The Extension of a Method of Risk Analysis from Aeronautics to Medicine. Application to Endoscopic Surgery

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Abstract: *The **6-4-3-5** method of risk analysis from Aeronautics is adapted and extended to Medicine with emphasis on Endoscopic Surgery. The new main risk factors are identified and the corresponding risk severity is evaluated. In the complete method "6"represents the number of persons in the evaluating team,"4" gives the used weights 1; 2; 3; 4; "3" is the number of variants required to each person from the evaluating team and "5" indicates the time for evaluation (five minutes). **The risk is defined as a product between the probability of an event and the event severity, S, taking one of the values 1; 2; 3; 4**. The value S = 1 represents the normal case and S = 4 corresponds to the maximum damage, for example, dead people resulting in one aviation accident. Three more simple variants are also given.*

Key Words: *risk factor, biliopancreatic endoscopy (E.R.C.P.), strategy level*

1. INTRODUCTION

A detailed application of risk analysis in Aeronautics is given in [1]. A PhD thesis [2] used this concept to evaluate the airport safety.

The risk analysis in Aeronautics is an important problem being related to the safety of air transportation according to ICAO regulations. As we know, there is no similar procedures in Medicine although the problem of safety is important.

Thus the necessity "to use the Mathematics in Medicine" was suggested [3; 5] by one of the authors, although it was not clear exactly how we will do it and the answer later came from the aerospace engineering [4; 6; 7]. By using the experience from the risk analysis in Aeronautics, the first step is to establish the main risk factors. First of them is obvious, ***the human factor***, denoted by $F1$.

The second one is ***the technical factor***, denoted by F_2. A third factor will be named ***the environmental factor***, denoted by F_3.

The risk factors F_i, $i = 1, 2, 3$ are represented by their components denoted by F_{ij}, $i = 1, 2, 3$; $j = 1, 2, ..., j_{max}(i)$; the weights w_{ij} are attributed to F_{ij}.

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The corresponding severities are denoted by $S_{ij}(\alpha)$, α = *a*; *b*; *c*, where "*a*; *b*; *c*" stand for "high level quality", "acceptable level quality "and" inacceptable level quality", respectively.

2. THE RISK FACTORS IN MEDICINE (SURGERY)

Similarly to the case of risk evaluation in Aeronautics, the main factor components adapted to Medicine are considered. One takes the endoscopic Surgery as guiding case. One considers the main component risk factors as follows;

a) For the human factor, F_1, one considers:
- the surgeon, F_{11}; - the anesthetist, F_{12}; - the surgeon's team, F_{13}; - the patient medical history, F_{14}; $j_{max}(1) = 4$.

b) For the technical factor, F_2, one considers:
- the endoscopy device, F_{21}; - the connection from the device to the patient, F_{22}; - the radiology device, F_{23}, if necessary; $j_{max}(2) = 3$.

c) For the environmental factor, F_3, one considers:
- patient preparation, F_{31}; - Operation room conditions, F_{32}; - , patient-family relationships F_{33}, - preparation of the patient for surgery, F_{34}, - preparation of the patient after the intervention, F_{35}; $j_{max}(3) = 5$.

3. THE CALCULATION OF PROBABILITIES, SEVERITIES AND RISKS

3.1 The calculation of probabilities

Two levels of the risk factors are considered: level one (I) of the main risk factors F_i, $i = 1; 2; 3$, and level two (II) of the main risk factors components, F_{ij}, $i = 1; 2; 3$; $j = 1; j_{max}(i)$. One presents four strategies for the calculation of probabilities:

a) the equal weights strategy;
b) the level (I) equal weights strategy,
c) the level (II) equal weights strategy, and
d) the two levels (I, II) strategy.

a) The equal weights strategy

In this strategy equal weights w_i, w_{ij}, $i = 1; 3$; $j = 1,2, ..., j_{max}(i)$ are assigned to all main risk factors: F_i, $i=1;3$ and to their components, F_{ij}, $i = 1; 2; 3$; $j = 1; j_{max}(i)$ as well.

To calculate the probabilities one can take $w_i = 1$; $w_{ij} = 1$, $i = 1; 3$; $j = 1, 2, \dots j_{max}(i)$. The corresponding probabilities p_i and p_{ij}, are obtained, as follows:

$$p_i = \frac{w_i}{\sum_i p_i} = \frac{1}{3}, \quad i = 1; 3; \quad w_{ij} = 1; \quad p_{ij} = \left(\frac{w_{ij}}{\sum_j w_{ij}}\right) = \frac{1}{j_{max}(i)} \tag{1.a1}$$

One has to take into account that the probabilities p_i and p_{ij} are independent, the total probability being their product. Of course, the severity is not constant; it will depend on indices i, j and α.

b) The level (I) equal weights strategy

In this strategy equal weights, w_i, $i = 1;3$, are assigned to the main category of the risk factors, F_i, but different weights w_{ij} inside each factor F_i.

Therefore, one has:

$$p_i = \frac{w_i}{\sum_j w_i} = \frac{1}{3}, \quad i = 1;\ 3;\ w_{ij}; \quad p_{ij} = \left(\frac{w_{ij}}{\sum_j w_{ij}}\right) \tag{1.b1}$$

c) The level (II) equal weights strategy

In this strategy different weights, w_i, i =1; 3 are assigned to the main category of the risk factors, F_i, but equal weights $w_{ij} = 1$ inside each factor F_i.

Therefore, one has:

$$p_i = \frac{w_i}{\sum_j w_i}, \ \ i = 1;\ 3;\ w_{ij} = 1;\ \ p_{ij} = \frac{1}{\sum_j w_i}, \ \ j = \frac{1}{j_{max}(i)}. \tag{1.c1}$$

d) The two level (I, II) strategy

In this strategy different weights, w_i, i = 1*;* 3, are first assigned to the main risk factors, F_i. This represents the first level (I).

Then, inside each factor F_i, i = 1; 3 different weights w_{ij}, are independently assigned. This represents the second level (II);

- At the level I, one has the weights w_i and the probabilities p_i given by:

$$p_i = \frac{w_i}{\sum_j w_i}, \ \ i = 1;\ 3; \tag{1.d1}$$

- At the level II, one has the different weights w_{ij} and the probabilities p_{ij} given by:

$$p_{ij} = \frac{1}{\sum_j w_i}, \ \ j = 1; \ \ \ j_{max}(i) \tag{1.d2}$$

The two levels being independent, the total probability, $ptot_{ij}$, is the product:

$$ptot_{ij} = \ p_i \times p_{ij} \tag{1.d3}$$

As a test:

$$\sum_{i,j} ptot_{ij} = \sum_{i,j} p_i \times p_{ij} = 1. \tag{1.d4}$$

3.2 The calculation of severities and risks

One attributes the following values defined above to severities $S_{ij}(\alpha(j))$, $\alpha(j)$ = a; b; c: $S_{ij}(a) = 1$; $S_{ij}(b) = 2$; $S_{ij}(c) = 3, 4$, or even larger in special cases. The risk, R_{ij}, is given by the product between the probability $ptot_{ij}$ (1.d3) and the severity $S_{ij}(\alpha(j))$

$$R_{ij} = \ \left(p_i p_{ij} S_{ij}(\alpha(j))\right). \tag{2}$$

The total risk, R is the sum of the partial risks R_{ij}:

$$R = \sum_{i,j} R_{ij}, \quad i = 1; 2; 3; \quad j = 1 \ \text{ to } j_{max}(i) \tag{3}$$

The minimal risk R_{min} is obtained for $S_{ij}(\alpha(j)) = 1$ for all respective indices i, j, α, of the adopted strategy:

$$R_{min} = 1 \times \sum p_i \times p_{ij} = 1. \quad (4)$$

The risk evaluation will be done in comparison with the minimal risk $R_{min} = 1$.

4. APPLICATION TO ENDOSCOPIC SURGERY (ERCP). A CASE STUDY

It is considered an example related to a patient who underwent biliopancreatic surgery [5]. All four strategies were used. The risk factors are evaluated as follows:

•The human factor, F_1
- $w_{11}a$ = 1; $S_{12}(a)$ = 1; (surgeon, experienced specialist);
- $w_{12}a$ = 1; $S_{12}(a)$ = 1; (anesthesiologist /anesthetist, experienced specialist);
- $w_{13}a$ = 1; $S_{13}(a)$ = 1;(the surgeon's helping team with long experience);
- $w_{14}b$ = 2; $S_{14}(b)$ = 2; (the patient medical history shows other previous operations/ surgeries);

•The technical factor: F_2
- $w_{21}a$ = 1; $S_{21}(a)$ = 1; (device in very good condition);
- $w_{22}b$ = 2; $S_{22}(b)$ = 1; (complicated connection of the device to the patient);
- $w_{23}a$ = 1; $S_{23}(b)$ = 2; (apparatus/ device for radiology in good condition, but the patient in an acceptable condition);

•The environmental factor, F_3
- $w_{31}a$ = 1; $S_{31}(a)$ = 1; (patient preparation for operation OK);
- $w_{32}a$ = 1; $S_{32}(a)$ = 1; (open, ventilable space);
- $w_{34}b$ = 2; $S_{34}(b)$ = 2; (the patient position needed change during operation);
- $w_{35}a$ = 1; $S_{35}(a)$ = 1; (the patient relationship is good);
- $w_{35}b$ = 2; $S_{35}(c)$ = 3; 4; (the patient postoperative conditions are inacceptable (food) with severe consequences).

With the above data one obtains the risks as given in Table 1. All risks are to be compared with the minimum risk, R_{min}.

Table 1. The risk factors, weights and severity for a case of endoscopic surgery (ercp)

Nr.	Risk factor	w_{ij}, weights		S_{ij}, severities	R_{ij}^a	R_{ji}^b	*RieII*	*RieI*	*Rew*
1	surgeon	1		1	1/25	1/30	1/20	1/15	1/12
2	anesthetist	1		1	1/25	1/30	1/20	1/15	1/12
3	surgeon help team	1		1	1/25	1/30	1/20	1/15	1/12
4	patient history	2		2	4/25	4/30	2/20	4/15	1/12
5	device	1		1	2/20	2/24	2/15	1/12	1/9
6	connections to device	2	1 (Rew)	2	8/20	8/24	4/15	4/12	2/9
7	radiography	1		2	4/20	4/24	4/15	2/12	2/9
8	preparaton of patient	1		1	2/30	3/36	2/25	1/18	1/15

9	surgery space	1		1		2/30	3/36	2/25	1/18	1/15
10	patient position	2	1	2		8/30	3/36	2/25	4/18	2/15
11	patient relations	1		1		2/30	12/36	4/25	1/18	1/15
12	Postoper. conditions	1		3 (R_{ij}^{a})	4 (R_{ij}^{b})	6/30	3/36	6/25	3/18	3/15
-	(R) two level strategy (a)	1.646		-	-	-	-	-	-	-
-	(R) two level strategy (b)	1.733		-		-	-	-	-	-
-	(R) equal level II strategy	1.557		-		-	-	-	-	-
-	(R) equal level I strategy	1.606		-		-	-	-	-	-
-	All weights equal strategy	1.506		-						

Table 2. The main level probabilities (p_i)

Strategy	Human factor	Technical factor	Environmental factor
All weights equal strategy	1/3	1/3	1/3
equal level I weights strategy	1/3	1/3	1/3
equal level II weights strategy	1/5	2/5	2/5
Two level strategy,(a)	1/5	2/5	2/5
Two level strategy,(b)	1/6	2/6	3/6

6. CONCLUSIONS

An extension of a method of risk evaluation from Aeronautics was improved, detailed and extended to Medicine (Surgery). Four evaluations risk strategies were given, permitting to make the choice easier by comparison.

This could make the procedure simpler as compared to the 6-4-3-5 method of risk analysis from Aeronautics.

A minimal risk (equal to 1) can be obtained irrespective of the applied strategy. By comparison with this minimum risk it can be assessed whether the risk is acceptable before the surgery, the patient being thus informed in advance.

A case study of endoscopic surgery (biliopancreatic intervention) is given in Table1. The selected probabilities for the different four strategies are given in Table 2.

One can see that the evaluated risk increases from 1,506 (for “all weights equal strategy”) to 1.646 (for “two level strategy a” with severity S_{35} = 3) and 1.733 (for “two level strategy b” with severity S_{35} = 4) which could explain the poor result obtained, especially due to the patient medical history and bad postoperative conditions (mainly food administrated to the patient).

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