

Perioperative complications at Linköping University Hospital

– a validation study of the Swedish Perioperative Registry.

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Abstract

Background: The Swedish Perioperative Register (SPOR) is a health care quality registry that collects information on health care in connection with surgery to evaluate and improve the perioperative process. Most of the data in the registry are automatically downloaded from the surgical planning system and have a high degree of completeness and validity. Complications, however, are variables that must be reported manually to SPOR because they only can be reported if they arise. The accuracy of this reporting is unknown and yet essential for quality improvement, benchmarking and conducting studies within perioperative care.

Aims: The aim of this study was to describe the incidence and severity of perioperative incidents and complications. We also determined the validity of registration of intraoperative and perioperative complications in SPOR. Our hypothesis was that not all events and complications are reported to SPOR thus compromising the quality and validity of the register.

Methods: We studied procedures conducted at OP-Nord and OP-Syd at Linköping University Hospital from 1 Jan to 31 Dec 2017. Data in SPOR's peroperative and postoperative events and complications register (PAKOP and PAKUVA respectively) were retrieved. These were compared with events and complications obtained from manual review of 414 randomly chosen patient records by an independent censor not involved in the care of the patient. We describe the incidence and severity of 24 predefined events and complications. The concordance between SPOR-and censor-registered events and complications was evaluated using kappa statistics.

Results: The incidence of any event or complication for PAKOP and PAKUVA was 55% and 33% respectively. The most common complication for PAKOP and PAKUVA was intraoperative hypotension and bradycardia respectively. 4% of events/complications were graded as severe enough to change care on the wards or requiring ICU admission. There was poor concordance between censor and SPOR-reported events and complications, with a κ -value of 0.233 for PAKOP and 0.248 for PAKUVA.

Conclusion: Generally, the reporting of events and complications into PAKOP and PAKUVA is poor on Linköping University Hospital, especially for the more common complications like hypotension and bradycardia both intraoperatively and postoperatively.

Populärvetenskaplig sammanfattning

Alla operationer för med sig risker. Dödsfall under operation är numer oerhört ovanligt. Däremot är komplikationer under och efter operation desto vanligare. Hur dessa komplikationer påverkar morbiditet och mortalitet under längre tid är i många fall inte kartlagt. För att kunna göra forskning och utveckla säkrare, evidensbaserad kirurgi, narkos och perioperativ vård krävs tillförlitliga kvalitetsregister som man kan göra studier på.

Svenskt Perioperativt Register, SPOR, är ett nationellt kvalitetsregister som samlar information om bland annat komplikationer i samband med operationer. Den här studien är en valideringsstudie av SPOR, utförd vid Linköpings Universitetssjukhus, för att utvärdera incidensen av avvikelser och komplikationer, och för se hur pass tillförlitligt registret är.

Data från SPOR med journaler från 4% av alla slutenvårdsoperationer på vuxna patienter som utfördes på Linköpings Universitetssjukhus under 2017 gick igenom. En oberoende censor utförde en manuell genomgång av journaler och registrerade 24 predefinierade avvikelser och komplikationer i den peroperativa och postoperativa komplikationslistan (PAKOP resp. PAKUVA). Vi utförde deskriptiv statistik över de vanligaste avvikelserna och komplikationerna, samt svårighetsgradering av dessa. Resultaten jämfördes med avvikelser och komplikationer inrapporterade i SPOR av användare. Överensstämmelse mellan data inrapporterad av censor respektive användare beräknades mha κ -statistik.

Den vanligaste avvikelser eller komplikationen var hypotension i PAKOP och bradykardi i PAKUVA. Det flesta hade svårighetsgradering 1 som innebär att händelsen saknar betydelse för vården på postop. Överensstämmelse mellan censor och användare-rapporterade data i SPOR var mycket dålig. Exempelvis var intraoperativ hypotension endast inrapporterat korrekt i 10 av 148 fall. Likaså bradykardi på postop som endast var inrapporterat i 1 av 40 fall. 4% av komplikationer graderades som tillräckligt allvarligt således att en ändring i fortsatt vård eller inskrivning till intensivvårdsavdelningen krävdes.

Tyvärr är resultaten för den här studien ganska nedslående, i alla fall för vanliga och kanske mindre farliga avvikelser och komplikationer. I studien ges tänkbara skäl till varför rapporteringen är så dålig, men det krävs ytterligare studier för att ta reda på de faktiska orsakerna och göra något åt dem. PAKOP- och PAKUVA-registrering är ett bra föremål för

kvalitetsfrämjande initiativ där följsamhet till korrekt rapportering bör följas och återkopplas till användare.

Introduction

Advances in anesthesiology and perioperative management have made anesthesia and surgery very safe for patients. In Sweden, the 30 day mortality rate is 1.3% and the corresponding rate for 12 months is 5%.(1) Intraoperative mortality is now exceedingly rare. However, the incidence of perioperative complications, ranging from those occurring intraoperatively to postoperative complications occurring during surgical convalescence on the ward are not well documented. To conduct studies on long term consequences of perioperative complications, prospective data collection, for example using a healthcare database containing information about the patient status and perioperative care, is essential. In this regard, proper registration of complications is important since accurate and validated data are needed to conduct studies and improve perioperative care through evidence based medicine.(2)

Healthcare databases are unique and powerful tools that serve a critical function in medical research to evaluate and follow up current healthcare policies. The full implementation of a healthcare registry has been associated with a significant reduction in mortality and morbidity, which is another reason to collect surgical data in a national registry.(3)

Complications have long-lasting effects and are a major predictor of death even 8 years after surgery.(4) Although many surgical registries exist in Sweden and register surgery-specific complications, there are none that record a more general spectrum of complications related to the whole perioperative process (i.e. including anesthesia and surgery). Moreover, there are no databases that we are aware of, that record adverse events in the early postoperative period. Gamil and Fanning identified over 25 years ago that a majority of those dying or suffering severe disability was direct result of a sequence of events beginning with an initial deterioration within 24h of surgery.(5) Thus, it seems logical to question whether poor outcomes are preceded by sentinel events early in the perioperative period. It is for this reason that it is relevant to collect data on intraoperative and postoperative (up to 24 hours) events and complications.

The Swedish Perioperative Register (SPOR) is a healthcare database (quality registry) that collects information regarding care in connection with surgery to evaluate and improve the perioperative process, including events and complications that occur intraoperatively and postoperatively on postoperative care units (PACUs). Many data are automatically reported

from the surgical planning system, e.g. information about the patient's age, sex, type of surgery and duration of surgery. Events and complications, however, are variables that must be reported manually to SPOR because they can only be reported if they arise. Events and complication variables are defined as according to current best evidence and/or by consensus of an expert panel appointed by SPOR. There is one list of definitions for events and complications occurring intraoperatively (peroperativa komplikationer och avvikelser operation, PAKOP) and another list of definitions for events and complications occurring postoperatively on PACUs (postoperativa komplikationer och avvikelser uppvakningsavdelning, PAKUVA).(6) In addition to the complication registration, a grading of severity is required. The grading system consists of 5 severity grades depending on the therapy used to treat the complication (table 1).

When conducting analyses using healthcare databases it is assumed that the data is complete and correct. Missing and incomplete data affect the quality of the analysis, leading to inaccurate conclusions. If data is missing completely randomly it will lower the power of the analysis but the effect will be unbiased and thus able to compensate with more observations. If, on the other hand, data is missing due to different reasons, and therefore non randomly, it may give a systematic bias and lead to inaccurate results. To draw correct conclusions it is important to understand the mechanisms behind missing and incomplete data and other errors in healthcare databases. Validation studies are therefore performed to identify such errors and the mechanisms behind them as well as to assess and improve the quality of healthcare databases.(7)

Validation studies obtain information on measurement errors in exposure and other covariates by comparing the reported measurements with "gold standard" measurements conducted by a group of experts. When assessing errors that occur during registration of variables, the healthcare databases are compared with patients' health records, which are assumed to be correct. If the information in the database is concordant with that in the patients' records, it is classified as correct. Otherwise it is classified as wrong, even if the patients' records are incorrect.(7)

An internal validation of the registration of PAKUVA in the SPOR database was conducted in 2015. Two censors assessed 297 medical charts from 10 different hospitals and compared their registration of PAKUVA variables with the registration in the SPOR database. A general tendency to underreport complications was noted. Only moderate agreement was observed

between censor and registry regarding the number and type of complications as well as their severity.(8)

Linköping University Hospital was the first university hospital to be included in SPOR. It has contributed data since November 2013 and although process data are subject to internal scrutiny, feedback on complications data are lacking. The purpose of the present study was therefore to provide a description of perioperative and postoperative complications registered in SPOR, and to test the validity of the entered data compared to that assessed by a blinded censor. The validation part of the study was based on the hypothesis that not all events/complications are reported to SPOR and thus compromising data quality in the register. The questions considered were:

1. What is the frequency for each of the events/complications?
2. What is the agreement between user and censor for any given event/complication?
3. Do the event/complication codes match?
4. Do the severity gradings match?

The specific aims of this study were to investigate the incidence and severity of 24 selected intraoperative and perioperative events and complications in SPOR, and to determine the validity of their registration.

Methods

Study design

This was a retrospective, cohort, assessor-blinded registry study.

Randomized selection

Data reported by users into SPOR were retrieved for all surgical procedures conducted at OP-syd and OP-nord at Linköping University Hospital from 1 January to 31 December 2017. The SPOR-data were then matched with the local surgical planning database (LINDA) to retrieve personal identity numbers. All surgery on children (<18 years old) were excluded, as well as all outpatient procedures. All burn wound debridement were also excluded, since these were commonly repeated multiple times on the same patient, and replaced by other procedures performed by the same clinic (hand and plastic surgery).

The remaining data was sorted by operating clinic and 4% of the procedures for each clinic was randomly selected using a random number generator, which resulted in 414 surgeries. Four percent was a convenience sample, based on the time limits imposed by the time given to complete this assignment. In large registry studies, this may be seen as adequate, provided that sampling is done at random.(9)

Data collection

The personal identity number were used to access medical records, operative records and PACU records. The operative and PACU records were assessed for 11 predefined PAKOP and 13 predefined PAKUVA events/complications (Tables 1a and 1b) by a censor blinded to the SPOR records. The events/complications were chosen based on request from the Department of Anesthesia at Linköping University Hospital, as well as based on previous findings in literature. Their occurrence and severity gradings were reported into a predefined data extraction template. The severity grading was assessed using information from the medical records. Events/complications with severity grades 1-2 are classified as ‘deviations’ whilst grades 3-5 are classified as ‘complications’ (table 1) in SPOR.

Cases where the patient are discharged directly from the operating theatre to the hospital ward the without bypassing PACU were excluded from the PAKUVA analysis since these cases do not have any PAKUVA registrations. If the PAKUVA record was not available despite the patient having been admitted to PACU, the data was reported as missing.

Grading	Definition
Grade 1	Saknar betydelse för post op omhändertagande; No consequence for postoperative care.
Grade 2	Påverkar omhändertagandet post op på UVA men saknar betydelse för fortsatt vård; Affects the postoperative care on PACU but does not have consequences for continued care
Grade 3	Påverkar omhändertagandet post op på vårdavdelning med förlängt omhändertagande och/eller fortsatt speciell observation; Affects the postop care at the hospital ward requiring extended care and/or continued special observation
Grade 4	Påverkar omhändertagandet så att intensivvård krävs postoperativt; Affects postoperative care so that intensive care is required
Grade 5	Medför sannolikt bestående skada eller död; Likely to result in permanent injury or death

Table 1: Grading definitions

Data management

Data from SPOR was entered in Excel as binary data for each analyzed complication. The complication grading was retrieved in a blinded fashion and reported alongside the complication. This data was then matched with the data extracted by the independent censor.

Statistical analysis

The concordance between the SPOR data and the censor assessment were assessed using Cohen's kappa. A kappa value of 1 indicates full agreement and a value of 0 indicates no agreement (table 2). Descriptive and kappa statistics were performed with IBM SPSS Statistics for Macintosh, Version 25.0. IBM Corp., Armonk, NY).

Kappa	Agreement
<0.20	Poor
0.21-0.40	Fair
0.41-0.60	Moderate
0.61-0.80	Good
0.81-1.00	Very good

Table 2: *The Altman scale for interpretation of kappa values.*

Cohen's kappa statistic is a method used to measure agreement among two observers. This may also be evaluated as percent agreement, calculated as agreement scores divided by the total number of scores. The advantage of the kappa statistic is that it also takes into account the probability of chance agreement. Although Cohen's Kappa is one the most common statistical methods to assess interrater reliability it has limitations that are important to be aware of.(10)

The Cicchetti paradox highlights that for high values of concordance, low values of kappa can be recorded if the marginal values of the 2x2 tables are very asymmetrical. The paradox appears because the kappa value is dependent of the chance agreement value (P_e in the formula below). The larger the chance agreement value, the smaller the kappa. Chance agreement is in turn dependent on the distribution of the reported values. Therefore kappa can be low when data is unevenly distributed as it is in this study.(11) The kappa values in table 6a and 6b should be interpreted with caution and not without comparing the number of reported complications for censor and user respectively and together.

$$k = \frac{(P_0 - P_e)}{(1 - P_e)}$$

Nevertheless, the Cichetti paradox cannot account for the poor concordance between censor and users in this study. As shown in table 4, concordance is very poor for both PAKOP and PAKUVA with a tendency to under-report complications.

Ethical considerations

The project was carried out in the context of clinical follow-up and quality improvement on behalf of the Department of Anesthesia at Linköping University Hospital thus, no ethical license was needed. We complied with the principles of the Good Clinical Practice Guidelines and the Swedish Patient Data Act (SFS 1998:204).

Results

414 surgical procedures were included in this validation study. 330 PACU stays were included. Three of them had missing PACU records which resulted in no censor assessment being made and the data was reported as missing.

The median patient age was 63 years and the interquartile range was 37-89 years. The most common ASA-class was ASA 2 (50.2%). Of the registered PAKOP cases, 55% were registered with at least one complication by the censor compared to 15% registered with at least one complication by the user. As for the PAKUVA cases, 33% were registered with at least one complication by the censor compared to 10% registered by the user. Patient characteristics are reported in table 3.

55% of the procedures had one or more complication occurring intraoperatively. In the corresponding user data, only 15% of the procedures had one or more complication. A kappa value of 0.233 indicates fair agreement. For PAKUVA, the censor reported one or more complication in 33% of cases and the user reported one or more complication in 10% of cases. Kappa value of 0.248 indicates fair agreement (table 2, table 4).

The incidence of the 11 predefined PAKOP complications and 13 predefined PAKUVA complications were 354 and 140 respectively. The most common intraoperative complication was hypotension occurring in 35.7% of all cases, followed by hypothermia (35.3%) and bradycardia (10.4%). For complications occurring immediately after surgery at the PACU, the most common observation was bradycardia (12.1%), followed by pain on arrival (10.9%) and hypotension (10.3%). The kappa values can't be calculated the one variable is considered a constant i.e. if no complications were reported, hence "ND" in tables 5a and 5b (table 5a and 5b).

Severity gradings were generally of grades 1-2, with 96.6% of PAKOP complications and 94.3% of PAKUVA complications within this category. Severe complications requiring ICU admission were rare (2 cases). There were no deaths in this cohort (table 6). The user generally graded complications higher than the censor of this study. This was true for both PAKOP and PAKUVA (table 7a and 7b).

Generally, the reporting of complications into PAKOP and PAKUVA is poor at Linköping University Hospital. The frequency of PAKOP complications reported by users to the SPOR registry was only 15% compared to 55% when assessed by the censor, with a κ -statistic of 0.233. The corresponding frequencies for PAKUVA complications were 10% for the user, and 33% for the censor, $\kappa=0.248$. Thus agreement is very poor. This was especially true for the more common complications like hypotension and bradycardia both intraoperatively and postoperatively (tables 5a and 5b). This degree of underreporting is alarming and could be a consequence of unclear definitions of variables, lack of time, reporting staff not having sufficient knowledge about the SPOR database, among other things. Another reason for underreporting is poor awareness of the types of variables collected and why they are collected. Staff may perceive SPOR-reporting as extra work without understanding why data are collected and their consequences. An example of this are cases where hypothermia but not hypotension are reported, even though both complications occurred with similar frequencies during surgery. The reporting staff put time and effort into reporting hypothermia but did not report hypotension alongside with it. The more frequent reporting of intraoperative hypothermia compared to hypotension could be due to a 'hypothermia quality improvement' drive at the Department of Anesthesia in 2017. Nevertheless, the reporting of this variable is still poor in general. Another possible, and concerning reason for underreporting, may be the fact that many adverse events occur so commonly that they are accepted as being a 'normal' part of perioperative care.

Although underreporting was generally widespread, there were a few cases where more complications were reported by the user than by the censor. This may be due to insufficient documentation in the operative and PACU records that did not allow the censor to extract data. For example, one patient received adrenalin without any preceding event being reported. In this case, the censor could not report ‘anaphylaxis’ because it was impossible to know why the patient received adrenalin. Another example is reporting of the PAKUVA variable “pain on arrival”. Very often the PACU documentation just consisted of “pain” without any record of the NRS value, which is required to be able to report pain on arrival in SPOR (table 8b).

Patient characteristics	
Age, median (IQR), y	63 (37-89)
ASA physical status class, No. (%)	
1	95 (22.9)
2	208 (50.2)
3	104 (25.1)
4	7 (1.70)
5	0 (0)
Type of surgery, No.	
Operationer på nervsystemet - Surgery on the nervous system	59
Operationer på endokrina organ – Surgery on endocrine organs	8
Operationer i ögonregionen – Surgery in the eye region	29
Operationer på öron, näsa, mun, svalj och hals – Surgery on ear, nose and throat	17
Operationer på bröstvägg och bröstkörtlar – Surgery on chest wall and mammary glands	9
Operationer på gastrointestinalkanalen – Surgery on the GI tract	35
Operationer på levern – Sugery on the liver	9
Operationer på gallvägarna – Surgery on the biliary tract	16
Operationer på pancreas – Surgery on the pancreas	10
Operationer på urinvägar och njurar – Surgery on the urinary tract and kidneys	18
Operationer på manliga könsorgan – surgery on male genitals	14
Operationer på kvinnliga könsorgan – surgery on female genitals	39
Obstetriska ingrepp – Obstetric interventions	9
Operationer på kotpelaren och nacken – Surgery on the vertebral column and neck	10
Operationer på övre extremiteten – Surgery on the upper extremity	25
Operationer på höftleder och lår – Surgery on hip joints and thighs	25
Operationer på nedre extremiteten – Surgery on the lower extremity	15
Operationer på perifera kärl och lymfsystemet – Surgery on peripheral vessels and the lymphatic system	8
Åtgärder på huden – Interventions on the skin	27
Transluminal endoskopi – Transluminal endoscopy	17
Diagnostiska åtgärder – Diagnostic procedures	11
Transplantater, lambåer och vävnadsexpandrar – Grafts, flaps and tissue expanders	4
Duration of surgery, median (IQR), min	81 (99)
Urgency of surgical procedure, No.	
Elective (%)	246 (59.4)
Urgent (%)	168 (40.6)
Emergency (% of urgent procedures)	5 (3.0)
Within 2 hours (% of urgent procedures)	18 (10.7)
Within 6 hours (% of urgent procedures)	41 (24.4)
Within 24 hours (% of urgent procedures)	76 (45.2)
Within >24 hours (% of urgent procedures)	28 (16.7)
Male, No. (%)	180 (43.5)

Table 3: Patient characteristics. Abbreviations: IQR, interquartile range; ASA, American Society of Anesthesiologists.

	Censor	User	Kappa value
PAKOP, No. (%)	228 (55.07)	62 (14.98)	0.233
PAKUVA, No. (%)	110 (33.33)	32 (9.69)	0.248

Table 4: Procedures with one or more registered complication in PAKOP and PAKUVA for censor and user respectively.

Complication	Definition	Censor	User	Registered by both	Frequency censor	Kappa value
A111	Svår intubation Difficult intubation	6	2	1	1.4	0.245
A126	Hypoxi Hypoxia	0	3	0	0.0	ND
A219	Hjärtstopp Cardiac arrest	0	0	0	0.0	ND
A222	Hypotension	148	12	10	35.7	0.075
A216	Arytmi Arrhythmia	1	0	0	0.02	ND
A215	Bradykardi Bradycardia	43	2	2	10.4	0.08
A311	Anafylaxi Anaphylaxis	1	4	1	0.2	0.398
A312	Allergi Allergy	0	0	0	0.0	ND
A315	Hypotermi Hypothermia	146	51	49	35.3	0.346
A515	Luftvägsskada Airway injury	1	0	0	0.2	ND
A921	Smärta väckning Pain on awakening	8	1	1	1.9	0.219

Table 5a: Number and frequency of registered PAKOP complications, and kappa values. Abbreviations: ND, no data.

Complication	Definition	Censor	User	Registered by both	Frequency censor	Kappa-value
U105	Tandskada Dental injury	0	0	0	0.0	ND
U111	Hypoxi Hypoxia	11	6	1	3.3	0.113
U122	Aspiration	0	0	0	0.0	ND
U202	Bradykardi Bradycardia	40	1	1	12.1	0.042
U203	Arytmi Arrhythmia	1	0	0	0.3	ND
U207	Hjärtstopp Cardiac arrest	0	0	0	0.0	ND
U221	Hypotension	34	4	4	10.3	0.209

U223	Anafylaxi Anaphylaxis	0	0	0	0.0	ND
U301	Smärta ankomst Pain on arrival	36	14	9	10.9	0.322
U302	Smärta svår Severe pain	7	6	1	2.1	0.134
U312	Illamående svår Severe nausea	1	3	1	0.3	0.665
U511	Överfylld blåsa Overfilled urinary bladder	10	5	4	3.0	0.522
U924	Rutinavvikelse Deviation for local procedures and routines	0	0	0	0.0	ND

Table 5b: Number and frequency of registered PAKUVA complications, and kappa values. Abbreviations: ND, no data.

Grade	PAKOP, No. (%)	PAKUVA, No. (%)
1	301 (85.0)	54 (38.6)
2	41 (11.6)	78 (55.7)
3	10 (2.8)	8 (5.7)
4	2 (0.6)	0 (0.0)
5	0 (0.0)	0 (0.0)

Table 6: Censor-registered severity gradings

	Grade 1		Grade 2		Grade 3		Grade 4		Grade 5	
	Censor	User								
A111	1	1	0	0	0	0	0	0	0	0
A126	0	0	0	0	0	0	0	0	0	0
A219	0	0	0	0	0	0	0	0	0	0
A222	4	6	4	3	2	1	0	0	0	0
A216	0	0	0	0	0	0	0	0	0	0
A215	1	1	0	0	0	1	1	0	0	0
A311	0	0	1	1	0	0	0	0	0	0
A312	0	0	0	0	0	0	0	0	0	0
A315	48	45	1	4	0	0	0	0	0	0
A515	0	0	0	0	0	0	0	0	0	0
A921	0	0	1	1	0	0	0	0	0	0

Table 7a: Grading by censor and user of individual PAKOP complications, where they have been registered by both censor and user.

	Grade 1		Grade 2		Grade 3		Grade 4		Grade 5	
	Censor	User								
U105	0	0	0	0	0	0	0	0	0	0
U111	0	0	1	1	0	0	0	0	0	0
U122	0	0	0	0	0	0	0	0	0	0
U202	0	1	1	0	0	0	0	0	0	0
U203	0	0	0	0	0	0	0	0	0	0
U207	0	0	0	0	0	0	0	0	0	0
U221	0	0	4	2	0	2	0	0	0	0
U223	0	0	0	0	0	0	0	0	0	0
U301	0	1	9	5	0	3	0	0	0	0
U302	0	0	1	1	0	0	0	0	0	0
U312	0	0	0	0	1	1	0	0	0	0
U511	0	0	3	2	1	2	0	0	0	0
U924	0	0	0	0	0	0	0	0	0	0

Table 7b: Grading by censor and user of individual PAKUVA complications, where they have been registered by both censor and user.

Discussion

Intraoperative complications

The PAKOP complications assessed in this validation study were chosen after requests from the clinic. The clinic was interested in the ten most commonly reported complications: hypothermia, hypotension, hypovolemia, bradycardia, electrolyte imbalance, anaphylaxis, hypoxia, difficult intubation, change of anesthetic method and pain on awakening. Hypovolemia, electrolyte imbalance and change of anesthetic method were excluded due to the difficulties in assessing those complications from medical charts as they require extensive documentation of clinical findings, which are often missing. Instead cardiac arrest, arrhythmia, allergic reaction and airway injury were included.

Intraoperative hypotension was the most common complication found by the censor and is very seldom reported by the user (table 5a). This may be because hypotension is often considered 'normal' during surgery and complications do not occur immediately. A growing body of evidence reveals that intraoperative hypotension is associated with dysfunction of vital organs, in particular the kidneys and the heart. Acute kidney injury occurs in 7.5% of patients who undergo non-cardiac surgery.(12) Myocardial injury manifested as an acute increase in cardiac biomarker concentration occurs in 11.6% of patients undergoing non-cardiac surgery.(13)

Intraoperative hypotension deserves a special mention due to its frequency and degree of underreporting in the present study. Clinical evidence now show the deleterious effects of this complication, even at blood pressures that are widely perceived to be 'acceptable'.(14,15) A study conducted on more than 33000 patients determined that a mean arterial blood pressure (MAP) under 55 mmHg is associated with acute kidney injury and myocardial injury even for short durations of time.(16) Another study concluded that management targeting an individualized systolic blood pressure within 10% of the patient's preoperative resting systolic blood pressure reduced the risk of postoperative organ dysfunction in patients that were at increased preoperative risk compared with standard treatment.(17) Regardless of whether absolute or relative thresholds are used, data indicate that intraoperative and postoperative hypotension are deleterious and should be avoided. We suggest that the findings be considered as a prelude for a quality improvement initiative.

The degree of underreporting of intraoperative hypotension may be partly due to unclear definitions in PAKOP. Here, hypotension is defined as hypotension that causes unplanned,

continuous administration of a vasopressor drug, a definition that might lead to hypotension not being reported if hypotension is not recognized or if no treatment is initiated. Similarly, bradycardia is defined as bradycardia requiring a specific pharmacological treatment or altered anesthesiologic strategy. This definition could lead to confusion and cases with untreated bradycardia not being reported (table 8a).

Hypothermia was the second most common complication reported by the censor (table 5a). It has been noted that patients' internal temperature decreases during surgery due to the vasodilatory effect of anesthetic drugs, infusion of liquids at room temperature and increased heat loss through surgical incisions. Hypothermia is associated with delayed post anesthetic recovery, compromised circulation, ischemic cardiac events and increased risk of wound infection.(18,19) In SPOR, hypothermia is defined as unplanned hypothermia with body temperature under 36 degrees Celsius. The definition is very clear and should not lead to any misunderstandings in reporting. Still, only about 1/3 of the hypothermia complications were reported into SPOR by the user.

Postoperative complications

The PAKUVA complications were chosen after requests from the clinic, who wanted the registration of overfilled bladder, pain on arrival and severe pain assessed. The other complications were chosen because they are clinically relevant for the patient's long term survival.(4,5) Very little is known about complications occurring immediately after surgery, yet early sentinel events may herald later, more serious complications and have a large impact on the patients' health.(5) In one of the few papers evaluating immediate postoperative complications, Gamil and Fanning found that patients with major complications, defined as serious and potentially life-threatening and resulting in disability were preceded by unstable condition in the first 24 hours after surgery.(5)

In this report, the censor recorded a PAKUVA complication frequency at 33.3% with minor complications such as pain on arrival, bradycardia and post anesthesia nausea and vomiting being included. In addition, this study only includes events at the PACU and therefore misses serious events happening at the hospital ward. There is no previous literature to compare this incidence of complications with, however, it is in line with the incidence of postoperative complications reported by Gamil and Fanning and the recent, large International Surgical Outcomes Study.(5,20)

A previous PAKUVA internal validation study conducted by SPOR showed an incidence of complications at 51.0% for the censor. The corresponding rate for the present study is 33.3%. The most common complications reported in the previous study were pain on arrival and severe pain with an incidence of 15.2% and 10.8% respectively. Pain on arrival and severe pain occurred in 10.9% and 2.1% of cases in this study which could indicate a better pain management and reduced frequency of this complication at Linköping University Hospital compared with the hospitals included in the previous study. In addition, the previous validation study examined all PAKUVA complications whereas this study examined only 13 complications, which may also explain the lower incidence of PAKUVA complications in this study.(8)

Overall, different complication variables, different complication definitions and different observed time after surgery makes it difficult to compare incidence of postoperative complications between studies. With this taken into account, the complication rate observed in this study seems reasonable.

Grading of complications

Where complications were reported by the user, the gradings of the complications are generally concordant between censor and user for both PAKOP and PAKUVA (tables 7a and 7b). A reason for the few complications with higher grading registered by user than by censor could be the difficulties to assess treatment from medical charts. In a similar way the complications graded lower by the user than by the censor could be a consequence of the difficulties to know how the complication affects the treatment on the hospital ward.

Limitations

We selected a random sample of 4% of all procedures or in total 414 cases for review. This was a convenience sample given the time limitation of the project. We attempted to mitigate bias by selecting cases by random and by selecting a set proportion of cases within each surgical clinic. The censor was also blinded to SPOR entries and registered the complications independently.

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References

1. Årsrapport SPOR 2016 [Internet]. [cited 2018 May 30]. Available from: http://www.spor.se/wp-content/uploads/2016/01/Årsrapport-SPOR-2016_v2.0_final_170926-1.pdf
2. Neuman MD. The importance of validation studies in perioperative database research. *Anesthesiology* [Internet]. 2015 Aug [cited 2018 May 30];123(2):243–5. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/26200176>
3. Khuri SF. The Comparative Assessment and Improvement of Quality of Surgical Care in the Department of Veterans Affairs. *Arch Surg* [Internet]. 2002 Jan 1 [cited 2018 May 21];137(1):20. Available from: <http://archsurg.jamanetwork.com/article.aspx?doi=10.1001/archsurg.137.1.20>
4. Khuri SF, Henderson WG, DePalma RG, Mosca C, Healey NA, Kumbhani DJ, et al. Determinants of long-term survival after major surgery and the adverse effect of postoperative complications. *Ann Surg*. 2005;242(3):326–43.
5. Gamil A, Fanning A. The first 24 hours after surgery. A study of complications after 2153 consecutive operations. *Anaesthesia* [Internet]. 1991;46(January):712–5. Available from: <https://onlinelibrary-wiley-com.e.bibl.liu.se/doi/epdf/10.1111/j.1365-2044.1991.tb09761.x>
6. Variabellista - SPOR [Internet]. [cited 2018 Jun 23]. Available from: <http://www.spor.se/spor-for-dig-som/varavgivare-tekniker/uppdatera-registret/>
7. Rosso A. Validation of healthcare databases: why to do it and how to do it [Internet]. 2016. Available from: http://www.scb.se/Upload/NSM2016/theme4/C_3_Aldana_Rosso.pdf
8. Chew M, Lyckner S. Report PAKUVA validation 20151028. 2015.
9. Suresh K. An overview of randomization techniques: An unbiased assessment of outcome in clinical research. *J Hum Reprod Sci* [Internet]. 2011 Jan [cited 2018 Aug 27];4(1):8–11. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/21772732>
10. McHugh ML. Interrater reliability: the kappa statistic. *Biochem medica* [Internet]. 2012 [cited 2018 Jun 12];22(3):276–82. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/23092060>
11. Flight L, Julious SA. The disagreeable behaviour of the kappa statistic. *Pharm Stat* [Internet]. 2015 Jan [cited 2018 Jun 12];14(1):74–8. Available from: <http://doi.wiley.com/10.1002/pst.1659>
12. Abelha FJ, Botelho M, Fernandes V, Barros H. Determinants of postoperative acute kidney injury. *Crit Care* [Internet]. 2009 [cited 2018 May 21];13(3):R79. Available

- from: <http://www.ncbi.nlm.nih.gov/pubmed/19463152>
13. Devereaux P, Chan M, Alonso-Coello P, Walsh M. Association Between Postoperative Troponin Levels and 30-Day Mortality Among Patients Undergoing Noncardiac Surgery. *JAMA* [Internet]. 2012 Jun 6 [cited 2018 May 21];307(21):2295. Available from: <http://jama.jamanetwork.com/article.aspx?doi=10.1001/jama.2012.5502>
 14. Sessler DI, Meyhoff CS, Zimmerman NM, Mao G, Leslie K, Vásquez SM, et al. Period-dependent Associations between Hypotension during and for Four Days after Noncardiac Surgery and a Composite of Myocardial Infarction and Death. *Anesthesiology* [Internet]. 2018 Feb 1 [cited 2018 Aug 23];128(2):317–27. Available from: <http://insights.ovid.com/crossref?an=00000542-201802000-00020>
 15. Salmasi V, Maheshwari K, Yang D, Mascha EJ, Singh A, Sessler DI, et al. Relationship between Intraoperative Hypotension, Defined by Either Reduction from Baseline or Absolute Thresholds, and Acute Kidney and Myocardial Injury after Noncardiac Surgery. *Anesthesiology* [Internet]. 2017 Jan 1 [cited 2018 Aug 23];126(1):47–65. Available from: <http://insights.ovid.com/crossref?an=00000542-201701000-00017>
 16. Walsh M, Devereaux PJ, Garg AX, Kurz A, Turan A, Rodseth RN, et al. Relationship between Intraoperative Mean Arterial Pressure and Clinical Outcomes after Noncardiac Surgery. *Anesthesiology* [Internet]. 2013;119(3):507–15. Available from: <http://insights.ovid.com/crossref?an=00000542-201309000-00010>
 17. Futier E, Lefrant J, Guinot P, Al E. Effect of individualized vs standard blood pressure management strategies on postoperative organ dysfunction among high-risk patients undergoing major surgery: A randomized clinical trial. *Jama* [Internet]. 2017;318(14):1346–57. Available from: <http://dx.doi.org/10.1001/jama.2017.14172>
 18. Costanzo S, Cusumano A, Giaconia C, Mazzacane S. A proposed methodology to control body temperature in patients at risk of hypothermia by means of active rewarming systems. *Biomed Res Int* [Internet]. 2014 [cited 2018 Jun 13];2014:136407. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25485278>
 19. Reynolds L, Beckmann J, Kurz A. Perioperative complications of hypothermia. *Best Pract Res Clin Anaesthesiol* [Internet]. 2008 [cited 2018 Jun 13];22(4):645–57. Available from: <http://www.sciencedirect.com>
 20. The International Surgical Outcomes Study group. Global patient outcomes after elective surgery: prospective cohort study in 27 low-, middle- and high-income countries. *Br J Anaesth* [Internet]. 2016;117(5):601–9. Available from: <https://academic.oup.com/bja/article-lookup/doi/10.1093/bja/aew316>

Appendix

Event/complication	Definition
A111	Oväntat svår intubation; innebär > 2 intubationsförsök av individ med adekvat kompetens, eller intubation av en andra tillkallad anestesilog/specialistläkare. Unexpected difficult intubation; >2 intubation attempts by competent operator, or intubation by another anesthetist requested to assist with the procedure
A126	Hypoxi som kräver terapeutisk åtgärd t ex ökat FiO ₂ ; hypoxi= SpO ₂ < 90%. Hypoxia requiring therapy, eg. increased FiO ₂ . Hypoxia=SpO ₂ <90%
A219	Hjärtstopp, asystoli eller arytmi som föranleder A-HLR. Cardiac arrest, asystole or arrhythmia requiring CPR
A222	Hypotension som föranleder oplanerad, kontinuerlig tillförsel av vasopressordrog. Hypotension requiring unplanned, continuous infusion of vasopressors
A216	Arytmi, här anges annan arytmi som kräver specifik farmakologisk behandling eller ändrad anesthesiologisk strategi. Arrhythmia requiring specific pharmacological therapy or change of anaesthetic strategy
A215	Bradykardi, här anges bradykardi som kräver specifik farmakologisk behandling eller ändrad anesthesiologisk strategi. Bradycardia requiring specific pharmacological therapy or change of anaesthetic strategy
A311	Anafylaxi. Anaphylaxis
A312	Allergiska reaktioner utöver anafylaxi som föranleder specifik åtgärd. Allergic reactions (not anaphylaxis) requireing specific treatment
A315	Hypotermi, oplanerad med kroppstemperatur < 36 grader. Hypothermia, unplanned with body temperature <36 degrees
A515	Luftvägsskada, avser slemhinneskada övre luftväg. Respiratory tract injury, refers to mucus membrane injury in upper respiratory tract
A921	Smärta vid väckning som medför behov av intravenös analgesi inom 15 min efter väckning (avser ej profylaktisk upptitrering av analgetika). Pain on awakening requiring intravenous analgesia within 15 minutes after awakening (does not refer to prophylactic titration of analgesics)

Table 8a: Complication codes and definitions for PAKOP – complications occurring intraoperatively

Event/Complication	Definition
U105	Tandskada: tandskada som upptäcks postoperativt. Dental injury that is detected postoperatively
U111	Hypoxi: Förekomst av SaO ₂ eller SpO ₂ ≤90% och/eller PaO ₂ ≤8 kPa på luftandning, oavsett premorbid tillstånd. Occurrence of SaO ₂ or SpO ₂ ≤90% and/or PaO ₂ ≤8 kPa on breathing room air, regardless of premorbid condition.
U122	Aspiration: Inandning av maginnehåll. Aspiration: inhalation of stomach contents
U202	Bradykardi: Hjärtfrekvens ≤50 slag per minut oavsett genes. Bradycardia: Heart rate ≤50 beats per minute regardless of origin.
U203	Arytmi: Nyttillkomna störningar i hjärtrytmen. Arrhythmia: New disturbances in the heart rhythm
U207	Hjärtstopp. Cardiac arrest.
U221	Hypotension: MAP ≤55 och/eller SBP ≤90 oavsett tid. Hypotension: MAP ≤55 and/or SBP ≤90 regardless of duration.
U223	Anafylaxi: Snabbt insättande systemisk överkänslighetsreaktion som medför behandling med adrenalin. Anaphylaxis: Rapid systemic hypersensitivity reaction requiring treatment with adrenaline
U301	Smärta svår vid ankomst: 6 eller mer i VAS/NRS noterat inom 60 minuter från ankomst till postoperativavdelning. Pain on arrival: 6 or more in VAS/NRS noted within 60 minutes of arrival to the PACU.
U302	Smärta svår: 6 eller mer i VAS/NRS som mest på postop i vila eller rörelse. Svårt att smärtbehandla. Oplanerat byte av smärtmetod t.ex. iv, PCA, blockad, annat. Severe pain: 6 or more in VAS/NRS at the PACU, at rest or movement. Difficult to treat. Unplanned change in analgesic method e.g. iv, pca, blockade, other.
U312	Illamående svår: Terapieresistent, där behandling med minst 3 preparat (inklusive förebyggande) inte hjälpt. Severe nausea: Therapy resistant, where treatment with at least 3 drugs (including prevention) did not help.
U511	Överfylld blåsa: Urinretention eller blåstamponad med överfylld blåsa/blåsdistention ≥500ml Overfilled bladder: Urine retention with overfilled bladder ≥500ml
U924	Pre-, per- och post-op rutinavvikelse: Avsteg från befintlig rutin som medicinsk påverkat den postoperativa vården. Pre-, per- and post-op routine deviation: Deviation from existing routine that has medically affected post-operative care

Table 8b: Complication codes and definitions for PAKUVA – complications occurring postoperatively on PACUs.