

On the history of medical risk

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Abstract

This article reviews the main approaches to the interpretation of the term “risk”, which has acquired the status of a general scientific and widely interpreted concept. The unresolved issues of surgical risk terminology make it extremely difficult to solve the problem of perioperative prognosis at the narrow professional (medical) level. The author considers the problem of objectifying operational risk at an interdisciplinary level. In his opinion, understanding risk as a specific form of the subject’s active relation to the surrounding reality is the most justified at the present time. The essential particular features of such activities are the lack of confidence and the subject’s uncertainty in achieving the stated goal since a doctor’s professional activity takes place under conditions of risk, uncertainty and in contradictory situations.

The author of the article suggests using the definition of “risk” proposed by A.P. Algin, according to which risk should be understood “as an activity connected with overcoming uncertainty and the situation of inevitable choice, in the process of which it is possible to quantitatively and qualitatively assess the probability of achieving the expected result, failure and deviation from the goal.” This definition prevents the use of antiscientific and scholastic views of this phenomenon. With reference to medical science (in particular, to surgery), this approach to risk allowed the author to formulate an individual quantitative prognosis and to distinguish five types of perioperative prognosis.

Keywords

history of medicine, history of surgery, operational risk, quantitative risk assessment in routine surgery, interdisciplinary approach, prognosis

Introduction

As it is well-known, medicine and surgery, in particular, is one of the areas of human activity associated with risk. Risk, its definition and decision making under risk is a global problem. Nowadays, “the word ‘risk’ has acquired the status of a general scientific concept that transcends the limits of any particular science.” “Risk has become a broadly interpreted term, close to such philosophical and methodological concepts as ‘matter’, ‘information’, ‘energy’”. However, there is not one interpretation of the concept of “risk” – “the concept hasn’t yet received a precise, satisfying definition”, and “there’s no experience of its philosophical comprehension” (Melnychuk 2017; Ruzavin 2001). The forms of the manifestation of risk are manifold, and “the emphasis in the study of risk in

different scientific disciplines and schools is different” (Melnychuk 2017).

The research tasks included: 1) studying historical and modern approaches to risk and choosing a universal (philosophical) definition of the concept of “risk” based upon an interdisciplinary approach; 2) performing objectification of operational risk in planned surgery with the help of mathematical-statistical analysis.

Background

The appearance of the term “risk” is associated with the era of geographical discoveries, the art of seafaring, the overcoming of various threats (“manoeuvring between rocks”), the expansion of trade ties and the associated dangers (loss of goods, ship losses, no return of

invested money)¹. It is assumed that the term “risk” derives from the Italian word *riscare* – “to weigh”. In addition to that, there’s also another version of the word – “to dare” (Melnychuk 2017). In this case, risk can be understood as the overcoming of possible dangers based upon thorough consideration (“weighing”) of all circumstances. A.S. Melnychuk connects the genesis of the term “risk” with the Greek word meaning “destiny”, “fate”, “fortune” (Melnychuk 2017). The author cites the point of view of American anthropologists who note that “at certain stages of the development of culture, before the emergence of the concept of ‘risk’, ‘sin’ was its definite semantic analogue”... “A person who chooses the path of sin, i.e., an action that transcends existing moral and religious norms, depriving themselves of the protection of the Higher Powers and the Church as a social institution of great import in the pre-industrial era, endangers themselves” (Melnychuk 2017).

The term “risk” came into the Russian language in the middle of the 18th century as a loanword from French (Melnychuk 2017). In the domestic dictionaries, the following meanings of the word “risk” are mentioned: 1) “to be subjected to accident, known danger, vicissitudes of fortune, or misfortune”; 2) “acting at a venture in the hope of a happy outcome”; 3) “to put oneself in potential trouble”. In foreign sources, the following meanings of the word “risk” are also encountered: “danger, a possibility of loss or damage”, “a possibility or probability of a fact or event considered as some kind of evil or damage”, “danger, a possibility of bad consequences, losses...” (Melnychuk 2017, p. 25, 29). A.S. Melnychuk emphasises that by the time the term “risk” appeared, words ‘used to describe danger, daring, chance, happiness, courage, fear, adventure’ were already in existence, and suggests that “a new word comes into use to indicate a problem situation which cannot be sufficiently clearly expressed with the help of already existing words” (Melnychuk 2017).

In surgery, there is currently no generally accepted definition of “operational risk” (Bokeriya 2007; Komorovskiy 1980; Kuznetsov 2009). However, N.I. Pirogov, had, in fact, already spoken about operational risk: “...Conscience itself – there are no other means – should decide the question of surgery for the truly honest surgeon, when the danger to life associated with it seems to them as significant as the danger from the disease against which the surgery is planned. But in this case, the surgeon cannot always rely upon their own conscience. Scientific knowledge, attachments and love for one’s art, which have nothing to do with morality, affect conscience, inclining it towards themselves” (Doleckij 1992, p. 10). Moreover, in Russia, as well as in most developed countries, “there is no gene-

rally accepted official classification of operational risk” (Bisenkov 2004; Chadaev et al. 1988), and the existing discrepancies in this issue (Doleckij 1992; Balagin et al. 1987; Belov and Isaev 2014; Glushkov 1988; Dyachenko and Galkin 1975; Sigaev et al. 1966) make it quite difficult to solve the problem of operational risk on a highly specialised (medical) level. Here are a few definitions of risk given by domestic physicians. Operational risk is understood as “the degree of perceived danger to which the patient is exposed during surgery, anaesthesia and the nearest postoperative period. Risk takes into account the amount of danger associated with the presence of the disease and the attempts to change its course and outcome through surgical interventions” (Malinovskij et al. 1973). Five degrees of operational risk assessment were proposed: “negligible” (1st degree), “minor” (2nd degree), “moderate” (3rd degree), “serious” (4th degree), “critical” (5th degree). According to another definition, risk in surgery is “the sum of dangers associated with the presence of the disease and attempts to change its course and outcome through surgical interventions” (Dyachenko and Galkin 1975), which can be negligible, minor, moderate, serious and critical. In the literature, there’s no “common opinion on the issues of terminology and classification of the risk of surgery and its factors”, or frequent use of the synonyms “operational risk”, “general operational risk”, “surgical risk” with the division of the last-mentioned one into “inevitable” and “unjustified” (Malinovskij et al. 1973). From the point of view of medical law, medical risk was suggested to be considered as “a legitimate use of medical and diagnostic methods that aren’t used under normal conditions due to a certain danger, for saving lives and preserving the health of the patient if the positive result cannot be achieved through generally accepted, proven means” (Glushkov 1988). According to Yu.V. Belov, “risk is a combination of the probability and consequences of an event... risk in medicine is usually understood as the probability of some adverse event. Risk factors are the characteristics of the body or external influences which lead to an increased risk of disease occurrence <...>. Knowledge of risk factors is used primarily for forecasting the disease” (Belov and Isaev 2014). Describing additional risk (risk difference), risk ratio, additional population risk, additional share of attributable risk per cent for the population, justified and unjustified risk, he emphasises that there’s currently no “absolutely reliable, practical and objective system for assessing the degree of anticipated operational risk, which leads to the impossibility of exact forecasting of an outcome in a concrete situation” (Belov and Isaev 2014). L.A. Bokeriya notes: “So far, there’s no generally accepted definition of the concept of ‘operational risk’ <...> despite the grandiose achievements of modern clinical medicine, the ‘gold standard’ of assessing the severity of patients’ conditions and the degree of operational risk has not been achieved yet. In this regard,

¹ The word “risk” comes from the Greek “*riskon*” – “cliff”, “foot of the mountain”.

the issue of an objective assessment of operational risk is truly the cornerstone of medicine” (Bokeriya 2007).

Thus, the concept of “operational risk” was introduced to judge the degree of danger of the surgical operation. However, the numerous factors upon which the successful outcome of the intervention depends make this concept quite vague. Due to this, it has been recognised that the objective accounting and analysis of all these factors for each patient is almost impossible (Kuznetsov 2009).

Operational risk

The literature data and the results of our own research enabled us to identify 43 operational risk factors, based upon which we have attempted to construct a simple, yet effective classification of operational risk factors. In our opinion, the following criteria should be taken into account when determining surgical risk: 1) age over 65; 2) the male sex; 3) smoking; 4) alcohol consumption; 5) drug allergy; 6) glaucoma; 7) thoracotomy in the anamnesis; 8) malignant tumour as the main disease; 9) anaemia; 10) chemotherapy as the first stage of treatment; 11) unsatisfactory condition of the patient, requiring pre-operative preparation; 12) morbid obesity; 13) decreased body weight; 14) chronic obstructive pulmonary disease; 15) respiratory failure; 16) long (more than 5 years) anamnesis of coronary artery disease (ischaemic heart disease); 17) silent myocardial ischaemia (SMI); 18) angina pectoris, functional class III; 19) widespread atherosclerosis; 20) hypertension (arterial hypertension); 21) arterial hypotension; 22) chronic myocarditis; 23) cardiomyopathy; 24) heart diseases; 25) hyperfibrinogenemia; 26) chronic venous insufficiency; 27) type 2 diabetes mellitus; 28) nephrolithiasis; 29) chronic pyelonephritis; 30) chronic nephritis; 31) nephrosclerosis; 32) chronic renal failure; 33) creatininaemia; 34) proteinuria; 35) primary biliary cholangitis (previously known as primary biliary cirrhosis) of the liver; 36) portal cirrhosis of the liver; 37) chronic cholestatic hepatitis; 38) chronic liver failure; 39) mechanical jaundice; 40) hyperbilirubinaemia; 41) hypoalbuminaemia; 42) traumatism of the intervention; 43) the psychological type of the patient’s attitude towards the disease. Subsequently, based upon our clinical experience and theoretical views on the factors of operational prognosis, we selected 26 criteria from this list.

We formulated a hypothesis on the importance of the 4 risk factors: 1) the age of the patient over 65; 2) severe (oncological, vascular, pulmonary) primary disease; 3) the presence of competing diseases – polymorbidity; 4) the traumatism of the intervention. However, due to the lack of adequate scientific classification of perioperative prognostic factors with quantitative assessment of each of them, for the period, we limited ourselves to simply

ascertaining the negative impact of these risk factors upon the course of the nearest postoperative period: a retrospective analysis (case-control) of the case histories (anamneses) allowed us to qualitatively evaluate them.

At the interdisciplinary level, we conducted the objectification of operational risk. This approach allowed us to apply the philosophical definition of risk, suggested by A.P. Algin: “Risk is an activity associated with overcoming uncertainty in the situation of inevitable choice when it is possible to quantitatively and qualitatively assess the probability of achieving the expected result, as well as failure and deviation from the goal” (Algin 1989).

To prove or disprove our hypothesis on the importance of the selected 26 risk factors, we analysed 500 case histories, selected by random and typological sampling, of the patients operated within the thirty-year time span for oncological diseases (226 cases), general surgical diseases (143 cases), thrombosis (obliterating atherosclerosis) vascular lesions and chronic venous insufficiency (131 cases)². The age of patients operated on was from 39 to 89 (the average age being $64,0 \pm 2,8$); there were 316 (63,2%) men and 184 (36,8%) women amongst them. Of the 226 patients with malignant neoplasms, 130 patients had lung cancer, and 99 had tumours of gastrointestinal tract (oesophagus, stomach, pancreas and major duodenal papilla, intestines). The group of 143 general surgical patients included patients with cholelithiasis (106 people) and anterior abdominal wall hernias (37 people). In 7 patients, obliterating atherosclerosis of peripheral arteries was combined with infrarenal abdominal aortic aneurysms. 23 patients had had several surgical diseases requiring simultaneous interventions.

The selection of case histories of surgical patients with a set of certain competing diseases was deliberate: selected patients had diseases of cardiovascular, pulmonary and other systems which, in a number of clinical situations, could have a negative (including also fatal outcome) effect upon the results of the operation. The majority of the selected patients had the following diseases: widespread atherosclerosis, coronary artery disease (ischaemic heart disease), hypertension, chronic obstructive pulmonary disease (combined with respiratory failure of various degrees), diabetes mellitus (requiring preoperative correction), chronic renal failure, etc. The most common disease encountered was widespread (multifocal) atherosclerosis. The group of patients who had severe and developed atherosclerotic lesions of several vascular pools (including coronary and carotid arteries) as the primary or competing disease (47,2% of the total number of patients selected) was the most severe. They had the following stages of arterial insufficiency (according to A.V. Porkovsky’s classifica-

² The study was conducted on the basis of data obtained under the N.N. Burdenko Faculty Surgical Clinic of the Federal Autonomous Educational Institution of Higher Professional Education of the I.M. Sechenov First Moscow State Medical University.

tion): stage I – in 3,9%, stage IIA – in 38,2%, stage IIB – in 31,6%, stage III – in 26,3%.

Of the radical operations performed for oncological diseases, pneumonectomies, lobectomies/bilobectomies (124, including 4 with main bronchus resection); gastrectomies, stomach resections, oesophageal extirpations, haemicolectomies (65 cases), should be mentioned specifically. In general surgical patients, traditional, mini- and laparoscopic cholecystectomies were, in a number of cases, supplemented by intervention on the extrahepatic bile ducts. In patients with peripheral vascular lesions, reconstructive surgeries were performed (with aortic aneurysm excision, when necessary), sympathectomies (including endoscopic surgeries).

Based upon the result of the mathematical-statistical analysis, 16 criteria of perioperative prognosis were drawn from the 26 considered risk factors: male sex; A (II) Rh+ blood group; tobacco smoking; drug allergy; more than one abdominal incision in the anamnesis; thoracotomy in the anamnesis; malignant disease as primary; duration of a malignant disease more than 1 year; class 3 obesity; type 3 respiratory failure in comorbidity with chronic obstructive pulmonary disease; class 3 angina pectoris; cardiac ejection fraction less than 49%; stage 2 hypertension; chronic renal failure; chronic liver failure; traumatism of the intervention. Thus, a classification of prognostic perioperative factors of planned interventions in the thoracic and abdominal cavities in patients with benign and malignant diseases was created.

Regression analysis allowed us to derive the formula for individual operational prognosis for these patients:

$$y = + 0,355 - 0,085 X_1 - 0,084 X_2 - 0,151 X_3 - 0,089 X_4 - 0,126 X_5 - 0,262 X_6 - 0,02 X_7 + 0,122 X_8 - 0,069 X_9 - 0,056 X_{10} + 0,103 X_{11} - 0,089 X_{12} - 0,211 X_{13} + 0,320 X_{14} + 0,103 X_{15} + 0,05 X_{16},$$

where Y is the predicted lethal outcome of the planned surgery; X₁ is male sex; X₂ is A (II) Rh+ blood group; X₃ is tobacco smoking; X₄ is drug allergy; X₅ is more than one abdominal incision in the anamnesis; X₆ is thoracotomy in the anamnesis; X₇ is malignant disease as primary; X₈ is duration of a malignant disease more than 1 year; X₉ is class 3 obesity; X₁₀ is type 3 respiratory failure in comorbidity with chronic obstructive pulmonary disease; X₁₁ is class 3 angina pectoris; X₁₂ is cardiac ejection fraction less than 49%; X₁₃ is stage 2 hypertension; X₁₄ is chronic renal failure; X₁₅ is chronic liver failure; X₁₆ is traumatism of the intervention + 0,355 – free member of the regression equation.

In addition to that, the interdisciplinary approach allowed us to distinguish five types of prognosis in planned surgery³:

1) Favourable (PM = 0÷5%; ARM = 0; MRM = 0);

2) Relatively favourable (PM = 5,1÷20,0%; ARM = 4,5%; MRM = 7,1%);

3) Nominally favourable (PM = 20,1÷ 32,9%; ARM = 15,5%; MRM = 18,1%);

4) Causing doubt in the favourable outcome (PM = 33,0 ÷ 50,0%; ARM = 52,6%; MRM = 64%);

5) Unfavourable (PM = 50,1 ÷ 88,1%; ARM = 81%; MRM = 100%).

Conclusion

One of the most accurate definitions of modern society (apart from definitions such as “information”, “post-industrial”, and “multipolar”) was suggested by the German sociologist U. Beck, who called it a “society of risk” – namely, the riskogenicity of the world and the riskiness of human life are gaining a new quality (Bek 2000). Risk assessment involves value judgements. In order to separate the objective factors from the subjective and value ones, it is necessary to have a criterion for their demarcation. This can be done by “separating risk analysis as a scientific study from risk assessment which has nothing to do with science” (Quantitative Risk Assessment, 1986). With regards to the separate science of medicine it should be emphasised that all physicians are confronted with inadequate data about risks and the efficacy of the methods of treatment that they apply (Hayat, Gojzman, 1994). That’s why it is natural to expect help in the allocation of the most valuable (informative) signs of the treatment prognosis from the mathematical-statistical method (Mincer et al. 1988).

The generally accepted empirical notions about risk (evaluation of criteria in points and/or through evaluation expressions, such as “high degree of risk”, “particularly high degree of risk”, “high risk”, “minimum risk”) in medical practice didn’t allow to come closer to its theoretical definition. The interdisciplinary approach facilitated the objectification of operational risk. The philosophical notion of “risk” allowed us to define the risk situation as “a combination or set of different circumstances which create a certain environment for a particular activity”, whose appearance is facilitated by “the presence of uncertainty, the need to choose alternatives and the opportunity to assess the probability of implementing the chosen options”. After all, the process of “removing” the risk situation by the person, i.e. choice of alternative and implementation of the said choice, is reflected in the very concept of “risk”; in other words, it’s “the process of practical resolution of the contradiction of opposing tendencies in specific circumstances” (Algin 1989).

For the surgeon, it is important to distinguish between two situations – a risk situation and an emergency situation. In an emergency situation (which characterises emergency surgery), two properties of a risk situation – alternativeness (availability of options) and uncertainty – are absent. Philosophers interpret the

³ In our classification we used three indicators: predicted mortality (PM), average real mortality (ARM) and maximum real mortality (MRM).

necessity as “a means of transforming possibility into reality, in which, in a certain volume, there is only one possibility turning into reality” (Algin 1989). Surgeons are constantly confronted with both the risk situation and the emergency situation. The risk situation is characterised by the possibility of the threat to the patient’s health and/or life, the availability of the treatment options and the possibility of avoiding harm to the patient due to the right treatment. In the emergency situation, when the threat to the patient’s health and/or life has

already emerged (or is about to), there’s practically no choice of treatment options – the circumstances impose the only treatment option upon the doctor.

The harm caused to the patient in an emergency situation cannot be avoided, but it is less severe than the consequences of failure to provide medical care at all.

At the moment, the problem of risk in surgery can only be solved at an interdisciplinary level – it is the mathematical-statistical methods that contribute to quantitative prediction in planned surgery.

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