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TRAVEL TO COUNTRY IATROGENIC. YATROGENIYA DIAGNOSTIC PROCEDURES (Message 3)

Abstract

A special group of iatrogenic complications are associated with various diagnostic manipulations — from a physical examination of the patient to angiographic studies, diagnostic laparoscopy or thoracoscopy. The article presents data on the frequency and nature of diagnostic iatrogeny in clinical practice. The range of diagnostic iatrogenies in terms of their manifestations, severity and prognosis is wide enough — from skin irritation with ultrasound gel to dissection of the coronary artery during coronary angiography. The article presents examples of diagnostic iatrogenies, starting with the clinical examination process (collection of complaints and medical history, physical examination), and ending with complex invasive examinations. Iatrogeny, which occurs with the use of contrast containing drugs (in particular iodine-containing drugs), which are widely used in clinical practice (enhanced CT, angiography, etc.) with a diagnostic purpose, are discussed in details. The article describes risk factors, understanding of which and awareness of their presence are mandatory before the administration of contrast containing drugs. The review of complications of endoscopic examinations was carried out. The author reminds that iatrogenic events in endoscopic procedures can be manifested not only by complications from the organ under examination (esophagus, stomach, intestines), but also depend on the patient's condition, his preparation for the procedure, and the specialist's skill of endoscopic technique. In conclusion, the author gives a clinical observation in which the risk factor of the iatrogenic event was the presence of an anomaly in the liver and pancreas duct systems in the patient. The author of the article encourages colleagues to pay more attention to the process of making a decision to conduct a diagnostic study, always to evaluate the benefit / risk ratio in terms of the real usefulness of the diagnostic study for the patient and the risk of complication development.

Key words: *iatrogeny, contrast-induced nephropathy, coronarography, endoscopy, esophagogastroduodenoscopy, colonoscopy*

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ICD — iodine-containing drugs, CIN — contrast-induced nephropathy, CCD — contrast containing drugs, ERCP — endoscopic retrograde cholangiopancreatography

The introduction into clinical practice of modern study methods, including invasive ones, carries a potential risk of iatrogenic events associated with various diagnostic manipulations — from physical examination of the patient to angiographic studies, diagnostic laparoscopy or thoracoscopy. There is currently no clear definition and classification of diagnostic iatrogeny.

Meanwhile, iatrogenic events may occur in the course of clinical examination of the patient (collection of complaints and medical history, physical examination). For example, an incorrectly formulated question without taking into account the situation and the psychological state of the patient may seem inappropriate or tactless to the patient and may lead not only to a negative attitude towards

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the doctor, but also serve as a source of psychogenic iatrogeny. Palpation of the abdomen in patients with certain pathology can also cause various complications, regarded as iatrogenic. Here are a few clinical situations observed in clinical practice.

1. Compression fracture of the spine after a test load on the spine axis in a patient with complaints of back pain. Later, according to densitometry of the spine, osteoporosis was diagnosed.

2. Ruptured spleen in a patient with infectious mononucleosis during "thorough" palpation of the left hypochondrium by several doctors (doubts about enlarged spleen). The diagnosis of infectious mononucleosis was assumed in the patient, according to clinical symptoms and peripheral blood parameters, but the risk of ruptured spleen in this category of patients described in 1861 by the Vienna pathologist K. Rokitansky was not taken into account. Spleen rupture can be spontaneous with a frequency of 0.1 to 0.5% [1] or after exposure to mechanical factors (injuries, exercise, etc.).

3. Hypertensive crisis with the development of myocardial infarction in a patient with pheochromocytoma after palpation of the abdomen. It is known that hypertensive crises in pheochromocytoma can be provoked by deep palpation of the abdomen, abrupt movements and other factors.

4. Cutaneous hematoma in the right hypochondrium after palpation of the liver in a patient with idiopathic thrombocytopenic purpura (blood platelets count — 20×10^9/L). This phenomenon is called "palpation symptom" in patients with hemostatic disorders. The appearance of the hematoma caused discontent and complaints from the patient and relatives who regarded this sign as unprofessional treatment of the patient.

Iatrogenic complications in the process of clinical examination of the patient are possible when using simple devices for examination, devices that do not require special skills and assistance from an assistant. For example, when using mercury thermometers, mercury may be spilled and the skin may be injured, and some cases describe wounds in the rectum during rectal thermometry.

As seen, even the traditional clinical examination of the patient, which every doctor begins with, can at this stage become a source of iatrogenic events with all the ensuing consequences. In some cases, these complications can be avoided (careful palpation of the spleen or alternative use of ultrasound in patients with suspected infectious mononucleosis and the risk of ruptured spleen), while in others the complications are unexpected. The development of complications at the stage of clinical examination of the patient, even before the use of additional methods, adds a new problem to the already existing and not yet solved one, which was the reason for patient to consult the doctor. It is obvious that the iatrogenic events acquire not only medical (further studies, consultations, etc.), but also deontological (loss of confidence for the doctor), economic (additional costs on examination and treatment), legal (possible complaints of patients and relatives) aspects.

The range of diagnostic iatrogenies, in their manifestations, severity and prognosis, is quite broad — from skin irritation with gel during ultrasound scanning to dissection of the coronary artery during coronary angiography. With the expansion of indications for diagnostic studies based on the data of physical examination of the patient, the potential risk of diagnostic iatrogenies increases. The patient is at risk of developing skin hematomas after collection of blood from the vein, arrhythmias and angina attacks during ECG recording during exercises, with pneumothorax after diagnostic thoracocentesis, bronchospasm when performing provocative tests with bronchoconstrictors (metacholine, β-blockers), and with severe systemic reactions after skin testing, etc.

According to the analysis of causes and outcomes of iatrogenies among the 38 deaths due to adverse effects of treatment, in 30 cases the deaths were due to diagnostic procedures, with diagnostic iatrogenies proving to be prognostically less favorable in comparison with medical complications [2].

Diagnostic Tests Using Contrast-Containing Drugs

There is a certain risk of iatrogenic complications when using contrast-containing drugs (CCD), in particular, iodine-containing drugs (ICD), which are widely used in clinical practice (contrast-enhanced CT, angiography, etc.) for diagnostic purposes. Usually such complications occur in patients with risk factors, about which the patients should

be informed and aware of before the administration of CCD. These risk factors include:

- Use of NSAIDs, diuretics.
- Creatinine clearance below 60 ml/min.
- Diabetes mellitus with nephropathy.
- Renal hypoperfusion (dehydration, heart failure, hypertension, nephrotic syndrome, liver cirrhosis, etc.).
- Multiple myeloma with the presence of proteinuria.
- Use of ICD for three days before contrast-enhanced examination.
- Age of patients over 65 years (high probability of risk factors).

The frequency of side effects with ICD administration in patients with kidney disease can reach 20%. Special attention should be paid to patients with diabetes, thyroid disease, pregnant women and persons with hypersensitivity to ICD. Among patients with diabetes ICD should be used with caution in young patients prone to hypoglycemia treated with metformin (risk of lactic acidosis with exacerbation of renal failure), patients with renal failure (risk of exacerbation of failure). While ICD may be used in the presence of hypothyroidism, the use of ICD is contraindicated in patients with untreated or poorly controlled thyrotoxicosis. In pregnant women ICD administration is undesirable after 12 weeks of pregnancy (duration of accumulation of contrast in the fetus) due to the risk of thyroidopathy in the fetus. One of the complications of diagnostic studies using CCD is extravascular transfer due to various reasons.

Contrast-Induced Nephropathy (CIN)

CIN is one of the manifestations of diagnostic iatrogeny, the incidence of which has been increasing lately, especially in patients after percutaneous coronary interventions [3]. CIN is defined as an increase in absolute and relative blood creatinine content (above 0.5 mg/dL and more than 25% compared to baseline, respectively) 48 to 72 hours after administration of CCD in the absence of other causes [4]. According to this definition the frequency of CIN in the general population ranges from 1 to 6% [5], and after percutaneous coronary interventions it increases to 3.3% with the need for hemodialysis in 0.3% of cases [6]. In some patients, especially in the presence of cardiovascular disease, the incidence of CIN reaches 20% [4]. There are known cases of acute CIN (2 to 25%, according to various data) after administration of CCD [7, 8]. Risk factors for acute CIN are given in Table 1.

Table 1. *Risk Factors of acute contrast-induced nephropathy [9]*

Patient	Procedure
Elderly age	The large volume of contrast containing drugs
Diabetes mellitus *(diabetic nephropathy)*	High osmolality of contrast containing drugs
Chronic Kidney Disease	Intraarterial administration (in relation to intravenous administration)
Hypertension	
Absolute and relative hypovolemia	
Use of diuretic drugs	
Use of NSAIDs	
Use of ACE inhibitors or angiotensin receptor blockers	

Carotid Angiography

Among 333 patients who underwent 347 diagnostic procedures of carotid angiography, complications were observed in 12 people (3.5%). In one case, a transient ischemic attack was diagnosed, and in two cases, blood transfusions were required due to bleeding. According to literature, the rate of transient neurological complications after carotid angiography ranges from 0 to 2.4%, and other severe complications account for 0.26 to 4.3% [10].

Coronary Angiography

which is the gold standard for the diagnosis and severity of CHD, can cause iatrogenic complications of various severity and prognosis [11]. Table 2 presents the main complications and their frequency in patients after coronary angiography.

In the blood culture performed immediately after and 12 hours after coronary angiography, a positive culture (mainly coagulase-negative

Table 2. *Major complications of coronary angiography*

Nature of complications	Frequency	Reference
Infections	< 1%	[12]
Contrast-induced nephropathy	3,3-16,5%	[13]
Cholesterol embolism	< 2% 25%-30% (according to autopsy data)	[14]
Damage of blood vessels	0,7% — 11,7%	[15, 16, 17]
Bradyarrhythmias	3,5%	[18]
Mortality	3% (left coronary artery dissection)	[19]
Myocardial infarction	0,05%-0,07%	[20, 21]
Cerebrovascular complications		
Dissection of coronary arteries	0,3-0,6%	[22]

Staphylococcus) was isolated in 18% and 12% patients, respectively [23], although clinical signs of infection were not observed. Mortality in coronary angiography increases with percutaneous coronary interventions [24], especially in the presence of risk factors (elderly age, cardiogenic shock, decreased left ventricular ejection fraction, urgent percutaneous coronary interventions, acute myocardial infarction, diabetes, renal failure, multivascular lesions). Mortality rates in these situations range from 0.65% in selective percutaneous coronary interventions to 4.81% in patients with ST elevation myocardial infarction [24].

Complications of Endoscopic Examinations

The development of complications in endoscopic examination depends on many factors and is determined by different situations (age and state of patients, the nature of the underlying and concomitant pathology, use of anticoagulants and antiplatelets, the degree of sedation before the procedure, postoperative period, technique of the procedure, etc.). Depending on the type and purpose of the procedure and specific complications, the following endoscopic iatrogenies may occur:

- Pulmonary and cardiac complications and disorders associated with patient sedation before the procedure.
- Complications of diagnostic endoscopy of the upper gastrointestinal tract.
- Complications of colonoscopy and irrigoscopy.
- Complications of endoscopic retrograde cholangiopancreatography (ERCP).

Iatrogenic events in endoscopic procedures may be manifested not only by complications of the examined organ (esophagus, stomach, intestines), but also depend on the patient's state, the preparation of the patient for the procedure, and the endoscopy technique [25, 26].

Pulmonary and cardiac complications and disorders associated with sedation of patients before the procedure include [27]:

- Excessive drug sedation of patients, making contact difficult during the procedure.
- Paradoxical excitement or sexual fantasies (rarely).
- Drug inhibition of the respiratory center with the development of hypoxia and hypercapnia.
- Aspiration pneumonia.
- Heart rhythm disturbances.
- Hypotension, hypertension, vasovagal reactions.
- Angina and myocardial infarction.
- Stroke.
- Nausea and vomiting.
- Generalized hyperemia and feeling of heat.
- Side effects of cholinergic drugs.

In upper gastrointestinal endoscopy (esophagogastroduodenoscopy) the following complications are possible [28]:

- General discomfort in the throat, abdomen (small complications) — reported by approximately 2% of patients.
- Pulmonary and cardiac disorders (cardiac arrhythmias, myocardial infarction, respiratory arrest, aspiration pneumonia) occur more often in patients with initial pathology.

- Infections (hepatitis B and C, HIV infection).
- Bleedings occur more often in individuals with hemostatic disorders (severe thrombocytopenia — below 20,000 × 10^9/L in mucosa biopsy). Use of antiplatelet agents and anticoagulants does not increase the risk of bleeding [29].
- Perforations (rare complication — 0.03%, mortality — 0.001%). They more often occur in the presence of pathological changes in the esophagus (eosinophilic esophagus) and stomach, or technical errors during endoscopy [30].
- Other rare complications (anaphylactic shock after topical anesthesia, dental injuries, dislocation of the mandibular joint, cases of posterior pharyngeal wall perforation during esophagogastroscopy with the development of neck phlegm).

According to an extensive study, the frequency of complications after esophagogastroscopy, including mucosal biopsy, is 0.13%, and mortality associated with this diagnostic procedure is 0.004% [31].

Colonoscopy complications are difficult to take into account due to the often retrospective diagnosis, non-obvious connection with the procedure, the lack of controlled epidemiological studies [32]. The main complications of diagnostic colonoscopy are:

- Perforation, which rate is 0.13 to 0.19% according to prospective studies [25, 33].
- Bleeding occurs in 0.1 to 0.6% of patients [26], and the risk of bleeding increases with polypectomy. In diagnostic (screening) colonoscopy without polypectomy, the bleeding rate was 3.7/1,000 colonoscopies, and in cases of polypectomy it increased to 8.7/1,000 [34]. Data on the role of antiplatelet agents and NSAIDs in the development of bleeding are contradictory [35].
- More rare complications, including ruptured spleen [36], acute appendicitis, diverticulitis [33], subcutaneous emphysema [37], chemical colitis due to poor removal of disinfectants from the endoscope [38], etc.

One hundred and twenty-eight fatal cases were reported in 371,099 colonoscopies, which determined a case fatality rate of 0.03% [33]. At the same time, 30 days-mortality after colonoscopy was estimated without taking into account specific reasons directly related to the procedure and other factors [39].

Another manifestation of endoscopic iatrogeny is complications associated with endoscopic retrograde cholangiopancreatography (ERCP) [40].
The most frequent and serious complications during ERCP and sphincterotomy are:

- Pancreatitis.
- Bleedings.
- Cholangitis (with septicemia).
- Perforations.

Complications after sphincterotomy occur in 5% of cases, with mild, moderate and severe complications recorded in 60%, 20% and 20%, respectively, and fatal cases in 1%, and, according to recent studies, in 0.2% [41]. The most serious iatrogenic event during ERCP is pancreatitis. High level of blood amylase occurs in 75% of patients after ERCP, but the clinical pattern of acute pancreatitis requiring hospitalization is observed in cases of hyperamylasemia only in 3 to 10% of patients [40]. Acute pancreatitis accounts for more than half of all complications caused by ERCP [42]. According to a study by Freeman M. L. (2002), pancreatitis after ERCP was observed in 5.4% of patients, with severe diseases, including fatal outcome, observed in 0.4% of cases.

Case Report

Patient M., 60 years old, was admitted to the hospital to undergo an examination for jaundice.
Magnetic resonance cholangiopancreatography: MRI-signs of biliary hypertension. Calculous cholecystitis. Common bile duct block cannot be excluded in the intramural part. Ultrasound examination (05/26/2015): multiple concrements of 3.6 mm with a clear acoustic shadow are imaged in the lumen of the gallbladder. The walls of the gallbladder are unevenly thickened and compacted. Diffuse changes present in the pancreas.
Diagnosis on admission: chronic calculous cholecystitis, choledocholithiasis. Mechanical jaundice. An urgent surgery due to the complication of choledocholithiasis is indicated.
There was an unusual situation during ERCP (06/08/2015): the contrast agent constantly

penetrated into the Wirsung duct when attempting to contrast the common bile duct. Under X-ray control the contrast agent is completely aspirated through the catheter. During consilium there were two attempts of cannulation and contrasting with the same effect: bile freely flowed through the catheter and parallel to it, while the contrast agent immediately penetrated into the Wirsung duct. The contrast agent was also completely evacuated. The situation was regarded as an anomaly in the development of liver and pancreas duct systems — single wide opening in combination with common bile duct block caused by the impaction of a concrement in the projection of the common bile duct terminal part. Given the high risk of pancreatitis with underlying choledocholithiasis, it was decided to refrain from full contrast of pancreatic ducts and further attempts of endoscopic treatment of choledocholithiasis. During patient follow-up the situation was initially regarded as acute edematous pancreatitis, but the condition subsequently deteriorated, clinical and laboratory signs of destructive pancreatitis appeared with the development of systemic manifestations of multiple organ failure and fatal outcome.

In this case, the iatrogenic event was due to the presence in the patient of an anomaly in liver and pancreas duct systems, in particular, a single wide opening of Wirsung and the common bile ducts in duodenum. This situation combined with the block of the common bile duct caused by impaction of a concrement inevitably led to the penetration of the contrast agent directly into the Wirsung duct, which subsequently caused the development of pancreatitis. Formally, this case is a typical example of the iatrogenia of diagnostic procedures, which is not always possible to provide. There are many cases of properly performed invasive examination or surgery leading to severe, often fatal complications in medical practice. An example is the case described in 1983 in N. V. Elstein's book titled *Dialogue on medicine.* In one female patient tonsils were removed; a simple, common operation, usually without consequences. But this patient experienced bleeding from the surgical wound, the cause of which was atypical location of the blood vessel, which was damaged during surgery. Fortunately, the bleeding was stopped on time.

When making a decision on the feasibility of any diagnostic examination the following aspects should be kept in mind:

- Will this examination help to verify the diagnosis?
- Will the results radically change the treatment and influence the prognosis?
- Is it possible to conduct a less invasive, but no less informative examination?
- Does this examination pose a potential danger to a particular patient?
- Recommend patients to undergo invasive diagnostic procedures only for strict indications.
- Endoscopic interventions should be carried out with extreme caution under monitoring using video endoscopic equipment.

Conflictum of interest

The authors declare no conflict of interests.

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