

# Overdiagnosis and overtreatment of bladder and kidney lesions: Ethical and clinical lessons from past experience

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## Abstract

**Background:** This review summarizes previously published and recently reported findings on overdiagnosis and overtreatment with special reference to the bladder and kidney. Among others, the following is discussed: (i) overuse of cystoscopy with biopsy associated with the overdiagnosis of malignant and premalignant urinary bladder lesions after the Chernobyl accident, (ii) suppositions about increased aggressiveness of renal tumors from radiation-contaminated areas potentially conducive to overuse of nephrectomy instead of kidney-preserving surgery, (iii) wedge biopsies from the renal cortex and medulla during lithotomy, and (iv) overuse of renal biopsy and overtreatment related to it. **Objective:** The objective was to update the previously reported information based on the international and Russian-language literature, as well as the author's observations. **Conclusion:** In conditions of paternalism, misinformation and persuasion of patients are regarded to be permissible. Suboptimal practices have been used in accordance with instructions by healthcare authorities and publications by leading experts. Collection of specimens is associated with risk, while the reliability of some studies is questionable. High quality of specimens and their examination must be a prerequisite for the use of biopsy in research and practice. In the author's opinion, biopsy of internal organs should not be performed merely for research purposes; it must always be performed according to clinical indications. If a patient provides informed consent for research on tissues obtained for diagnostic purposes, it can be done, provided that sufficient material remains for the diagnosis. International trust and cooperation are needed to reassess potentially outdated and suboptimal methods. Authorized foreign advisors should be engaged in Russia.

**Keywords:** Bladder; Urothelial dysplasia; Carcinoma *in situ*; Lithotomy; Renal biopsy

## 1. Introduction

Numerous examples of overdiagnosis and overtreatment have been documented in a recently published book.<sup>1</sup> Invasive methods were applied without sufficient indications in patients diagnosed with alcohol-related disorders, including for research purposes. Cauterization of endocervical ectopies was performed without prior Pap smear testing. Excessive radical breast cancer management, thyroid surgery after the Chernobyl accident, the overuse of surgery for peptic ulcers, and certain respiratory conditions were discussed in more detail.<sup>1</sup>

## 2. Methods

This review is based predominantly on Russian-language sources and, to a lesser extent, on international literature. The literature search was performed primarily through PubMed, eLibrary.ru, general web searches, and library resources. The data from the literature have been reviewed and summarized on the basis of the author's observations since the early 1980s.

## 3. Bladder lesions

The diagnostic reliability depends on the quality of histological specimens. If the sections are thick, the urothelium may appear hyperchromatic. Compounded with tangential sectioning, this may result in a picture resembling dysplasia. In the presence of inflammation, basement membranes may be obscured and

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distorted, simulating invasion. The most common mimicker of a papillary urothelial neoplasm is polypoid cystitis. Another difficult differential diagnosis is between a papillary urothelial neoplasm with inverted growth and an inverted urothelial papilloma. On the other hand, some histological variants of bladder cancer can mimic non-neoplastic conditions, such as cystitis cystica, proliferative von Brunn nests, nephrogenic adenoma, and inverted papilloma.<sup>2</sup>

Diagnosis uncertainty is a probable explanation for the fact that in different groups of males with benign prostatic hyperplasia (BPH) and women with chronic cystitis, from the radioactively contaminated regions after the Chernobyl accident and Kiev (which was not officially classified as a contaminated territory), severe urothelial dysplasia and carcinoma *in situ* (CIS) were diagnosed by bladder biopsy as frequently as in 56–92% of random cases.<sup>3–6</sup> The random selection mode was stressed: The Institute of Urology in Kiev during 1994–2006 collected all BPH patients who underwent suprapubic prostatectomy, and all these patients were included in our study in different years without exception.<sup>6</sup> The frequency of neoplastic and preneoplastic lesions quoted above is remarkably overrated. The topic of cystectomy has not been discussed at our interviews with cited researchers, but it appears probable that some patients likely underwent cystectomy based on questionable histological diagnoses of urothelial CIS and microinvasion; some images are reproduced in the preceding paper.<sup>7</sup> It can be reasonably assumed that the so-called Chernobyl cystitis or “irradiation cystitis,”<sup>6,8</sup> characterized not only by dysplasia or CIS but also by reactive epithelial proliferation associated with hemorrhage, fibrin deposits, fibrinoid vascular changes, and multinuclear stromal cells<sup>8</sup> was at least in part caused by repeated cystoscopies, mapping biopsies, and electrocoagulation. Flat CIS is frequently associated with papillary or invasive carcinoma. If left untreated, a considerable percentage of CIS cases are expected to progress to invasive carcinoma. The high frequency of bladder CIS, reported in random patients with BPH, is incompatible with the bladder cancer incidence in Ukraine (50.3 cases/100,000 inhabitants/year) mentioned by the same authors in their reply.<sup>9</sup> It is known that urothelial dysplasia can overlap with cytological abnormalities seen in reactive conditions, which could have contributed to the overdiagnosis of severe dysplasia and CIS; more details about false-positivity and histological images are included in the preceding publications.<sup>1,7</sup>

In studies of bladder lesions, differences between the exposed and unexposed groups may have been due to selection bias and specimen quality.<sup>3–6</sup> Several images from the articles are identical.<sup>6,10</sup> Based on these studies and earlier illustrations by the same authors, it appears probable that overdiagnosis of dysplastic and neoplastic bladder lesions also occurred in the 1980s: Both latter articles used the same poor-quality

image of bladder leukoplakia with invasion according to the caption, which is not clearly recognizable.<sup>11,12</sup> The images are reproduced in the preceding article.<sup>7</sup> Histological images of the bladder mucosa and thyroid, potentially conducive to overdiagnosis, published in widely used Russian-language editions on tumor histopathology, have been reproduced and commented.<sup>1,13</sup>

## 4. Renal lesions and biopsy

Overtreatment tendencies may have occurred with respect to renal lesions. Surgeons might overuse nephrectomy instead of kidney-preserving procedures if they read that renal-cell carcinoma from radiation-contaminated regions is aggressive, while the surrounding parenchyma is described as exhibiting proliferative atypical nephropathy with tubular epithelial nuclear atypia and CIS.<sup>14</sup> As discussed previously, the supposed high aggressiveness of renal cancer from radiation-contaminated territories was probably caused by the later average stage at diagnosis in the former Soviet Union compared to Spain, from which control cases were obtained,<sup>15,16</sup> and discovered by the screening of advanced cases after the Chernobyl accident.<sup>17</sup>

The overuse of renal biopsies (RBs) associated with potential overtreatment has been discussed in the book.<sup>1</sup> Key prerequisites for RB are high-quality thin sections, silver stain, and, wherever necessary, immunohistochemistry (immunofluorescence) and electron microscopy. The following subsections provide an updated summary.

### 4.1. Pyelonephritis (Pn)

Core and wedge RBs are generally not indicated in Pn. Only a limited number of studies are available regarding RB in acute Pn.

In previous studies, wedge RBs were taken at kidney-preserving surgeries, such as lithotomy, from patients with chronic or acute (including purulent and abscess-forming) Pn.<sup>18,19</sup> In the international literature, Pn is not listed among conditions where RB is indicated, while hydronephrosis and infections of the upper urinary tract are generally regarded as contraindications. In particular, a surgical wedge RB in acute Pn is associated with a risk of abscess formation. In another study of Pn, including its acute and chronic varieties, biopsies were collected simultaneously from cortical and medullary tissues of the kidney. Around this time, in the Urology Clinic of the Sechenov Medical Academy, excisional RBs measuring 0.5–1.0 cm were taken during kidney-preserving operations (lithotomy, ignipuncture, revision of the renal vessels), including surgery on a single kidney.<sup>20</sup> In the studies from the same institution, RBs were collected from patients with chronic Pn and hydronephrosis, while conclusions were based

on linear correlations between ultrastructural morphometric and clinical data.<sup>21</sup> However, the statistical significance of the correlation coefficients in this and some similar studies was overstated. A comparison with reference tables demonstrated that many claimed *p*-values were too low for the given correlation coefficients and quantities of correlation pairs; details and references are in the books.<sup>1,22</sup> Renal medulla was studied using core RBs collected during lithotomy surgeries from patients with urolithiasis and secondary Pn.<sup>23</sup> RBs were also taken from patients with Pn by other researchers.<sup>1</sup>

#### 4.2. Glomerulonephritis (Gn)

Renal biopsy has been generally regarded in the Russian literature as indicated for patients with suspected Gn, including children. According to the international literature, RB in isolated (in particular, orthostatic) proteinuria and isolated glomerular microhematuria without renal insufficiency may not be warranted. Nevertheless, RBs were taken from individuals with “inactive nephritic” or latent forms of supposed Gn.<sup>1,24-27</sup> At the same time, classifications of Gn differed from those used internationally, hindering the implementation of guidelines from the foreign literature. For example, immunoglobulin A (IgA) nephropathy was not considered to be a separate entity; it was not mentioned even in the article from the Sechenov Academy dedicated to the “hematuric form” of Gn.<sup>28</sup> IgA nephropathy was usually diagnosed on RB as mesangioproliferative Gn (MG). In recent editions, controversies can be found; for example, in the textbook,<sup>29</sup> IgA nephropathy and Berger’s disease are discussed separately, and different treatments are recommended. Novel classifications of glomerular diseases were proposed.<sup>26,30</sup> In the National Manual, probably the most authoritative Russian-language edition in nephrology, IgA nephropathy and MG are discussed in one chapter titled “Mesangioproliferative (IgA) Gn” as follows (from Russian): “The term IgA nephropathy is used to designate an entity, the morphological equivalent of which is MG.”<sup>31(p215)</sup> This differs from the known fact that glomeruli in IgA nephropathy may be inconspicuous at light microscopy, may exhibit a morphological picture of various Gn types, of segmental mesangial proliferation, and/or focal sclerotic lesions.

Comparisons of the percentages of glomerular diseases diagnosed by RB in Moscow and Rostock, Germany (Table 1) suggest regular overdiagnosis of Gn and, hence, overtreatment.<sup>32,33</sup> I participated in a study using epoxy resin sections cut using a modern LKB pyramitome equipped with glass knives; after that, I found it difficult to examine diagnostic paraffin sections, as basement membranes and mesangial matrix were less clearly visualized. The paraffin slides were thick and uneven. Overstained or thick sections can mimic a glomerular capillary wall thickening. This is probably

**Table 1. Percentages of glomerular diseases diagnosed by renal biopsy in Moscow and Rostock<sup>32,33</sup>**

Condition	Moscow	Rostock
Diffuse Gn	81.7	59.3
MG	55.5	40.2
Membranous Gn	9.2	4.1
Minor glomerular abnormalities	7.1	20.8 (1978–1983) 30.0 (1990–1999)
Focal/segmental Gn	11.1	20.0
Insufficient material	9.1	14.5

Abbreviations: MG: Mesangioproliferative glomerulonephritis;

Gn: Glomerulonephritis.

a reason why membranous Gn was diagnosed in Moscow more than twice as frequently as in Rostock (Table 1). In recent studies from Germany, Japan, and the United States, percentages of both Gn in total and of IgA nephropathy plus membranoproliferative Gn (non-IgA MG was rare) were lower than in Moscow (Table 1), which agrees with the above conclusion about overdiagnosis.<sup>34-36</sup> Finally, the frequent detection of focal/segmental Gn in Rostock (Table 1) indicates thinner sections.

The diagnosis of MG was applied broadly, encompassing 55.5–60.8% of all Gn cases diagnosed by RB at the Sechenov Academy.<sup>32,37</sup> I publicly discussed the problem, and the reported percentage of MG decreased to 48.9%.<sup>38</sup> Epoxy resin sections and silver stain were not regularly used for diagnosis, while electron microscopy was utilized only occasionally. Using these methods, the collecting box of MG could have been partly sorted out, excluding from it some cases morphologically bordering on the norm, that is, isolated proteinuria and/or hematuria without renal or systemic disease, not requiring immunosuppressive therapy.

As mentioned above, RBs were collected from patients with “inactive nephritic” or latent clinical types of Gn, i.e., minimal proteinuria and/or hematuria. As a result of the histological overdiagnosis of Gn, some patients were treated with corticosteroids and immunosuppressive drugs, such as azathioprine, cyclophosphamide, or chlorambucil, sometimes without sufficient indications.<sup>24,25,39</sup> Of note, 83.5% of MG cases were clinically classified as the inactive nephritic form of Gn.<sup>24</sup> In this context, it is not surprising that the 18-year survival rate of patients with the inactive nephritic Gn type was reportedly as high as 100%.<sup>24</sup> It also indicates the young age of treated patients. In another paper by the same researchers, the “actuarial survival” up to 18 years approached 100%.<sup>37</sup> In another study, it was stated that active therapy of Gn was reported to increase 10-year renal survival to 100%.<sup>25</sup> The difference in meaning between these statements is minor in view of the relative rarity of dialysis and of functioning kidney transplants in Russia.<sup>40</sup> Considering comparatively lower survival rates in the international literature than the

Russian literature, figures up to 100% provide additional evidence in favor of overdiagnosis.<sup>24,25,37</sup>

### 4.3. Alcoholism

Biopsies were obtained from the kidneys, pancreas, liver, lung, salivary glands, stomach, and skin of patients with suspected alcoholism, in some cases repeatedly.<sup>41,42</sup> Intraoperative lung biopsies were taken from patients with purulent pulmonary conditions.<sup>42</sup> In many cases, the tissue fragments from various organs were collected for research purposes without clinical indications. The attitude to suspected alcoholics was at times inferior to that provided to other patients.

Furthermore, RBs were taken from individuals with chronic alcoholism and nephritic symptoms, while “intracapillary proliferative Gn” was identified in almost every case.<sup>43</sup> In a subsequent study by the same team, the histopathological results in 40 of 43 alcoholics with nephritic symptoms were classified as mesangiocapillary Gn; whereas in 29 of 31 individuals with nephritic symptoms but no alcoholism, “fibroplastic” Gn was identified.<sup>44</sup> The noticeable disparity between the two groups raises concerns about the data’s reliability. Other invasive techniques performed without clinical indications in individuals diagnosed with suspected alcoholism<sup>41</sup> are discussed in the book.<sup>1</sup> Repeated invasive manipulations performed in conditions of suboptimal procedural quality may cause transmission of hepatitis B and C. It is not surprising that anti-HCV antibodies were detected sevenfold more frequently in Russian alcohol abusers than in the general population.<sup>45</sup>

### 4.4. Congenital conditions

The questionable concept of hypoplastic renal dysplasia was developed on the basis of pediatric RBs,<sup>47-52</sup> described as follows: “Racemosely arranged glomeruli with single capillary loops, abundant rounded cells freely lying in the cavity of a capsule; single mesangial cells; irregular enlargement, loosening, and thinning of the basement membrane,”<sup>46(p62)</sup> narrow extracapillary space, glomeruli having irregular form and singular capillary loops or total absence of capillaries, which has no analogues in the international literature.<sup>26,46</sup> The terms “renal hypoplasia” and “dysplasia” are used in the literature with different meanings. Apparently, the descriptions are at least in part based on tangential sections of glomeruli, which is evident from the illustrations in the articles commented previously.<sup>1,46,47</sup> It was recommended to Severgina and Paltsev<sup>46</sup> to verify their concept of classifying glomeruli “with singular capillary loops” in autopsy or nephrectomy specimens, but it has not been done. The common feature of such papers is the presentation of ultrastructural findings without comparison with light-microscopic images, while variants of the norm,

artifacts, and accidental findings were interpreted as specific pathological phenomena. For example, hypoplastic dysplasia was diagnosed by electron microscopy in 8 of 34 randomly selected patients with nephrotic syndrome and histologically minimal glomerular changes.<sup>48</sup> At the same time, there was not a single case of Alport syndrome or thin basement membrane nephropathy among 4,440 overviewed RBs.<sup>38</sup> Alport syndrome or thin basement membrane nephropathy jointly comprises >1% of all RB diagnoses in Germany<sup>33</sup> and 1.3% in Japan.<sup>36</sup> The concept of hypoplastic dysplasia is discussed with clinicians collecting biopsies, which may have interfered with the diagnosis of Alport syndrome, which is of importance for genetic consultation of patients.

The same research team Severgina and Gurevich<sup>47</sup> and Severgina *et al.*<sup>52</sup> later applied the term hypoplastic dysplasia to the glomerular changes in congenital hydronephrosis and other renal abnormalities in children, interpreting them as inborn nephropathy affecting a major part of the glomeruli.<sup>49-52</sup> A regular combination of diffuse glomerulopathy and hydronephrosis due to ureteropelvic stenosis is improbable. Glomerular changes in hydronephrosis caused by the urine retention (collapse of the glomerular tuft with the widening of urinary space) are different from those described within the concept of “hypoplasia” and “dysnephrogenesis” in accordance with the article.<sup>47</sup> In another study, 167 intraoperative RBs from children with suspected urogenital malformations, and RBs for the control group from adult urological patients, had been collected.<sup>53</sup>

### 4.5. Renal and pancreatic biopsies in diabetes mellitus

Severgina<sup>54,55</sup> and Severgina *et al.*<sup>56</sup> harvested wedge biopsies from the pancreas during the surgery, “pancreatic blood shunting into the systemic blood flow in insulin-dependent diabetics.”<sup>54(p9)</sup> Core RBs were taken from the same patients.<sup>54</sup> No equivalent procedures for the surgical treatment of diabetes mellitus were found in the international literature. In the studies of RBs from diabetics, Gn and mesangiolytic were designated as consecutive stages of diabetic glomerulosclerosis.<sup>55</sup> Ultrastructural descriptions include interposition with displacement of mesangial cells to the periphery of glomerular capillary loops and formation of double-contour basement membranes and are typical for membranoproliferative Gn.<sup>55,56</sup> Morphological features of Gn, if found in a diabetic patient, are usually interpreted as a superimposed condition that may require immunosuppressive therapy. It should be noted that in diabetes mellitus, RB is generally indicated for patients with suspicion of non-diabetic renal disease, in rapidly progressive decline of kidney function, and/or sudden development of nephrotic proteinuria. However, clinical recommendations are not discussed here.

#### 4.6. Renovascular hypertension

Renal biopsy in renovascular hypertension has been previously described in Russia.<sup>1</sup> Some risk for patients may be due to bilateral RBs taken for research. RB in renovascular hypertension is generally not indicated. As mentioned above regarding Pn, ultrastructural morphometry was also used on RB from patients with renovascular hypertension. During that period, biopsy specimens from patients with renovascular hypertension were examined; the specimens were usually small, and most contained only 1–3 glomeruli and arterioles, while some contained none of these structures. There were also larger wedge biopsies.<sup>57</sup> A majority of the specimens were unsuitable for a reliable morphometric assessment, let alone prognosis of the results of surgical treatment,<sup>58,59</sup> calculation “of the vascular index for both kidneys” to determine indications for surgery, or “choosing the method of operative intervention in vasorenal hypertension.”<sup>60(p23)</sup>

#### 5. Conclusion

In conditions of paternalism, misinformation and persuasion of patients are regarded as permissible. Suboptimal practices have been used in accordance with the instructions of healthcare authorities and in accordance with the leading professors’ publications. Invasive procedures applied without evidence-based indications have been reviewed elsewhere.<sup>1</sup> The same considerations pertain also to RB. The RB material used in the studies discussed above was unique: wedge or core biopsies from patients with hydronephrosis, acute and chronic Pn. The collection of specimens is associated with risk, and the reliability of several results and conclusions is questionable. Apart from the articles discussed here, no other studies on RB in hydronephrosis and acute Pn are known to us, whereas for chronic Pn, no large studies have been conducted abroad since the 1960s. In particular, wedge biopsy from the kidney in acute Pn may result in abscess formation. The overdiagnosis of MG resulted in the overtreatment of some patients with immunosuppressive drugs. High-quality specimens and their examination must be a precondition for the use of RB in research and practice. RB should not be performed solely for research purposes; it must always be justified by clinical indications. If a patient provides informed consent for research on renal tissue obtained for diagnostic purposes, it can be done, provided that sufficient material remains for the diagnosis.

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The author declares that he has no competing interests.

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This is a single-authored article.

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#### Data availability statement

Not applicable.

#### Additional disclosure

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