high frequency of bladder CIS, reported in random patients with prostatic hyperplasia and/or cystitis, is incompatible with the bladder cancer incidence in Ukraine 50.3/100,000/year mentioned by the same experts in their reply to [84]. It is known that dysplasia can overlap with cytological abnormalities seen in reactive conditions, which probably contributed to the false-positivity [82].

The same low-quality images have been published repeatedly 9 years apart [80,85]. Based on these studies and earlier illustrations by the same experts, it appears probable that false-positive

diagnosis of dysplastic and neoplastic bladder lesions occurred also prior to the Chernobyl accident: articles used one and the same image of bladder leukoplakia with invasion according to the figure legend, which is not clearly recognizable [86,87]. The images are reproduced and commented in [82]. Other histological pictures of the bladder mucosa and thyroid, potentially conducive to false-positivity, published in authoritative Russian handbooks, were reprinted and commented [37,41].

Renal Lesions

Surgeons may decide for nephrectomy in cases when a kidney-preserving procedure would be indicated, if they read that renal-cell carcinoma from radiation-contaminated regions is aggressive, while the surrounding renal parenchyma exhibits “proliferative atypical nephropathy with tubular epithelial nuclear atypia and CIS” [88]. On the author’s opinion, the above statement is unfounded. Supposed extraordinary aggressiveness of renal cancer from radiocontaminated territories and other regions of Ukraine was probably caused by on average later stage at diagnosis compared to the control cases from Colombia and Spain, commented in [89-93].

Lung Cancer

Dubious research of lung cancer patients residing on territories surrounding the nuclear test site in Semipalatinsk oblast was summarized in the dissertation by Sagindikova (Kazakhstan) [94-98]. The following is stated in the abstract about radiation doses: “17 patients (group 1) lived close to the testing area from the childhood to 1993 and were exposed to the radiation at the year dose 0.1 ber.” A radiation dose unit “ber” (Biological Equivalent of Rad) is designated internationally as rem. The annual individual dose of 0.1 rem (1 mSv) is below the global average for annual doses from the natural radiation background, which is 2.4 mSv. Average annual doses from radiation background are higher than 4 mSv in many countries. The term “radiation carcinoma” was used in the study of lung cancer of unknown etiology, whereas suppositions were made about its rapid growth and poor prognosis [94]. The following quotes are remarkable: “The specific cytogenetical feature of lung carcinoma in patients from the area of Semipalatinsk was the neuroendocrine differentiation of cancer cells in all tumors independently of their histological structure. We have established it by means of immunohistochemical and ultrastructural methods.” At the same time, “no neuroendocrine differentiation was shown in the control group” [94]. It implies that the marker determined by two independent methods appeared in all 17 cases of the first group and not in a single patient from 40 control cases. The extremely high statistical significance of the difference between the two groups is supposed to confirm that the “lung carcinoma in persons exposed for a long time to radionuclide radiation pollution” is a special entity, different from spontaneous cancer [94]. It was concluded that “lung cancer in patients, who resided in the area of Semipalatinsk and underwent elevated radioactivity, can be classified as neuroendocrine carcinoma”. However, the distribution according to age and sex in the first group was typical for spontaneous cancer caused by smoking, air pollution and other factors: 15 from 17 patients belonged to the age group of 51-70 years. In particular, typical for spontaneous cancer is the male predominance due to cigarette smoking and professional exposures. Environmental radiocontamination would probably exert similar impact on both sexes. In the group from Semipalatinsk province were 16 males and one female patient [95]. Speculations about rapid growth and poor prognosis of the “radiation carcinoma” may contribute to overtreatment. Some other research on Semipalatinsk and Chernobyl by the same scientists contain similar drawbacks [96-99]. For example, in

the study, discussion of molecular-genetic features of supposedly Chernobyl-related “radiation cancer” is based of 15 random autopsy and surgical lung cancer cases from areas quite distant from Chernobyl (eight cases were from Tula oblast) [99]. Some papers on the nuclear test site in the Semipalatinsk area and other contaminations in the former SU have common features: large volume, many details and mathematical computations, but no real insight into medical consequences. Papers on dosimetry or retrospective dose estimation contain lengthy discourses, for example, about consumption of cow and horse milk or ethnic origin of people living in or compulsorily resettled to the Semipalatinsk area (ethnic Germans) but provide no clear information on annual or total individual doses.

Conclusion

Among factors contributing to the use of invasive procedures with questionable indications have been the partial isolation from the international scientific community, insufficient consideration of the principles of professional autonomy, informed consent and scientific polemics, as well as paternalistic attitude to patients. Most importantly, the human factor has not sufficiently changed since the Soviet time. The ethical and legal basis of medical practice and research has not been sufficiently known and observed in some post-Soviet countries. Textbooks and monographs on medical ethics or deontology explained the matter somewhat vaguely, with truisms and generalities, but not much practical guidance. Today, the growing economy enables the acquisition of modern equipment; and medical research is on the increase. Under these circumstances, the purpose of this commentary was to remind us that, performing surgical or other invasive procedures, the risk-to-benefit ratio must be kept as low as possible. 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.

Conflict of Interest

The authors declare no conflict of interest.

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