Statistical process control methods allow the analysis and improvement of anesthesia care

[Les méthodes de contrôle statistique du processus permettent d'analyser et d'améliorer les soins anesthésiques]

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Purpose: Quality aspects of the anesthetic process are reflected in the rate of intraoperative adverse events. The purpose of this report is to illustrate how the quality of the anesthesia process can be analyzed using statistical process control methods, and exemplify how this analysis can be used for quality improvement.

Methods: We prospectively recorded anesthesia-related data from all anesthetics for five years. The data included intraoperative adverse events, which were graded into four levels, according to severity. We selected four adverse events, representing important quality and safety aspects, for statistical process control analysis. These were: inadequate regional anesthesia, difficult emergence from general anesthesia, intubation difficulties and drug errors. We analyzed the underlying process using 'p-charts' for statistical process control.

Results: In 65,170 anesthetics we recorded adverse events in 18.3%; mostly of lesser severity. Control charts were used to define statistically the predictable normal variation in problem rate, and then used as a basis for analysis of the selected problems with the following results:

- Inadequate plexus anesthesia: stable process, but unacceptably high failure rate;
- Difficult emergence: unstable process, because of quality improvement efforts;
- Intubation difficulties: stable process, rate acceptable;
- Medication errors: methodology not suited because of low rate of errors.

Conclusion: By applying statistical process control methods to the analysis of adverse events, we have exemplified how this allows us to determine if a process is stable, whether an intervention is required, and if quality improvement efforts have the desired effect.

Objectif : La qualité du processus anesthésique se vérifie par le taux d'événements peropératoires indésirables. Nous avons voulu illustrer comment analyser la qualité de l'anesthésie en utilisant les méthodes de contrôle statistique du processus et comment cette analyse peut améliorer la qualité.

Méthode : Nous avons prospectivement recueilli des données anesthésiques sur cinq ans. Elles comprenaient des événements indésirables, classés selon quatre niveaux de sévérité. Nous avons sélectionné quatre événements indésirables qui représentent des aspects importants de la qualité et de la sécurité pour l'analyse du contrôle statistique du processus. Il s'agissait : de l'anesthésie régionale inadéquate, du retour à la conscience difficile après une anesthésie générale, des difficultés d'intubation et des erreurs de médicaments. Nous avons analysé le processus d'origine à l'aide des "graphiques-p" pour le contrôle statistique du processus.

Résultats : Pour 65 170 anesthésies réalisées, nous avons noté des événements indésirables dans 18,3 % des cas, la plupart bénins. Nous avons utilisé les graphiques de contrôle pour définir statistiquement la variation prévisible normale du taux de problème et, ensuite, l'utiliser comme base de l'analyse des problèmes sélectionnés. Les résultats sont les suivants :

- Anesthésie régionale inadéquate : processus stable, mais taux d'échec élevé inacceptable.
- Réveil difficile : processus instable à cause des efforts d'amélioration de la qualité.
- Difficultés d'intubation : processus stable, taux acceptable.
- Erreurs de médicaments : méthodologie inappropriée à cause du faible taux d'erreurs.

Conclusion : En appliquant le contrôle statistique du processus à l'analyse d'événements indésirables, nous avons montré comment il permet de déterminer si un processus est stable, si une intervention est nécessaire et si les efforts d'amélioration de la qualité ont produit les effets recherchés.

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QUALITY can be achieved by evaluating and improving production processes, or service delivery. The quality of the anesthetic process can in part be evaluated by the occurrence of adverse events during anesthesia. However, as anesthetic mortality and serious morbidity are becoming exceedingly rare, such an analysis is of limited value. An alternative recommended approach is to study a broader range of adverse events, which are less severe and more frequent, but which still contain a potential for accidents.^{1,2}

Conclusions drawn from simple 'snap-shot' measurements of the frequency of adverse events are, however, not useful unless the characteristics of the underlying process is understood.³ Statistical tools, such as process control methods, may be applied to make inferences about process performance.

We have established a system for mandatory routine reporting of adverse events during anesthesia.⁴ This investigation is intended to demonstrate the application of statistic process control methods to such data. These methods enable us to distinguish between natural variability and significant changes in the anesthetic process, and to continuously evaluate different aspects of anesthetic process quality. To exemplify this, we have analyzed four selected adverse events which reflect different aspects of quality and safety of anesthetic practice.

Methods

We have established a system for routine data recording during anesthesia.⁴ The standard anesthetic record includes specific data fields, all of which must be completed at the end of the case. The fields are checked for completeness and accuracy by a consultant anesthesiologist (SF or SEG), before data are entered into a database. Missing data are provided either from information on the chart, or by the attending anesthesiologist. A copy of the anesthetic chart is stored.

The data field for 'intraoperative adverse events' includes a list of 22 common anesthetic problems (Appendix I, available as additional material at www.cja-jca.org), as well as a field for severity.⁴ Other data fields on the chart relate to the patient, the operation, type of anesthetic, and timing of events.

An intraoperative adverse event is defined as an event which requires one or more measures - either to prevent further complications, or to treat a situation that is currently or potentially serious, and which does not routinely occur during the conduct of anesthesia. The events are graded according to severity: 'grade 1' is a trivial problem, easily dealt with and not affecting the patient's condition; 'grade 2' indicates moderate

difficulty, with some effect on the patient, but of a minor severity; 'grade 3' is a serious event which is difficult to manage, or causing a serious deterioration in the patient's state, and which may or may not have consequences for the patient postoperatively; 'grade 4' events imply a fatal outcome.

Our department at the Trondheim University Hospital (930 beds, annual admission rate 43,000 patients) delivers 17,500 anesthetics per year, and most types of surgery are performed. The anesthesiologist works in cooperation with a qualified nurse anesthetist, who has 18 months postgraduate education plus 12 months practical training in anesthesia. The adverse events are coded and graded jointly by the anesthesiologist and the nurse.

Data were retrieved from the department database for the years 1997–2001. All general and regional anesthetics (spinal, epidural, plexus) were included, except those involving patients under 16 yr and cardiac anesthesia cases. This represented a total of 65,170 cases. In 661 cases, an initial regional anesthetic was converted to a general anesthetic, mainly because of inadequate analgesia. Adverse events in these cases were ascribed to regional or general anesthesia depending on the type of event.

We analyzed the type, occurrence, and severity of intraoperative adverse events.

To evaluate different aspects of the anesthetic process, we selected four intraoperative adverse events, of relevance to anesthetic quality and safety. Their occurrences were analyzed using 'control chart analysis', a statistical process control method. The events chosen were: inadequate analgesia during brachial plexus block, emergence from general anesthesia, intubation problems, and medication errors.

Inadequate analgesia during brachial plexus block, insufficient for surgery, must be supplemented with large doses of *iv* analgesics or converted to general anesthesia. The failure rate for such blocks reflects one aspect of service quality in regional anesthesia.

Emergence from general anesthesia may be associated with life threatening problems with the airway or circulation during awakening. The rate of these problems reflects aspects of the quality of our work during the critical phase of awakening, re-establishment of reflexes and spontaneous ventilation. We addressed our problems during emergence in the first quarter of 1999 as their occurrence was found to be unacceptably high. We found that the problems most likely were due to residual drug effect, or misjudgment of the patient's respiratory status before extubation. Educational department meetings focused on preventive strategies, including the use of opioids and neuro-

TABLE I Patient characteristics - 65,170 anesthetics

	<i>Regional anesthesia</i>		<i>General anesthesia</i>		<i>Total</i>	
Anesthetics (<i>n</i>)	20,083		45,087		65,170	
Age (yr, mean $\pm$ SD)	59.3 $\pm$ 19.9*		45.7 $\pm$ 18.8		49.9 $\pm$ 20.2	
Sex (male/female, %)	48 / 52		39 / 61		42 / 58	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Types of surgery						
General surgery	4,561	22.6	15,505	34.4	20,066	30.8
Orthopedic surgery	12,902	64.2	10,867	24.1	23,769	36.5
Neurosurgery	17	0.1	3,564	7.9	3,581	5.5
Gynecology/obstetrical surgery	1,973	9.8	12,284	27.2	14,257	21.9
Other	630	3.1	2,867	6.4	3,497	5.4
ASA physical status*						
ASA 1	4,783	23.8	12,967	28.8	17,750	27.2
ASA 2	9,079	45.2	22,836	50.6	31,915	49.0
ASA 3	5,434	27.1	7,237	16.1	12,671	19.4
ASA 4	778	3.9	1,906	4.2	2,684	4.1
ASA 5	9	0.0	141	0.3	150	0.2

Age and American Society of Anesthesiologists (ASA) status was higher in regional than general anesthesia (* $P < 0.001$). SD = standard deviation.

TABLE II Adverse events, by severity of event and type of anesthesia

<i>Severity</i>	<i>General anesthesia</i>		<i>Regional anesthesia</i>		<i>Total</i>	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Grade 1	5,847	13.0	2,718	13.5	8,565	13.1
Grade 2	1,946	4.3	1,084	5.4	3,030	4.6
Grade 3	225	0.5	41	0.2	266	0.4
Grade 4	40	0.1	---	---	40	0.1
All events	8,058	17.9	3,843	19.1	11,901	18.3

muscular blocking drugs. At that time, we changed from long- to intermediate-acting muscular relaxants.

Intubation problems can have catastrophic outcomes. We studied grade 2 and 3 problems, i.e., severe or moderately severe. These are caused in part by patient factors (anatomy), and in part by anesthetic factors, including failure to recognize anatomical signs of difficult intubation, choice of intubation techniques, and their correct use. The frequency of intubation problems thus reflects aspects of both patient safety and anesthetic quality.

Medication errors also reflect a quality aspect of our service. We have previously shown these to be rare in our department,⁵ and therefore we increased the sampling period for these events to three months. The chart exemplifies the difficulties related to charting rare events, and their use as quality indicators.

Statistical methods

We charted the occurrence of adverse events during a defined time interval (bi-monthly or tri-monthly), the

rate being the number of adverse events per hundred anesthetics. The rate of adverse events is expected to vary from period to period. This demonstrates the 'natural' variation caused by the random combination of many different causes, e.g., time of day, the patient's physical condition, methods used, and working routines. It represents 'the systemic variation inherent as a regular part of the process' and characterizes a 'stable' process.⁶

'Unnatural' variations, on the other hand are observations that are very unlikely to occur within a 'stable' process. They characterize the 'unstable' process, and are usually presumed to represent special events or deviations from the regular process.

The frequency of adverse events during the defined time intervals were compared to the average of the entire 1997–2001 period in a 'control chart', used for statistical process control.^{6–9} The control chart used was a 'p-chart', where each data point expresses the proportion (percent) of cases with adverse events in a given interval. It also includes probability limits for

'natural' process variation. These were calculated from the binomial-based standard deviation (SD) of proportions [$SD = \sqrt{p(1-p)/n}$], where 'p' was the long-time average proportion of events, and 'n' the number of cases in the interval. The 'upper/lower control limits' for natural variability were set to ± 3 SD from the long-time average, in accordance with recommendations from the literature.^{7,9} We used normal distribution as an approximation to the binomial-probability distribution, which is acceptable when 'n' is large and 'p' is low.¹⁰ Consequently the likelihood for data points within these 3 SD limits to represent natural variability is high ($P = 0.9973$).

Observations beyond the 3 SD 'control limits' are unlikely to occur within an unchanged process ($P = 0.0027$), and probably represent 'unnatural variation'. Numerous supplementary tests for 'out of control' based on other statistical calculations have been suggested, for example nine or more successive points on the same side of the average, or 12 of 14 consecutive points on the same side of the average.⁷⁻⁹

Whether the process is in statistical control (stable) or not in control (unstable) determines what kind of action is appropriate to improve the process. To improve a 'stable process' the regular underlying factors included in the process must be changed. In an 'unstable' process the new special causes must be identified and removed from the regular process.

Age was compared using t test. American Society of Anesthesiologists (ASA) physical status class using Wilcoxon Rank-sum test. We used a Chi-square test for categorical data. Values of $P < 0.05$ were considered statistically significant.

Results

Patient characteristics (Table I)

Sixty-five thousand, one hundred and seventy anesthetics were given, 30.8% regional, and 69.2% general anesthetics. Patients receiving regional anesthesia were older and of higher ASA physical status than the others. The main regional techniques were spinal or combined spinal/epidural anesthesia (84.1% of cases), and the main type of airway management in general anesthetics was endotracheal intubation (62.3% of cases).

Recorded adverse events (Table II, Appendix II)

Table II presents the rate and severity of adverse events. The overall frequency was 18.3%, and was greater during regional anesthesia (19.1%) than general anesthesia (17.9%; $P < 0.001$). However, serious events (grades 3 and 4) occurred more often during general anesthesia (0.6%), than during regional anesthesia (0.2%; $P < 0.001$).

The frequencies of specific adverse events during general and regional anesthesia are presented in Appendix II (available as additional material at www.cja-jca.org). Circulatory events dominated, hypotension being most common. During general anesthesia - hypotension apart - the most common problems were difficult emergence from anesthesia, intubation difficulties, bleeding and arrhythmia. During regional anesthesia - hypotension apart - inadequate analgesia and arrhythmia (mostly severe bradycardia) dominated.

Use of control charts (Figures 1, 2a, 2b; Appendices III-IV)

These control p-charts show the recorded variation in rate of the selected problems, and illustrate how charting of adverse events can be used as a technique for statistical process control.

Figure 1 shows 'inadequate analgesia' during regional brachial plexus block as a control-chart. Of 2,228 blocks, 358 were recorded as inadequate (16.1%). The variability between bimonthly periods was from 26% to 8%. The process is statistically stable, as no points are outside 'control limits'.

Figure 2a shows a control chart of the difficulties during emergence from general anesthesia. There were 1,123 cases among 45,087 general anesthetics (2.5%), and the variation ranged between 3.85% and 1.25%. There is a trend towards a decrease in difficult emergence during the years 1997-2001. The process is statistically unstable, with points outside or at the control limits both at the beginning and towards the end of the time period. In addition, 12 of 14 consecutive points are on the same side of the centre line both at the start and at the end of the study period, indicating an unstable process, influenced by special causes.⁷⁻⁹ We addressed our problems with emergence in early 1999. In Figure 2b the data points are treated as two different processes, before and after the intervention. They present as two different stable processes, with a lower mean value in the second time period. If the rates of the two periods are compared, there was a decrease in adverse events after the intervention (613 events/20,540 cases) *vs* (510 events/24,547 cases; $P < 0.001$).

The chart of intubation difficulties is presented in Appendix III (available as additional material at www.cja-jca.org). There were 429 grade 2 and 3 problems within 28,081 intubations (1.5%), and the variation was between 0.52% and 2.20%. The process is statistically stable, as there were no points outside the control limits or any trends to either side of the long time mean.

FIGURE 1 Control p-chart showing the rate of inadequate brachial plexus blocks. Data points (O) are bimonthly percentages. UCL = upper control limit; LCL = lower control limit.

The chart of 'drug/medication errors' is presented in Appendix IV (available as additional material at www.cja-jca.org), with three-monthly time periods. There were 81 drug errors in 65,170 anesthetics (0.12%), with a variation from 0.03% to 0.25%. The process is stable, as no points are outside the control limits. Note that the 'lower control limits' are not applicable, as the limit calculation returns negative numbers.

Discussion

Our system for routine recording of adverse events is based on the assumption that non-fatal adverse events are useful indicators of the quality of the anesthetic process and predictors of possible morbidity. We have shown how the rate of adverse events can be analyzed for quality purposes by the application of statistical process control methods. The determination of process stability or instability indicates what type of action is required to improve the process, and if new data points are part of an unchanged process or not. We also supply an overview of rates of adverse events, as recorded in our system.

Why is it important to record near misses?

Since anesthetic mortality and serious morbidity occur infrequently, they have limited value as indicators of quality in single institutions.^{1,11-13} Alternatively, one may include a broader range of less serious but more frequent events.^{1,2,11,14} Such minor intraoperative anesthesia-related events have been said to be irrelevant, being merely 'surrogate outcomes' for 'real'

FIGURE 2A Control p-chart showing the rate of difficult emergence from general anesthesia. Data points (O) are bimonthly percentages. UCL = upper control limit. LCL = lower control limit.

FIGURE 2B Control p-chart showing the rate of difficult emergence from general anesthesia separated in two processes; before and after intervention. Data points (O) are bimonthly percentages. UCL = upper control limit. LCL = lower control limit.

postoperative morbidity,¹⁵ but have been shown to influence postanesthesia care.¹⁶ Previously, in our subgroup of serious non-fatal intraoperative events (grade 3),¹⁷ one third led to a change in the patient's postoperative course, either by unplanned admittance to the intensive care unit, or postponement of surgery. In a study by Boëlle and coworkers, 'undesirable' anesthesia and recovery room events were associated with development into 'critical' events with an odds ratio of

3.4–4.8.¹⁸ Therefore, intraoperative adverse events may be used to analyze the safety and quality of the anesthetic process.

Adverse event rates

Most studies of mandatory case reporting are either more than ten years old,^{1,2} or group intraoperative and postoperative problems together.^{19–21} Our method of recording problems has been described earlier.⁴ In contrast to studies where information is collected on a voluntary basis, our recording is mandatory and is completed for every anesthetic. Even an uneventful anesthetic is recorded. Minimal extra workload, relevant feedback, and a non-punitive atmosphere are important to improve compliance. However, underreporting is a recognized problem in such systems.^{22,23}

We do not imply that the rates of adverse events in our study represent an acceptable level of quality; further analysis is needed to determine this. However, such rates can be used internally for quality comparisons. If an event occurs more commonly than is acceptable, the process can be analyzed and corrective measures taken, and the 'quality circle' closed.²⁴

Statistical process control - as a quality improvement tool

Statistical process control methods, first proposed by Walter Shewhart,²⁵ have been used for many years for process improvement in the industry. They have also been applied in health care for describing and analyzing processes that affect quality of care in healthcare organizations,^{3,26–28} as well as in anesthesia.^{18,24,29–31}

Variation is expected in any process. Different conditions, patients, staff, and methods all combine randomly and contribute to variation in performance, even when the process itself remains unchanged. Under such conditions, isolated observations provide insufficient information on which to base decision-making, as they may be the result of chance, rather than real deviation in process performance. Decision-making requires a series of observations, so that recognizable and predictable patterns can be appreciated. Statistical process control methods, and 'control charts' can be used to accomplish this.^{6–9,32–35}

If a new data point on the chart has a higher value than the previous one, but both points are within the 'control limits', this reflects natural variation within a stable process. Were this 'increase' to be acted upon as if the process had fundamentally changed, the analysis and action taken could be wrong (as the process probably is unchanged). The probability of measurement points occurring outside control limits, within an unchanged process is very small when using 3 SD lim-

its. Such wide limits prevent too many 'false alarms', but may also conceal significant trends, as too few 'true alarms' may go off.⁹

A special cause is most often intermittent, and will show up as a spike on the chart. However, a trend in the data points may indicate that a special cause is making the process unstable. A quality improvement initiative may result in such a trend. There are a separate set of 'within limit' rules for instability, including rules for trends.^{7–9}

In summary, the control chart shows whether a process is stable or subject to special cause variation. This determines if valid comparisons can be made, and indicates the correct approach to improve the process. It will also show if a quality improvement initiative has been effective. However, the control chart says little, by itself, about quality, as a process can be 'stable' with minimal natural variation, and still reflect poor quality if the frequency of a quality associated adverse event is too high.

Examples of control chart application

The department's ability to supply well functioning brachial plexus blocks is illustrated in Figure I. The process is statistically stable. However, the average failure rate is high compared to published studies.³⁶ Clearly the department must take corrective action, but we have not solved this problem, as can be seen from the chart. The chart illustrates that even if the process is stable it still may reflect poor quality.

Figure 2a presents the rate of difficulties during emergence from general anesthesia as an unstable process. A quality improvement initiative in 1999, may be the special cause that destabilized the process. Figure 2b presents two different processes, before and after the intervention. There are clearly two stable processes; the lower mean value in the second time period indicates a successful intervention. The current rate of emergence problems must now be reevaluated for acceptability from a quality and safety viewpoint, thus closing the quality circle.

The chart presenting intubation difficulties shows a stable process, with an average rate of 1.5%. This is, for example, comparable to 1.8% difficult intubations in a study by Rose and Cohen,³⁷ and such comparisons with the international literature will determine if our frequency is acceptable.

We found a low rate of drug errors. As a consequence of this, the lower control limit falls below zero, and therefore the p-chart methodology cannot detect decreases in the error rate if quality efforts are made. There are other methods for charting infrequent events,^{7,8} or alternatively a qualitative analysis may

form a basis for preventive strategies.⁵

Conclusion

We recorded intraoperative adverse events in 18.3% of anaesthetics, using a routine based recording system, and have analyzed the frequency of selected adverse events as a reflection of the quality of the anesthetic process. The variability of the process was analyzed by the statistical process control method of 'control charts'. This analysis can be used as a basis for monitoring and improving quality. It remains an important challenge to define and record those adverse events that are best suited as indicators of the quality of the anesthesia process.

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