A CROSS-VALIDATED MULTIFACTORIAL INDEX OF PERIOPERATIVE RISKS IN ADULTS UNDERGOING ANAESTHESIA FOR NON-CARDIAC SURGERY

Analysis of Perioperative Events in 26907 Anaesthetic Procedures

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ABSTRACT. Objective. To develop a severity index of anaesthetic risk that predicts relevant perioperative adverse events in adults. **Design.** Prospective cross-sectional study. **Setting.** Department of anaesthesiology at one university hospital. **Patients.** 26907 consecutive anaesthetic procedures in patients over 15 years of age and a complete preoperative evaluation. Patients undergoing cardiac and obstetric surgery were excluded. **Measurements and main results.** Demographic data, preoperative health status, type of anaesthesia, operative procedures, and perioperative incidents (standardised on a national basis) were acquired by means of a computerised anaesthetic record system. Occurrence of at least one perioperative event with impact on postanaesthetic care was computed by a multivariate logistic regression model against 17 variables with different characteristics representing possible risk factors. Fourteen variables proved to be independent risk factors. The weighting of the variables was expressed in scores which added up to form a simple index for each patient. Patients without major risk factors (0–10 points) had a 0.3% risk of suffering from a relevant incident. Patients with more than 60 points had a 28.6% risk. The results were well demonstrated by cross-validation. **Conclusions.** The index seems to reflect the risk of relevant perioperative incidents. It can be used for audit purposes. In daily routine, the index could focus our attention on patients with increased perioperative risk. However, it is limited in detecting particular constellations of factors which interact on each other with regard to perioperative risk.

KEY WORDS. Anaesthesia, epidemiology, perioperative events, risk factors, complications.

INTRODUCTION

There is no doubt that perioperative morbidity and mortality are influenced by the patient's preoperative health status, the surgical procedure involved, and the anaesthetic technique used. Different approaches have been made to verify and quantify relations between risk factors and the incidence of perioperative adverse events. Until now, aims of various investigations have been:

- particular factors focusing on special events, e.g. differences in anatomic findings and incidence of difficult intubation [1];
- multiple factors focusing on particular events, e.g. factors contributing to postoperative cardiac complications [2] or to perioperative bronchospasm [3];
- particular factors contributing to various kinds of events, e.g. obesity and its impact on perioperative problems [4, 5].

Several studies have evaluated multiple factors as well as

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multiple events (6, 7, review in 8]. In particular, the Canadian group of M. Cohen et al. published a series of papers with this approach [9–11].

While there is still a lack of international agreement on how to define "adverse event" or "adverse outcome," papers from various countries differ substantially in the criteria for reporting event. Some authors restrict observations on events with legal or disciplinary consequences [12], others report mortality or major morbidity only [13]. The definition of the "perioperative" period is inconsistent too: Some reports cover the time from induction of anaesthesia until discharge from the recovery unit [14], others from the beginning of anaesthesia until 24 hours postoperatively [13] or even longer [15, 16]. Furthermore, the method of data acquisition varies from voluntary individual reporting of critical incidents [17] to prospective studies covering all anaesthetics during a certain period for one [9] or several [11] departments.

Our university hospital has been participating in a national incident reporting project since its inception in 1992 [18, 19]. We started to report incidents, events, and complications (IECs) routinely in 1991 [20] according to the definitions of a pilot study which was the basis for the later recommendations by the German Society of Anaesthesiology and Intensive Care [18].

In the study presented we try to quantify risk factors which are usually known preoperatively and which affect the occurrence of relevant adverse events during the first perioperative period, i.e. from induction of anaesthesia until discharge from the recovery unit.

Quantification of risk shall be available in the form of scores adding up to give an index. This index shall indicate an overall estimation of risk, similar to the approach by Goldman et al. [2]. This methodology may be easily implemented in clinical routine without handling complex equations; the philosophy of this approach is well known from other authors [21, 22]. The probability of events and the association of risk factors shall be validated for their reliability.

At the end of the preoperative evaluation, the anaesthetist should be able to get a quick and straightforward answer to the question: *What is the probability of a certain patient to experience a relevant perioperative event?*

MATERIALS AND METHODS

Patients

Included were all adult patients (aged 16 years or more) undergoing any diagnostic or therapeutic intervention at our university hospital, where an anaesthetic procedure (carried out by any staff member of the anaesthesia department) was involved.

Excluded were patients with missing pre-anaesthetic information due to language difficulties or need of immediate action because of life-threatening situations (e.g. in case of polytrauma or ruptured aortic aneurysm). Additional criteria for exclusion were patients scheduled for obstetric and cardiac surgery.

The study period lasted from July 1992 to June 1994.

Design

The project was a cross-validated prospective cross-sectional study for institutional audit purposes.

Data acquisition

All patient data were acquired by means of a standardised automatically readable anaesthetic record (ARAR) system. Each record contained three pages:

- Preoperative evaluation with demographic data, patient history, pathological findings, American Society of Anesthesiologists' (ASA) classification of physical status, and surgical discipline. Most of the items are shown in Table 3.
- Intraoperative documentation of anaesthesia, surgical procedure, monitoring techniques, and notes on transfer.
- Postoperative course in the recovery unit, timing of opearation and anaesthesia, length of stay in the recovery unit, type and severity of IECs, and the patient's transfer destination.

On a time axis, the ARAR also included the course of vital signs, type and dosage of anaesthetics, and the administration of other drugs in the operating theatre and recovery unit. These data were not for automatic reading and not subject of this study. The ARAR was the only medium for documentation. It was routinely completed for every patient by the anaesthetist responsible for the specific part of the patient's care.

Before storing in a data base, every single ARAR set was checked in four different ways and corrected if necessary:

- The consultant in charge reviewed the ARARs for clinical correctness and completeness.
- Documentation staff checked the ARARs for formal accuracy to guarantee proper automatic reading.
- Plausibility rules implemented in the electronic system checked each data set for consistency and completeness.
- If there were any doubts in the second or third step of

the control system, the anaesthesiologists in charge of the documentation system (B.S. or U.B.) were asked for assistance. If necessary, the anaesthetist who had performed the anaesthesia was asked to complete the data.

The whole procedure has been described in detail elsewhere [23].

In a pilot phase from September 1991 to June 1992, clinical and documentation staff were trained in the use of the ARAR and how to classify IECs. This was backed up by several written guideline broadcasts and educational meetings. Since identification of the anaesthetists was not part of the data assessment scheme, none of the participating staff physicians had to be afraid that the "personal incidence of IECs" could be attributed or blamed on individual physicians.

Definitions of incidents, events, and complications (IECs)

The DGAI has published recommendations for a standardised classification of adverse perioperative events [18]. This was performed in the context of a large quality assurance project.

IECs are events:

(1) occurring during the period of the anaesthetist's responsibility (from induction of anaesthesia until dismissal from the recovery unit);
(2) which lead to an intervention by the anaesthetist;
(3) which have or could have caused morbidity or mortality if the anaesthetist had not intervened.

All three conditions have to be fulfilled

By definition, there is no difference if the incident occurred by chance, was caused by the patient's preoperative condition, or was a consequence of improper treatment by the attending physician. Usually, physicians are able to assess IECs with clinical standard methods.

The DGAI has defined 63 different kinds of IECs (Table 2) and five grades of severity as follows:

I. IEC without any impact on postoperative care – no particular postoperative care necessary (including near incidents).
II. IEC clinically important only for care in the recovery unit – no impact on transfer to the ward.
III. IEC clinically relevant for postoperative care – clearly prolonged stay in the recovery unit or particular observation on the ward necessary.
IV. IEC clinically important for postoperative care – problem cannot be solved satisfactorily in the recovery unit, transfer to intermediate or intensive care unit necessary.
V. Presumably severe and permanent damage or death.

This study only considers IECs of grade III or higher; we call them "relevant adverse events" (RAEs).

Statistics

For establishing a model cross-validation, the whole data set was randomly divided in two parts: (1) the modelling data set contains all anaesthetic procedures in uneven months (January, March, etc.); (2) the validation data set includes all anaesthetic procedures in even months (February, April, etc.). All calculations for the modelling process were performed exclusively on the modelling data. The validation data were used to test the model accuracy, consistency, and predictive ability.

As a first step in model building, we supposed 17 clinical candidate risk factors: Fourteen of these variables are shown in Table 3. Three additional variables in consideration were preoperative cardiac status (NYHA), circulatory function, and vascular status.

In separate univariate analyses, each level of the candidate variable was tested for an association with the occurrence of RAE (level with the lowest incidence as a reference). A variable level was assumed to be significant with a p value < 0.05 (Chi-square testing) and considered for further calculations. Variable levels with small patient counts were combined if the incidence of RAE in the respective categories differed less than two-fold and if this was acceptable from the clinical point of view. This was done to keep the resulting model neat.

In a third step, multivariate analyses were achieved with the logistic regression procedure [24]. This method studies the influence of the presence or absence of an independent variable (risk factor) on a binary (yes/no) outcome variable (RAE) adjusting for all covariables, i.e. other types of simultaneously occurring risk factors according to the equations below:

$$p = e^z/(1+e^z) = 1/(1+e^{-z}) \text{ and}$$
$$Z = \beta_0 + \beta_1 * X_1 + \beta_2 * X_2 + \ldots + \beta_n * X_n$$

where p = probability of event (RAE), Z = linear combination of the Generalised Linear Model, X_n = value of the nth independent variable (e.g. disease present = 1, not present = 0), β_0 = intercept (constant), β_n = estimate of the coefficient of the nth independent variable.

Given that the incidence of RAE is low, it can be assumed that Relative Risk equals Odds Ratio which is

Table 1. Overview of the cohort

Item	Modeling data set (n = 13697)	Validation data set (n = 13210)
Age (years)		
Median	49	49
Min/max	16/99	16/98
25%-quartil	32	32
75%-quartil	64	64
Anaesthesias with RAEs	498 (3.64%)	533 (4.03%)
	number of patients	
Sex		
Female	7090	6742
Male	6607	6468
ASA-class		
1	4071	3755
2	5694	5544
3	3430	3441
4	490	458
5	12	12
General condition		
Good	10809	10299
Others	2888	2911
Nutritional state		
Normal	10180	9756
Others	3517	3454
Coronary state		
Normal	10942	10443
Pathologic	1672	1655
n.a.	1083	1112
Airway and lungs		
Normal	9962	9404
Pathologic	3315	3379
n.a.	420	427
Grade of urgency		
Elective	10699	10320
Urgent	2050	1939
Emergency	948	951
Operation		
Thoracotomy	244	234
Laparotomy	1651	1611
Others	11802	11365
Duration of the operation (minutes)		
0–60	6472	6252
61–120	4187	3924
121–240	2349	2350
>240	689	684
Anaesthetic technique		
Regional	2305	2265
Others	11392	10945

the natural antilogarithm of the regression coefficient (e^{β}). The Relative Risk expresses how many times the incidence of RAE in a patient with the risk variable present is increased as compared to a patient with the risk variable not present. This estimation is corrected for either status of all other risk variables included in the model.

For variable selection in the model building process we performed a backward dropping procedure [25] starting with the full model. The significance criterion for keeping a variable in the model was $\alpha = 0.2$. Since all prediction variables have the same measuring level (binary yes/no), the regression coefficients from the regression equation are directly comparable as a weighting factor of risk influence on RAE of the respective variable.

In a last step to make risk prediction straightforward, clinically practicable, and easily computable, several simplifications were achieved: The lowest regression coefficient (beta) in the equation can be set as one and the higher betas expressed as a multiple of the lowest beta. Thus an indexing weight of each risk variable (x_n) can be obtained in further dividing by 10 and rounding to the nearest integer. If a patient presents with the respective risk variables existent, each weight can be added to form the summary scoring index.

Finally the index was checked for its prediction characteristics by applying the scores to the validation data set.

Classification according to ascending index points is intended to identify apparent and distinct risk groups.

RESULTS

26 907 anaesthetic procedures including 1031 with RAEs were studied. 13 697 (498 with RAEs = 3.64%) anaesthetics counted for the modelling data set and 13 210 (533 with RAEs = 4.03%) for the validation data set. An overview of the two groups is given in Table 1. 7520 of all the anaesthetics were associated with a total of 10 530 IECs. Incidence and grade of severity of the various events are shown in Table 2. Hypotension and hypertension are the most frequent adverse events, but, similar to changes in perioperative heart rhythm, they have mostly low severity grades (median I). Respiratory events are generally less frequent. The most frequent respiratory events, however, have a median severity grade of II. Equipment failures and lesions are rare events and mostly grade I. 4028 patients had an IEC with a maximum grade I, 2461 with grade II, 792 with grade III, 229 with grade IV, and 10 with grade V. The number of IECs within one anaesthetic procedure increases with higher grades of severity (compare with the incidence of IECs in Table 2).

In the logistic modelling process we were able to reduce the full model with 17 variables by omitting the variables "cardiac status," "circulatory function," "vas-

Table 2. Incidence of the various incidents, events and complications (IECs) in the entire study population (n = 26 907). The numbers in front of the single IECs represent the original code-numbers as defined by the German Board of Anaesthesiologists

	Grade of severity					Totals
	I	II	III	IV	V	
Respiratory						
01 Deconnection	9	1	0	0	0	10
02 Kinking/ obstructed tube	12	5	2	0	0	19
03 Accidental extubation	9	7	0	0	0	16
04 Unexpected diff. intubation	166	72	20	3	0	261
05 Impossible intubation	3	8	5	1	0	17
06 Failed intubation	31	9	1	1	0	42
07 Mainstem intubation	14	4	3	0	0	21
08 Re-intubation	23	4	14	11	0	52
09 Laryngospasm	10	27	7	1	0	45
10 Bronchospasm	124	140	45	11	0	320
11 Aspiration	1	6	4	8	0	19
12 Hypoventilation/ hypoxemia	65	95	97	50	2	309
13 Pulm. edema	0	4	7	4	0	15
15 Other resp. disturbances	83	78	67	34	0	262
Cardiovascular						
18 Hypotension	1726	802	132	47	3	2710
19 Hypertension	601	449	104	5	0	1159
20 Arrhythmia	445	240	74	27	0	786
21 Tachycardia	233	156	81	29	1	500
22 Bradycardia	531	194	39	3	1	768
23 Hypovolemia	61	94	63	27	3	248
24 Decompens. heart failure	0	1	3	12	0	16
25 Pulm. embolism	2	0	2	6	1	11
26 Circul. arrest	4	5	6	7	5	27
27 Myocardial infarction	0	0	0	2	0	2
30 Other cardiovasc. disturbances	20	29	22	12	0	83
General reactions						
33 Nausea/vomiting	366	286	44	0	0	696
40 Anaphylactic reactions	40	20	8	6	0	74
41 Shivering	290	254	11	0	0	556
42 Hypothermia	7	25	52	18	0	103
43 Malignant hyperthermia	0	0	0	0	0	0
44 Transfusion-reaction	1	0	2	0	0	3
45 Oliguria/acute renal failure	6	11	10	3	0	30
48 Other general reactions	68	51	29	4	1	153
Laboratory results						
51 Anemia	38	90	40	10	1	179
52 Disturb. in acid-base-status	4	20	13	8	0	45
53 Disturbances of electrolytes	23	44	23	5	0	95
54 Disturbances of serum glucose	6	18	18	2	0	44
55 Other dist. in lab results	2	16	9	3	1	31
Central nervous system						
58 Central anticholinerg syndrome	2	2	4	1	0	9
59 Ischemia	0	0	0	1	0	1
60 Seizure	1	0	3	1	0	5
64 Other central neurologic dist.	9	10	28	6	0	53
Equipment						
67 Anaesthetic machine/ ventilator	64	11	0	0	0	75
68 Ecg-monitor	4	2	1	0	0	7
69 Monitor of blood pressure	51	3	2	0	0	56
70 External pacemaker	0	0	0	0	0	0
71 Defibrillator	0	0	0	0	0	0
72 Pulse Oximeter	31	3	0	0	0	34
73 Intubationset	6	0	0	0	0	6
74 Drug application (pumps, infusion kits)	7	1	0	0	0	8
75 Other kind of equipment	47	9	3	1	0	60
Lesions						
77 Failed or repeated puncture (regional anaesthesia)	142	56	8	0	0	206
78 Failed or repeated puncture (blood vessels)	141	42	4	1	0	188
79 Teeth	14	1	6	0	0	21
80 Vessels	4	0	0	0	0	4
81 Muscles/soft tissue	5	3	1	1	0	10
82 Skin	6	2	0	0	0	8
83 Airway	0	0	2	0	0	2
84 Eyes	0	0	0	0	0	0
85 Epistaxis	8	5	2	0	0	15
86 Pneumo-/ hematothorax	0	0	0	0	0	1
87 Nerves	1	1	0	0	0	2
89 Other lesions	11	16	5	1	0	33
Totals	5578	3432	1126	374	20	10530

cular status." The reduced model had the same performance without loss of predictive quality. For further considerations we favoured the latter model. The resulting scores of the single characteristics of the 14 remaining variables, which added up to form the index, are shown in Table 3. As this table further demonstrates, the raw incidence of RAEs has no consistent relation to the scores (points). This is due to the fact that the multi-

Table 3. Distribution of scores contributing to the index

Variable	Points	Incidence of RAEs (%) in the whole population
Sex		
Female	0	3.14
Male	1	4.57
Classes of age (years)		
16–39	0	1.25
40–59	5	3.83
60–74	6	6.45
>74	8	7.81
ASA-status		
1	0	0.73
2	8	2.91
3	12	7.15
4	17	15.61
5	23	33.33
General condition		
Good	0	2.59
Others	2	8.36
Nutritional state		
Normal	0	2.96
Others	1	5.84
Coronary state		
Normal	0	2.77
Pathologic/n.a.	2	7.93
Airway and lungs		
Normal	0	2.15
Pathologic	4	8.40
n.a.	2	6.26
Airway patency		
Normal/mallampati 1	0	3.02
Pathologic	1	5.49
n.a.	2	5.56
Fluid balance and electrolytes		
Normal	0	3.10
Pathologic	1	7.89
n.a.	2	3.99
Metabolic state		
Normal/n.a.	0	2.91
Pathologic	1	6.79
Grade of urgency		
Elective	0	2.93
Urgent	2	5.92
Emergency	7	9.48
Operation		
Thoracotomy	11	12.76
Laparotomy	2	8.49
Others	0	2.99
Duration of operation (minutes)		
0–60	0	2.07
61–120	4	3.69
121–240	8	6.60
>240	14	11.51
Anaesthetic technique		
Regional	0	1.84
Others	7	4.24
Possible maximum sum:	85	

variate procedure is able to detect the adjusted impact of a risk factor. There is an example where a higher incidence of RAE is associated with a lower score (fluid balance and electrolytes). In the full model the distribution of the single scores was nearly identical for the individual organ systems. Only the various classes of the ASA status had lower scores in the classes 2 to 5.

Table 4. Incidence of anaesthesias with RAEs (percentage of anaesthesias within the respective range of points; n is number of anaesthesias)

Range (points)	Modelling data set		Validation data set	
	(%)	(*n*)	(%)	(*n*)
0–5	0.0	304	0.4	275
6–10	0.3	1829	0.4	1677
11–15	0.5	1372	1.0	1266
16–20	0.9	1581	0.9	1608
21–25	2.5	1996	2.4	1902
26–30	2.4	2031	2.8	1905
31–35	4.2	1777	5.3	1748
36–40	7.2	1331	7.5	1299
41–45	10.6	763	9.7	812
46–50	14.3	426	15.1	449
51–55	16.8	209	21.1	185
56–60	35.1	57	20.0	65
61–65	21.1	19	50.0	16
>65	100.00	2	33.3	3
All	3.6	13697	4.0	13210

Table 5. Relevant adverse events (RAEs) in different risk strata (index-point groups) compared to a low risk reference group (index-points 0–10). Calculations are based on the validation data set

Range (points)	Relevant adverse events				
	Yes	No	RR[a]	−95% CI[b]	+95% CI[b]
0–10 (Reference)	7	1945	1.0	–	–
11–20	28	2846	2.3	1.2	6.2
21–30	100	3707	7.3	3.4	15.7
31–40	190	2857	17.4	8.2	36.9
41–50	147	1112	32.6	15.3	69.3
51–60	52	198	58.0	26.6	126.3
>61	9	10	132.1	54.9	317.9

[a] Relative risk.
[b] Confidence interval.

The associated incidences of RAEs in the modelling and validation data set are shown in Table 4 within five-point-steps of the index. Steps of 10 points lead to distinct and significant classes of risk as shown in Table 5, where the relative risk (RR) is calculated for the validation data set. Figure 1 shows the incidence of RAE in

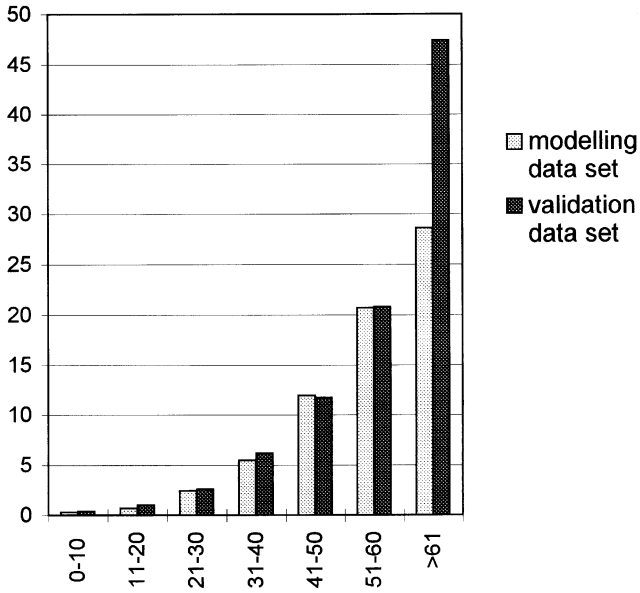

Fig. 1. Percentage of anaesthesias with relevant adverse events (RAEs) (y-axis) within the respective range of index-points (x-axis).

steps of ten points for both data sets. The cross-validation reveals a good performance of the model.

DISCUSSION

What are complications?

Reports on perioperative events often focus on certain findings in particular patient groups. The aim of our study was to document perioperative problems and their clinical impact *on a comprehensive population* at our hospital *during a considerable long period* of time. Our guideline was the official national list of perioperative incidents, events and complications (IECs) defined by the DGAI. The list was designed to answer the questions: What happened perioperatively? What was the clinical impact of the event in respect to the immediate postoperative course? Grades of severity are not mainly defined on numerical cut-off values. Many problems cannot be measured by technical equipment (e.g. intubation problems, aspiration, difficult punctures etc.), nor can the significance of an event be assessed by a numerical threshold value alone (e.g. decrease of systolic arterial blood pressure from 130 to 80 mmHg in a young woman or in an old patient suffering from carotid artery or coronary heart disease).

Reasonably well, the DGAI did not define a criterion for who has to take responsibility for an event (e.g. anaesthesiologist or surgeon). First, in acute situations we are often not quite sure about whose responsibility it is, and second, it would probably be a reason to refrain from documenting certain incidents at all.

Incidence, reported incidence and problems in incident reporting

The incidence of 28% anaesthetics with perioperative IECs in our study is higher than in other reports using the same definition [26, 27]. Unfortunately, in these publications there is no detailed information about the patients' risk factors. The documentation of perioperative events in a large cohort is still a challenge, as we experienced in an auditing project of documentation difficulties [23]. Eight percent IECs proved to be far too low when the records were reviewed [28]. "Complication rates" of 0.05% [12] may only be explained if very close inclusion criteria are considered (incidents with potential medico-legal consequences). Cooper et al. [14] found adverse events in 18% of the anaesthetics. These events are called "recovery room impact events" (RRIEs) and their definition was very similar to our IECs when considering IECs of grade II or higher only. The corresponding rate in our study was 13%. The incidence of anaesthesias with "moderate, serious or catastrophic sequelae" in Cooper's study was 2.7%–3.6%. Our results (3.8%) tally well with these figures. We have to face the fact that our study – in contrast to Cooper's – included patients transferred to an intensive care unit immediately after surgery (see definition of IEC grade IV). Cohen et al. [9] found a rate of 25%–32% of anaesthesias with events and a rate of 0.4% with "major postoperative complications." Forrest et al. [6] used a definition similar to ours and five grades of severity as well. They found at least one "severe adverse outcome" (corresponding to our RAEs) in 4.9% of the study population as compared to 3.8% in our study. The "total complication rate" in the Gothenburg study of perioperative risk [7] was 30%. It covered, however, a longer postoperative period. The rate of severe adverse events is difficult to compare because of different severity grading systems and criteria for inclusion in studies. Other authors reported complication rates of 3.6% [29] and included various cardiopulmonary events which are quite similar to our IECs starting from grade III.

We must be aware of the fact that the incidence of perioperative events is always the *reported* incidence only. And reporting will be influenced by many aspects. If, in addition to the usual anaesthetic record, any further reporting activity is required (e.g. to fill in a particular report from), there is the tendency among anaesthetists to report only the severe events or even to wait until

successful recovery has occurred [30]. For this reason we have installed an anaesthetic record keeping system with an integrated module for incident reporting. This meets the recommendations of the National Society of Anaesthesiologists in Germany [18].

Epidemiological studies in anaesthesiology suffer from the problem that many patients (i.e. procdures performed by many anaesthetists) should be included in a uniform manner and without major bias. Thus we have to demand that reporting of incidents should neither be influenced by the anaesthetist's fear, nor by his individual attitude to what is worth being documented. In our department of anaesthesiology the introduction of incident reporting was supported by a series of introductory lectures and written guidelines. Critical incidents are discussed in daily meetings. A working group keeps up with the continuous and standardised documentation of adverse events.

Our rate of events (overall, severe) is mostly withing the range of other publications or above it. Although we have to consider some restrictions in the accuracy of reporting particular incidents (see later), we conclude that our results are useful and reliable enough to be used for further processing.

Frequent events

The incidence of several frequent events is similar to other studies in Germany using the same definitions [26, 27]. Cohen et al. found more arrhythmias [9, 11]. The incidences of severe cardiovascular events (hypotension, hypertension, tachycardia, arrhythmia) are slightly below the values reported by Forrest et al. [31].

Unexpected difficult intubation is reported to occur in about 1% of the patients [11, 14], which tallies quite well with our results. This is similar in the case of bronchospasm. In our study the incidence of hypoxaemia is higher than in the report of Cooper et al. [14] (0.9% vs. 0.4%).

The study from Gothenburg [32] revealed an even lower incidence of various rare respiratory events. The other events in our study play a minor role, especially if we consider that this analysis focuses on the relevant complications (IECs > grade II). Only one quarter of all RAEs were not cardiovascular or respiratory. In particular, equipment failures are rare (7 out of 1520 RAEs = 0.46%). In an inquiry Cooper et al. [33] found that in *avoidable* severe incidents, equipment was involved in only 4% of cases. However, this investigation was carried out more than ten years ago. Technical standards and system checks may have improved in the meantime.

Table 2 reveals some typical peculiarities. The frequency of deconnection, of nausea/vomiting, and of disturbances in lab results is probably much too low. The reasons could be various: The anaesthetist often will not consider a short deconnection to be an event worth to be reported. Instead, he will reconnect the tubes within some seconds without any consequences for the patient's further course. Most of events concerning nausea/vomiting will occur in the recovery room. One doctor is responsible for several patients and will perhaps not recognise the event because the nurses are able to cope with most of such situations by standardised interventions. Although the nurses are asked to make a remark in the records, they will often forget about this. The true incidence of nausea and vomiting might be probably 15% to 25% and not 2.6% as reported. We believe, however, that these problems have minor impact on the calculated index because IECs with an obviously under-detected incidence are mostly not severe and will rarely reach the grade III or higher. For the calculation of the index we only used the relevant events (= RAEs = IECs of grade > II).

The impact of risk factors

Most of the risk factors are identified and qualitative relations to perioperative severe adverse events are thoroughly reported. In the context of this paper the quantitative impact is of special interest.

If we take a look at our list of IECs, we may notice a lot of events which might be associated with risk factors (disturbances in blood pressure, hypoxaemia etc.) while others (e.g. equipment failures) seem to be rather independent from the patient's age or preoperative disease. Nevertheless we have integrated all IECs of grade > II in the model. Frist, the incidence of RAEs having no obvious relation to risk factors is very low so that the contribution of these events to the model remains limited. Second, there are some events which are mostly not related to risk factors, but could be related to certain factors in certain cases (e.g. disconnection of tube in an emergency situation). In any case, we wanted to get an information about the probability of all occurring RAEs.

Age is a known risk factor [13, 34, 35]. The high scores of the index emphasise the importance in respect to severe events. From other investigations we know an interesting phenomenon: elderly "healthy" patients do not differ so much from patients with additional risk factors of the same age. The difference between healthy young patients and those with pre-existing diseases is more pronounced [5, 35]. This could probably explain

the missing impact of the three *cardiovascular variables* (cardiac, circulatory and vascular state). These diseases are mostly diagnosed in the elderly and are associated with an impaired general condition of health and a higher ASA classification. Thus most cardiovascular problems are already represented in those items. The weighting of coronary disease in the model remains moderate. The calculation of the impact of cardiovascular diseases in our collective is influenced by the fact that most of these diseases are observed in the elderly. In the rare cases of cardiovascular diseases in younger patients this may lead to a certain underestimation of risk. The consideration of the different levels of interaction between different risk factors would require a further step of refinement of the calculation method. We did not intent that, because this would mean to abandon a simple index of risk for all adults.

Respiratory risk factors are more frequent among young patients (smoking, chronic bronchitis). This may explain the more marked impact of "pathological airway and lungs."

Renal and metabolic disturbances and diseases are of minor impact in the model. In some cases there is a *lack of information concerning certain variables* (coronary, respiratory, renal or metabolic status). This leads to a certain weighting pattern of index points. The reason for this is as follows: We provide the item "emergency" (= operation required during the next two hours) in the data. Within this definition, however, there are still differences. In some patients there is enough time for preoperative screening (laboratory, X-rays), while other patients are decided to be operated on within the next 30 minutes. This means that we have to refrain from conducting some basic preoperative investigations for patients with a rather urgent problem. The *degree of urgency* is a relevant predictor of adverse events [2, 13]. Therefore, we should not interpret a lack of information as the true problem, rather as an additional aspect of emergency.

Male gender is also reported to be a risk factor [6, 10], but this could not be confirmed in the recent Gothenburg study [32].

Obesity has an impact on perioperative risk [5, 35]. The moderate weighting in our model may be explained by the fact that a major part of this effect is already covered by the ASA classification. Another reason might be that obesity is not so important as a risk factor in the elderly [5].

The significance of the *ASA classification* as a predictor of perioperative risk is beyond discussion [6, 10, 13]. As expected, this variable is the one with the strongest impact in the model.

Extent and duration of the operation are also found to be relevant for the determination of risk [6, 10, 13, 36]. When combined, these two variables reach even higher scores than the ASA classification. We may learn from this, that any report on severe perioperative incidents must enclose detailed information concerning surgical aspects of the respective group, otherwise the results will be hard to judge or compare.

Investigations concerning the impact of *anaesthetic technique* allow different statements:

- The influence of other factors on *mortality* is dominant in a way that even in a large population a significant contribution of anaesthetic variabes is not found [10].
- Some *typical problems* are detected in the Multicenter Study of General Anesthesia [6], i.e. an increased incidence of arrhythmias in halothane anaesthesia and tachycardia associated with isoflurane. This was a randomised clinical trial without application of balanced anaesthesia. The calculated risk of anaesthetic variables was not very high. In contrast to this trial, however, we do not apply anaesthetics randomly in clinical practice and most anaesthetists would not try to avoid combinations of volatile anaesthetics and opioids (balanced anaesthesia). In this study, preoperative diseases and surgical factors were more relevant in respect to severe adverse events than demographic factors.
- Specific investigations are required to examine the impact of regional vs. general anaesthesia. For some situations we prefer regional anaesthesia in daily routine [37, 38]. In spite of certain advantages of regional anaesthesia for selected anaesthetic populations, some studies suggest that there are little differences to general anaesthesia [39], and if there are any, they will nearly disappear if we look at severe events only [40]. Perhaps this statement is not valid for certain obstetrics situations [41, 42], but obstetric patients were not included in this study.
- We have considered all kinds of RAEs. Some of them are strictly related to specific techniques (e.g. difficult intubation, failed puncture in regional anaesthesia). This may lead to further limitations in risk interpretation.

With this background knowledge we must be cautious in interpreting the high weighting of general anaesthesia in our results. We believe that the classification of the surgical influence in our data is too rough. More critical operations are performed under general anaesthesia. Similar to the problematic with urgency, our classification of operative procedures is not subtle enough to detect problems which may finally lead to an increased likelihood of adverse events. We should therefore use the results in the following way: if the surgical circum-

stances allow a regional anaesthesia we may expect a lower incidence of severe perioperative events. If we are able to improve the precision of documenting operative procedures, we might see more clearly if general anaesthesia is associated with additional risk.

Implications and application of the index

The score can easily be calculated for each patient. It refers to the changing likelihood of experiencing an adverse event, which, at least, will lead to a prolonged stay in the recovery room or require special observations on the ward. In this regard, our index differs considerably from others. Unertl et al. [43] assigned 1–4 points for various risk factors, which can be added to a total score. The points assigned for each risk factor did not result from an analytic modelling procedure but were well defined in advance. Osswald et al. [44] presented a checklist including ten risk factors. The weighting of each factor was purely ordinal. They based their analysis on only 700 patients undergoing general surgery. Other study groups used regression analysis as we did, but they only included mortality and were unable to provide a summary score [10] for easy use in daily routine. Similar to what Goldman et al. pointed out in their well-known study [2], one has to bear in mind that our reported risks refer to only one university hospital. On the other hand, we think that our case mix, as well as our methods of practising anaesthesia, are similar to many other large hospitals.

The index could help us to focus even more on patients with potential risks. Furthermore, it could give the patient and the surgeon additional information which could be useful when assessing the surgical risk. It could be included in the patient information sheet required to obtain informed consent.

One of the most promising applications of the index could be for audit purposes. A lot of hospitals are just about to join the project of the German Society of Anaesthesiology and Intensive Care. This could provide the opportunity to use the index for inter-hospital comparison. In a further step the index could be recalculated on a multicenter data basis. The Commission for Data Management and Quality Assurance of the DGAI has already identified two problems associated with such a project: the accuracy and reliability of data acquisition and the integration of a more detailed classification of surgical procedures in the data set.

The use of comprehensive data for audit purposes has been highly recommended in the recent literature [45, 46]. Analysis of data for audit purposes revealed that "system errors" account for more than 90% of all errors, whereas "individual errors" are rare. "System errors" are defined as problems of the department and include situations when residents are left alone to solve anaesthesiologic problems without the support of an attending anaesthesiologist [47]. In this context we would like to emphasise that the index is not suitable to evaluate the performance of an individual anaesthetist nor the adequacy of a single patient's treatment. It rather contributes to quality assurance of anaesthetic departments during a longer period of time. Also we have to be aware that any variation from "reference numbers" does not automatically indicate substandard care nor does it provide sufficient information about the character of potential problems. A more detailed analysis of the data and an intra-institutional discussion is required to answer the questions about possible specific problems and their solution.

A totally different aspect could gain importance: it is getting more and more customary to charge a flat reimbursement rate for the hospital stay which is based on the diagnosis or the operative procedure performed (e.g. gallstones/cholecystectomy). The index demonstrates that apart from the operation itself, a variety of factors influence the incidence of serious perioperative problems. Resolving these problems requires a lot of manpower and this is expensive. Compared with a 37-year-old healthy patient (e.g. index of 14), a 62-year-old with several pre-existing diseases (e.g. index of 37) scheduled for elective laparotomy would have a seven- to ten-fold higher risk of suffering from a serious perioperative event according to our results. This shows that just a little variation in the patients' characteristics may have quite marked economic implications for a hospital.

An ubiquitous use of the index, however, is limited. The index does not offer a pathophysiological model of perioperative problems, rather it is a probability model of potential adverse events. We know that some risk factors intensify their effects mutually on each other (e.g. ASA classification and degree of urgency) while other factors do not (e.g. old age and obesity). Such complex interactions cannot be reflected by an index model which is created to suit almost all anaesthetics in adult patients. Particular interactions between particular risk factors in our collective are described elsewhere [5, 19].

CONCLUSIONS

1. Our risk index differs from previously presented models:
   - multivariate logistic regression modelling on more than 13000 cases;
   - cross-validation on the same number of cases;

- all immediate perioperative events with defined degree of severity included, all other events excluded;
- 14 variables with up to 5 different characteristics.

2. If harmonisation of the various approaches in defining "incidents" [7, 14, 18, 48] can be obtained, such an index could compare large groups of patients and departments on an international level, as is already done using severity scores in intensive care medicine. Before using the index for inter-hospital comparison, it seems desirable to recalculate it on a multicenter database.

GLOSSARY

ARAR: automatically readable anaesthetic record
DGAI: Deutsche Gesellschaft für Anaesthesiologie und Intensivmedizin (*German Society of Anaesthesiology and Intensive Care*)
IECs: incidents, events and complications
RAE: relevant adverse events

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