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A knowledge-based alarm system for monitoring cardiac operated patients – assessment of clinical performance

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Abstract

An intelligent alarm system for the postoperative monitoring of cardiac surgery patients, which did not require any manual data entries, was tested in two phases. A clinician monitored at bedside the patients' recovery and verified clinically abnormal physiological states. After the first test with ten patients, the system's rulebase was upgraded and then tested with an additional 15 patients. The alarm system employed two PC/ATs and was programmed to give notice of four pathological states (hyperdynamic state, hypovolemic state, hypoventilation and left ventricular failure) at two levels of urgency (alarm and alert levels). The monitoring lasted 5.4 ± 1.7 hours per patient (mean ± S.D.), totalling 134.7 hours. The system alarmed 27 times during the first and 73 times during the second phase of the testing. The sensitivity of the alarms was 100% in both phases, and the specificities increased from 20.0% to 73.9% and from 59.1% to 70.0% for the alarms and the alerts, respectively. This computerized decision support system based exclusively on data available in the automatically collected data base had a low false positive rate and gave early warnings about pathological states in the homogeneous group of adult postoperative cardiac patients.

Introduction

The great amount of data recorded in intensive therapy units may overload the clinician [1, 2]. The working tempo is intense, especially when new patients are being admitted or when imminent critical events occur in some patients. The medical staff may need to focus their attention towards the most critical case. This may, in turn, increase the risk of failure to notice the signs of deterioration in the state of another patient. The determinants of outcome after cardiac surgery appear to depend greatly on the prompt appropriate management of hemodynamic disturbances [3]. These may be detected by setting the limit alarms of hemodynamic monitors appropriately to notify the medical staff of a change in one or more critical variables [4]. The specificity of limit alarms is so poor that they cannot be efficiently used for this purpose [5].

Computerized knowledge-based systems (KBSs) have been developed to assist monitoring, therapeutic decision-making and management both during anesthesia and for the intensive care of cardiac surgical patients [6–12]. Medical KBSs have not become widely accepted, probably because they often require a physician's active interaction with the computer. In addition, these systems need to be carefully evaluated before their true value as beneficial therapeutic tools can be estimated [13].

In this study, we tested the prototype of a knowledge-based alarm system for cardiac postoperative monitoring to determine its performance when using automatically accessible data alone.

Materials and methods

The study was performed on cardiac surgical patients at the intensive care unit of Kuopio University Hospital.

A preprocessing subsystem [14] acquired the heart rate, the systemic arterial pressures, the pulmonary

arterial pressures, the central venous pressure and the peripheral temperature directly from the bedside monitor (Kone 565, Kone Monitoring Systems, Instrumentarium Co., Helsinki, Finland). Intermittently measured values of the pulmonary capillary wedge pressure, the cardiac output and the end-tidal CO_2 were obtained during the first phase from the patient data management system [2], but during the second phase they were obtained directly from the patient monitor to speed up the acquisition.

The intensive care nurses measured the urine output rate and evaluated the degree of peripheral vasoconstriction hourly. These data, together with the blood gas values, were obtained from the patient data management system [2], which had a sampling rate of four times per hour for the manually recorded bedside monitoring data and once per hour for laboratory data. The knowledge-based alarm system operated in real time. The preprocessing subsystem processed all continuously measured hemodynamic and respiratory data, calculated their trends and transformed these into symbolic form [14]. The KB system based its patient state assessment on predetermined sets of findings distinctive for each monitored pathological condition [15]. Four pathological states were monitored: hyperdynamic state, hypovolemic state, hypoventilation and left ventricullar failure. The intelligent alarm system gave notice of the pathological states at two levels of urgency: the alert level indicated an imminent and the alarm level an existing pathological condition.

The clinical validation of the intelligent alarm system was performed in two phases, with intermediate upgrading of the rules. The upgrading consisted mostly of increasing the precision of the rules by altering certain limit values and by adding a few more accurate rulles.

The monitoring lasted from the admission of the patient to the ICU until one hour after the patient's peripheral temperature had reached 31°C. All patients had undergone a coronary by-pass operation, except one patient in the first study group who had had her aortic and mitral valves replaced with prostheses. The test periods lasted 5.9 ± 1.2 hours per patient in the first and 5.0 ± 1.9 hours (mean ± S.D.) per patient during the second phase of the study, totalling 59.5 and 75.3 hours, respectively.

The monitoring was started by activating the system when all patient monitoring lines had been connected to the monitors and the baselines of the hemodynamic variables had been zeroed. In addition to an intensive care nurse assigned to monitor only the recovering patient, an experienced study clinician stayed at the patient's bedside and continuously observed closely both the patient and the patient monitoring equipment. Every time the nurse, the knowledge-based alarm system or the study clinician observed that a pathological state was imminent or manifest, the clinician on-call was summoned to verify the situation. He or she was then asked to determine whether or not a pathological state existed and the degree of the observed pathological state, basing the estimation on his or her clinical experience. The clinicians on-call were either specialists in anesthesiology or, having more than three years of practice in anaesthesia and/or intensive care, close to obtaining this speciality. Both the study clinician and the clinician on-call made independent evaluations of the urgency of the observed pathological states. The judgements of the intelligent alarm system were compared against those of the clinicians. The study clinician based his estimations on clinical consideration using clinical criteria roughly similar to those applied in the system's rule base. The on-call clinicians made the clinical conclusions on their own.

Results

The patients' state was evaluated 1577 and 1319 times, and the evaluation intervals were 2.3 ± 0.2 and 3.5 ± 0.4 minutes (mean ± S.D.), respectively, for the first and second phases of the study.

The combined incidence of alarms and alerts for the first and second phases of the study were 1.4 ± 0.8 and 3.5 ± 3.0 (mean ± S.D.) per patient for the correct alarms, and 1.4 ± 1.5 and 1.4 ± 1.2 (mean ± S.D.) per patient for the false alarms, respectively. The respective intervals between true alarms were 276 ± 111 minutes and 105 ± 59 minutes, and 232 ± 111 and 246 ± 158 minutes between false alarms.

One of the five alarms and 13 of the 22 alerts issued during the first phase were considered correct, their respective specificities being 20% and 59.1% (Table 1). No errors were caused by software faults in this phase. Excessive delay in data acquisition caused the majority of false alarms. During the second phase, the system recorded 23 alarms and 50 alerts, of which 17 alarms and 35 alerts were regarded as correct (Table 1). The specificities for the alarms and for the alerts were 73.9% and 70.0%, respectively. Vasoactive medications induced transients that led to most false alarms.

Although the knowledge-based system occasionally was late in notifying of a pathological state, no cases

Table 1. Accuracy of the knowledge-based alarmed in the detection of pathological states.

	Clinician's Evaluation						
State detected by the alarm system	True	Over-stating	False				Total
			Excessive delay in data aqcuisition	Inaccurate data symbolization	Transient reaction to medication	Medically unsound reasoning	
Study phase 1							
Hyperdynamic state							
– alarm	0	0	0	0	0	0	0
– alert	1	0	0	0	1	0	2
Hypoventilation							
– alarm	0	0	0	0	0	0	0
– alert	1	0	0	0	0	0	1
Hypovolemia							
– alarm	0	0	0	0	0	0	0
– alert	7	0	3	1	0	1	12
Left ventricular failure							
– alarm	1	0	2	0	2	0	5
– alert	4	0	1	2	0	0	7
Total	14	0	6	3	3	1	27
Study phase 2			Software fault				
Hyperdynamic state							
– alarm	1	0	0	0	1	0	2
– alert	11	0	0	1	5	2	19
Hypoventilation							
– alarm	1	0	0	1	0	0	2
– alert	3	0	0	0	0	0	3
Hypovolemia							
– alarm	15	3	1	0	0	0	19
– alert	19	0	0	3	1	3	26
Left ventricular failure							
– alarm	0	0	0	0	0	0	0
– alert	2	0	0	0	0	0	2
Total	52	3	1	5	7	5	73

of missed alarms or alerts were observed despite most vigilant observation. The delay in the program's notification of a correct alarm averaged 3.0 ± 3.5 minutes during the first and 3.2 ± 3.2 (mean ± S.D.) during the second phase (Fig. 1). The program recognized 10 (71%) of the first 14 and 43 (83%) of the second 52 correct alarms/alerts within three minutes of either observer's detection of the state.

The study clinician's and the on-call clinicians' estimations of the observed pathological state coincided during the first phase in 26 of the 27 cases, and during the second phase in 64 of the 73 cases. In the first phase, the study clinician considered true one alarm of left ventricular failure which the on-call clinician regarded false. In the second phase, the on-call clinicians estimated the knowledge-based system's notification to be overstated on five occasions and false twice in cases which the study clinician regarded appropriate (Table 2). The study clinician considered the system's

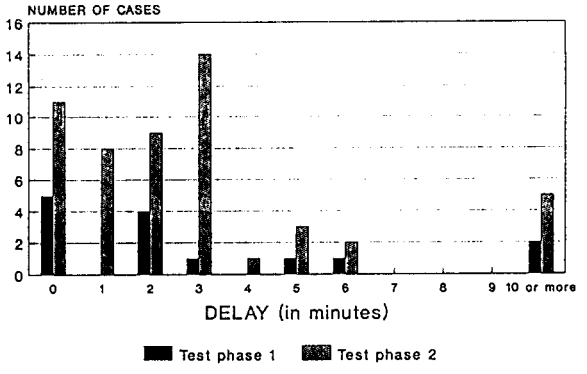

Fig. 1. Distribution of delays in correct alarms/alerts.

Table 2. The study clinician's and the on-call clinicians' verifications of the alarm system's notifications.

Phase 1	On-call clinician's estimate		
	correct	overstating	false
Study clinician's estimate			
correct	13	0	1[1]
overstating	0	0	0
false	0	0	13
Phase 2	**On-call clinician's estimate**		
	correct	overstating	false
Study clinician's estimate			
correct	45	5[2]	2[3]
overstating	0	1	2[4]
false	0	0	18

Case types: [1] alarm left ventricular failure; [2] alert hyperdynamic state, alert hypovolemia, three cases of alarm hypovolemia; [3] alarm hypovolemia, alert hypovolemia; [4] two cases of alarm hypovolemia.

alarm of hypovolemia overstated in two cases which the on-call clinician found false.

Discussion

An automated knowledge-based alarm system for the monitoring of adult postoperative cardiac patients was validated. The observed sensitivity was good when compared with the observations of the clinician, who continuously monitored the patient for the predefined disorders. Although a borderline case may have been missed both by the clinician and the system, such an incident could have borne only minimal clinical signifance.

The response time of the system was reasonably short because only a few alerts were given later than three minutes after clinical observation of the change in the patient's state. The overdue (> 6 minutes) correct alarms consisted in the first phase of two cases of developing hyperdynamic state, and in the second phase of two cases of slowly developing hypoventilation, two borderline cases of hypovolemia and one case of marginally inadequate left ventricular function. Since the algorithm employed not only the values but alto the trends of the monitored variables, it had at least some predictive power, which is considered advantageous in the detection of developing pathological states [16]. Although data preprocessing causes a reasonably long delay, the system could detect the monitored pathological states early enough to allow effective therapeutic responses, as only a minority of notices were of the alarm class. Hypovolemia was the most frequent cause of both alerts and alarms.

The specificity of alarms was reasonable and considerably better than the specificity of conventional limit alarms [17], as observed also in our previous studies with comparable patient material [5, 18]. The upgrading of the system consisted mainly of revisions of classification boundaries in the rule base with the addition of a few new rules, and it enhanced the system's specificity. This suggests that the performance of the system may be increased by further modifications.

Despite the improvements, the incidence of false alerts due to medically unsound rules increased. This may be due to variations in the patient material. The highest incidence of false alerts was seen either at times of modifying the infusion or following a bolus administration of vasoactive medication. A few false alerts resulted from inaccuracies in data symbolization and medically inexact rules. The oversensitive alarms for hypovolemia were all regarded to be correctly oriented although somewhat overstated.

The test clinician's and on-call clinicians' estimations of the observed pathological states were rather similar, denoting reasonably good diagnostic performance of the system. The inconsistences between the clinicians' estimations resulted from differing views with respect to what value combinations of systemic arterial pressure, pulmonary capillary wedge pressure, and cardiac index denote left ventricular failure or

hypovolemia. Such inconsistencies in the clinicians' opinions are not uncommon.

The overall performance of this intelligent alarm system was promising, although its domain and the patient material were rather narrow. With further development this type of expert system could be implemented as an integrated module of a data management system in intensive care. Although the upgrading of the rule base greatly enhanced the system's performance, the final benefits of this kind of system can be determined only by additional field-testing. The fact that knowledge-based alarm systems for intensive care have to be repetitively clinically evaluated to obtain acceptable levels of performance leads to extremely long design times for such systems, which makes their implementation both expensive and time-consuming.

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