A COMPARISON OF AN EVIDENCE BASED REGIME WITH THE STANDARD PROTOCOL FOR MONITORING POSTOPERATIVE OBSERVATION: A RANDOMISED CONTROLLED TRIAL

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Key words: postoperative, post surgery, monitoring, vital signs, observations

ABSTRACT

Background

Monitoring patients' vital signs is an important component of postoperative observations.

Objective

To compare the safety and efficacy of the current standard practice for monitoring postoperative observations in one hospital with an experimental protocol.

Method

Patients who were classified as American Society of Anaesthesiologists (ASA) Class 1 or 2 and who met the inclusion criteria were randomised to one of two groups. Following their return to the ward from the recovery unit, these patients were monitored according to either the standard practice (n=96) or the experimental protocol (n=93). Data collected included patient demographics, medical and surgical history, the postoperative observations and the number and type of untoward events.

Results

The findings indicated that there was no statistically significant difference in the incidence of abnormal vital signs between the groups in the first four hours as well as within the 24 hours following return to the ward from the recovery unit. Additionally, none of the patients required either transfer to the intensive care unit /high dependency unit or management by the intensive care team. Patients in both groups were successfully discharged within 24 hours following surgery.

Conclusion

This study provides evidence to inform clinicians of a safe and cost effective regime in the management of the patient in the postoperative period following discharge from the recovery to the ward. Clinicians, however, must utilise clinical judgement to determine which patients require close monitoring during the postoperative period.

INTRODUCTION

Monitoring of patients' vital signs is an important component of postoperative observations, undertaken for the early detection of complications that may require an intervention, thus preventing further clinical deterioration (Botti and Hunt 1994). Research has demonstrated that 5% of patients develop postoperative complications (Gamil and Fanning 1991), 0.21% of patients developed an early postoperative emergency within 48 hours after surgery (Lee et al 1998), and the incidence of mortality is 0.24% in the first 24 hours following surgery (Gamil and Fanning 1991).

A large number of studies have been published which provide recommendations specifically for monitoring patients in the recovery room, however there has been limited research relating to management of patients following their transfer to the ward.

The commonly monitored vital signs include temperature, pulse, respiration and blood pressure (Evans et al 1999). Nurses usually assess these vital signs in accordance with the individual hospital protocols (Botti and Hunt 1994), although the rationale for these protocols are rarely based on scientific evidence (Arsenault 1998; Burroughs and Hoffbrand 1990).

Policies and protocols for monitoring patients following return to the ward varies between facilities as well as between wards within each facility. For example half hourly monitoring for two hours, hourly monitoring for four hours and hourly monitoring for six hours have been reported (Zeitz and McCutcheon 2002).

Findings from a systematic review of the literature (Centre for Applied Nursing Research 1998) investigating the optimal frequency for monitoring patients on return to the ward, recommended that vital signs should be monitored half hourly for two hours followed by fourth hourly for 24 hours if the patients were stable. However, the systematic review did not include recommendations for the type of observations, therefore a further review of the literature was undertaken to identify the common complications occurring in the first three postoperative days and the associated vital signs to be monitored.

The findings from this literature review identified hypotension as a common complication occurring within the first three hours after surgery (Gamil and Fanning 1991) therefore the value of blood pressure monitoring was confirmed. Likewise, the recording of pulse rate was justified because bradycardia has been reported as the second most common complication occurring within the first two hours after surgery (Field 1998). The literature also indicated that monitoring the temperature in the first four hours has been frequently recorded to detect hyperthermia, which is primarily an indicator of infection (Litwack 1997; Wipke-Tevis 1999), DVT, pulmonary emboli, atelectasis (Pett and Wernly 1988) and anastomotic breakdown. Researchers have also demonstrated that these complications are uncommon in the first few hours following surgery and are more likely to occur from the second postoperative day (Heidenreich and Giuffre 1990).

The importance of monitoring the respiratory rate was debatable, as adequate breathing did not necessarily indicate optimal ventilation (Thompson 1983). Rather, monitoring oxygen saturation levels has been demonstrated to be an important predictor of the patient's respiratory status (Moller et al 1992; Moller et al 1993; Rosenberg et al 1989). With the availability of bedside technology (pulse oximetry) to record the patient's oxygen saturation, monitoring the physiological results of respiration rather the respiratory rate is a much more appropriate indicator of respiratory status (Bayne 1997).

Based on the findings of the systematic review and a comprehensive literature review of the commonly occurring complications in the early postoperative period and in consultation with expert clinicians an evidence based postoperative monitoring regime was developed. The objective of this study was to investigate the safety and efficacy of the evidence based regime for monitoring postoperative observations with the existing standard practice.

RESEARCH QUESTION

What is the effect of a modified regime compared to existing practices for monitoring vital signs in postoperative patients on their return to the ward from the recovery unit?

MATERIALS AND METHODS

A randomised controlled trial was undertaken comparing the incidence and nature of untoward events that occurred in the first 24 hours following return to the ward after surgery in patients monitored according to the study protocol and those monitored according to the standard hospital protocol. This study design was chosen due to the ability of randomised controlled trials to eliminate selection bias thus making them the best method to obtain evidence on the effects of health care interventions.

The study was conducted in a metropolitan health service in New South Wales, Australia, over six consecutive months. As such a study had not been previously undertaken it was determined that only patients classified by the American Society of Anaesthesiologists (ASA) as Class 1 or 2 would be included. The ASA Classification status (table 1) was used as an estimate of operative risk (Wolters et al 1996).

Table 1: ASA Classification

ASA I	The patient has no organic, physiological, biochemical, or psychiatric disturbance. The pathological process for which the operation is to be performed is localised and is not a systemic disturbance.
ASA II	Mild to moderate systemic disturbance caused either by the condition to be treated or by other pathophysiologic processes.
ASA.III	Severe systemic disturbance or disease from whatever cause, even though it may not be possible to define the degree of disability.
ASA IV	Indicative of the patient with severe systemic disorder already life-threatening, not always correctable by the operative procedure.
ASA V	The moribund patient who has little chance of survival but is submitted to operation in desperation.

Patients having surgery under general anaesthesia were identified on admission to the peri-operative unit and assessed by the departmental staff to determine their eligibility for entry into the study. Patients were eligible for the study if they were scheduled for surgery under general anaesthesia, between the ages of 18-80 years, transferred to the ward from recovery, and had a minimum length of stay of six hours following surgery.

Patients who failed to give consent, had surgery under spinal or local anaesthesia, patient controlled anaesthesia following surgery, neurosurgery, vascular surgery or were transferred to the intensive care (ICU) or high

dependency units (HDU) from the recovery unit were excluded from the study. The surgeons and anaesthetists reviewed the experimental protocol and consented to have their patients participate in the study. The study was approved by the South Western Sydney Area Health Service Research Ethics Committee and the University of Western Sydney Ethics Review Committee (Human Subjects).

An intensive education program for staff in the surgical wards was undertaken to provide details of the study, procedures to be followed, and the documentation to be completed for each client enrolled in the study.

At the time of admission to the peri-operative unit, patients who met the inclusion criteria were informed of the study and written consent was obtained prior to allocation to a study group. The randomisation sequence was generated from a statistical table of random numbers and concealed in sequentially numbered, opaque, sealed envelopes. Following their return to the recovery unit after surgery, envelopes containing the monitoring regime were placed by the nurse in charge, in front of the patients' medical notes. On transfer to the ward, the envelope containing the protocol was located; the random number recorded on the data sheet, and the patient was monitored according to the assigned protocol. Nurses were instructed that in the event that a patient became unwell and required further monitoring, the patient was to be discontinued from the study and treatment commenced according to medical/nursing advice.

Patients in the control group had their observations monitored according to the standard hospital protocol (table 2) while those in the experimental group had their observations monitored according the study protocol (table 3). Owing to the nature of the intervention, it was not possible to blind the participants, nurses or the data collectors to the treatment allocation. However, in order to maintain the rigour of the study and to avoid bias during documentation, the nurses and the data collectors were not informed of the criteria used to describe abnormal vital signs.

Table 2: Standard protocol (control)

Temperature to be recorded on return to the ward then at the end of four hours followed by daily until discharge if the patient is stable. Respiratory rate, pulse rate, blood pressure, oxygen saturation and level of arousal to be recorded on return to the ward followed by fourth hourly for 24 hours if the patient is stable.

Table 3: Experimental protocol

Temperature to be recorded on return to the ward then at the end of four hours followed by daily until discharge if the patient is stable. Respiratory rate, pulse rate and blood pressure to be monitored and recorded on return to the ward then one hourly for two hours followed by fourth hourly for 24 hours. Oxygen saturation and level of arousal to be monitored and recorded on return to the ward then one hourly for two hours followed by four hourly for 24 hours.

Data collection was undertaken by an independent staff member not associated with the research project. Standardised data collection was undertaken using a tool developed by the researchers. The data collector was provided with extensive education regarding transcription of the data and the data collection method. Data collected included the patient's age, gender, date of admission, surgery and discharge, name of the surgical procedure, medical history, ASA class, duration of anaesthesia, duration of the procedure, length of time in recovery, the observations recorded, and any variations in the condition of the patient during the first 24 hours following surgery. Random audits by the researchers were conducted to ensure accuracy of the data collected.

Adverse outcomes of interest included the number of patients who developed any untoward events such as chest pain, required management by an intensive care team, were transferred to the ICU/HDU for intense monitoring or had an abnormal vital sign. An abnormal vital sign was defined as a value outside the predetermined parameters (Davis and Nomura 1990) (table 4).

Table 4: Definitions and parameters of abnormal vital signs for the purpose of this study

Fever	Temperature of 38.3º or higher
Hypoventilation	Respiratory rate of 10/min or less
Hyperventilation	Respiratory rate of 30 or more
Hypotension	Fall in blood pressure (BP) >20mm of Hg from baseline BP or systolic BP <80mm of Hg
Hypertension	Systolic BP >180mm Hg and diastolic BP > 120mm of Hg; a rise in BP of 20% or more than the highest preoperative BP
Bradycardia	Pulse <60/min Severity classified B1 –50 –60/min B2 <50/min
Tachycardia	Pulse >100/min Severity classified T1 100 –120/min T2 >120/min
Hypoxia	0_2 saturation 90% or less

Statistical analysis

Statistical analysis was carried out using SPSS version 10. Descriptive statistics were calculated for all variables. Chi-square analysis was undertaken to determine the differences between the two groups. All patients who were monitored could potentially have up to five vital signs outside normal limits. Therefore, the analysis was performed on the number of occurrences of abnormal vital signs, rather than the number of patients. For example, patients in the experimental group had two sets

of observations recorded in the first four hours following transfer to the ward.

Therefore the total number of potential abnormal vital signs for this group of patients (n=93) would be 930, if all parameters ie temperature, pulse, respiratory rate, blood pressure and oxygen saturation were monitored at both times. As more frequent monitoring can result in an increase in the detection of abnormal vital signs the proportion of the abnormal vital signs in each group was calculated.

RESULTS

Two hundred and twenty seven patients who met the inclusion criteria were randomised to either group. However, 38 patients were subsequently excluded as they were administered either spinal or local anaesthesia for the surgical procedure or were commenced on PCA following surgery. These results are therefore based on an analysis of 189 patients (experimental=93; control=96). Forty-two of these patients were not monitored according to the assigned protocol however their data have been included in an intention to treat analysis (table 5).

There were no significant differences between the experimental and control groups in any of the baseline characteristics (table 6), nor were there any statistically significant differences in the observations recorded at admission or in the recovery unit (table 7).

The majority of patients had a general surgical procedure (n=151), whilst the other operations involved the head and neck (including faciomaxillary) (n=3), ear, nose and throat (n=1), orthopaedics (n=8), gynaecology (n=14), urology (n=10), breast (n=1), and plastic surgery (n=1) (table 6).

Incidence of adverse outcomes

During their period of hospitalisation, none of the patients in either group developed a postoperative emergency that required management and treatment by an intensive care team or transfer to the ICU/HDU.

Two patients in the experimental group complained of chest pain. The first patient, a 29 year old, complained of chest pain seven hours after transfer and was treated with intravenous Ranitidine. The second patient, a 36 year old, had chest pain 15 hours after transfer, was treated with sublingual nitrates and cardiac investigations were undertaken. The chest pain resolved within the hour in both patients and they were discharged home the following day.

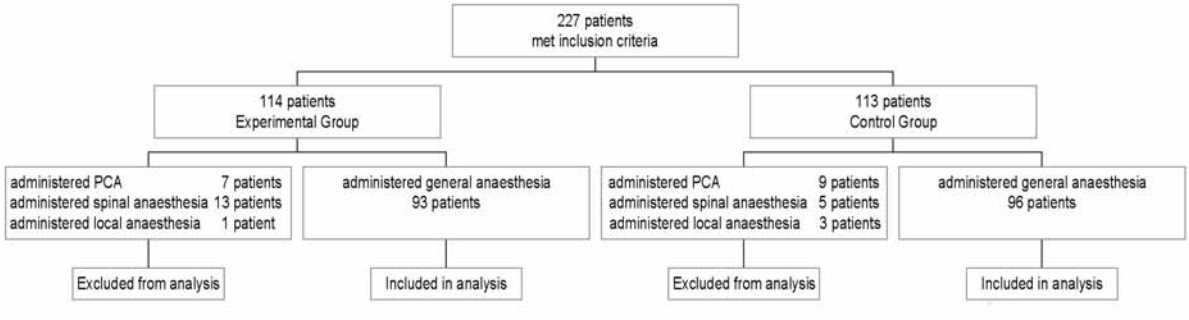
Five hours after returning to the ward one patient in the control group tried to sit out of bed and fell. Vital signs recorded at the time of the fall were stable and the patient exhibited no signs or symptoms of complications, although, the patient was asked to remain in bed for a further two hours, and was discharged home the next day.

Incidence of abnormal vital signs

The number of abnormal vital signs that were documented has been reported in table 8. Ten patients in the experimental group and five patients in the control group had a pulse rate of less than 60 beats/minute at baseline. When these patients' data were removed from the analysis there was no statistically significant difference in the number of abnormal vital signs at any point in the first 24 hour period. Therefore the data from these patients were included in the final analysis.

Although monitoring the respiratory rate and oxygen saturation was a requirement of the protocol, these vital signs were monitored in less than 70% of all patients. Abnormal events relating to these vital signs have, therefore, not been included in the final analysis. In those patients who did have this vital observation monitored, none had tachypnoea or bradypnoea in the 24 hour period and only one patient had an abnormal oxygen saturation (89%) on transfer to the ward. It could be postulated that the low level of oxygen could be due to the fact that this patient had a diagnosis of pulmonary embolism and was transferred to the ward without oxygen therapy. Treatment with oxygen supplementation for one hour resulted in the patient attaining normal oxygen saturation.

Table 5: Flow chart of patients through the study



Incidence of abnormal vital signs on transfer to the ward

On their return to the ward from the recovery unit, all patients had their temperature, pulse, and blood pressure monitored. However, the respiratory rate was monitored in only 28% and oxygen saturation was monitored in only 77% of patients, therefore these parameters were not considered in the analysis. Twenty-one patients in the experimental group and 17 patients in the control group had one untoward event each, however, these results were not statistically significant (p=0.44) (OR 1.30, 95% CI 0.67, 2.51) (table 8). The most commonly occurring untoward events were bradycardia (n=18: 3.1%) followed by hypotension (n=11: 2%).

Incidence of abnormal vital signs in the first four hours following transfer to the ward

In the first four hours after returning to the ward from the recovery unit, patients in the experimental group had two sets of vital signs and those in the control group had only one set of vital signs recorded (these do not include the vital signs recorded at transfer). Therefore, the number of potential untoward events that could occur in the experimental group and control group was 558 and 288 respectively.

A total of 33 untoward events (experimental=21; control=12) were identified in 30 patients (experimental=18; control=12). These results were not statistically significant (p=0.77) (OR 0.90; 95% CI 0.44, 1.86) (table 8). Hypotension (n=12) (1.5%) and bradycardia (n=11) (1.4%) were the most commonly occurring untoward event during this period.

In the 12 patients who developed hypotension and 11 patients who developed bradycardia, six had a low blood pressure and three had a low pulse rate at baseline. Hyperthermia was recorded in one patient in the control group.

Incidence of abnormal vital signs in the first 24 hours following transfer to the ward after surgery

In the 24 hours following transfer to the ward, patients in the experimental group (n=93) had seven and those in the control group (n=96) had six sets of observations recorded. Again these do not include the vital signs recorded at transfer. Therefore, the number of potential abnormal vital signs that could occur in the experimental group and control group were 1953 and 1728 respectively.

One hundred and fourteen abnormal vital signs (experimental=52; control=62) were identified in 65 patients (experimental=33; control=32) in the first 24 hour period following transfer to the ward from the recovery unit (p=0.11) (OR 0.74; 95% CI .51, 1.07) (table 8). These abnormal vital signs occurred at any time during the 24 hour postoperative period and not necessarily in the first four hours.

Hypotension (n=32) (0.9%) and bradycardia (n=46) (1.2%) were the most common untoward events documented (table 8). In the 20 patients who developed hypotension and 23 patients who developed bradycardia, 14 had a low blood pressure and five had a low pulse rate at baseline. Severe bradycardia (HR <50 beats/minute) was not identified in any of the patients in the first 24 hours following surgery. None of the patients who had an abnormal blood pressure or pulse complained of dizziness, nausea or weakness.

All patients who developed untoward events were managed with appropriate nursing interventions and the attending doctor was notified of the changes in vital signs. Assistance from the doctor was required in only three patients: two who developed chest pain and one who had a fall.

Table 6: Patient demographics

	Experimental group	Control group
Total number of patients analysed	93	96
Males	44	41
Female	49	55
Age	53.98 (SD 17.53)	
Range 20-85 years	48.23 (SD 16.45)	
Range 19-81 years		
Types of surgery		
General surgery	74	77
Head and neck including faciomaxillary	1	2
Ear, nose and throat	1	
Breast	1	
Orthopaedics	3	5
Gynaecology	8	6
Urology	5	5
Plastic	0	1

Table 7: Demographics

	Experimental group Mean (Std. deviation)	Control group Mean (Std. deviation)
Length of hospital stay	2 days (1.33)	1.8 days (1.36)
Length of stay after surgery	1.92 days (1.34)	1.8 days (1.6)
Length of anaesthesia	83 minutes (37)	82 minutes (30)
Length of surgery	63 minutes (33)	66 minutes (70)
Length of time in recovery	87 minutes (47.5)	84 minutes (43)
Systolic blood pressure at baseline	137 (27)	134.8 (22.2)
Diastolic blood pressure at baseline	79.4 (11.7)	79.7 (13.3)
Pulse rate at baseline	72 (11)	73.7 (11)

Table 8: Incidence of abnormal vital signs

Time	Vital sign	Experimental group No. of abnormal vital signs (%)	Control group No. of abnormal vital signs (%)	p value	Odds ratio (95% CI)
Transfer	Temperature >38	0	0		
	Bradycardia	13	5		
	Tachycardia	2	3		
	Hypotension	6	5		
	Hypertension	0	4		
	Total	21 (7.5%)	17 (6%)	0.44	1.30 (0.67, 2.51)
4 hours	Temperature >38	2	1		
	Bradycardia	8	3		
	Tachycardia	4	2		
	Hypotension	7	5		
	Hypertension	0	0		
	Total	21 (3.8%)	12 (4.1%)	0.77	0.90 (0.44, 1.86)
24 hours	Temperature >38	6	7		
	Bradycardia	24	22		
	Tachycardia	8	5		
	Hypotension	10	22		
	Hypertension	4	6		
	Total	52 (2.7%)	62 (3.6%)	0.11	0.74 (0.51, 1.07)

DISCUSSION

Various regimes for monitoring vital signs in the postoperative period have been used, although there is limited documentation of research relating to this practice. This randomised controlled trial was undertaken to compare the safety and efficacy of a modified protocol to the usual hospital protocol for monitoring patients on their return to the ward from the recovery unit. The experimental protocol was developed from the findings of a systematic review, literature review of commonly occurring complications in the first 24 hours following surgery and expert advice.

The major difference between the two monitoring regimes was the number of times the patients were monitored in the first four hours following return to the ward from the recovery unit. Although all patients were monitored on transfer, patients in the experimental group were monitored for a further two hours while patients in the control group were monitored only once again in the following four hours. The main outcome of interest was the number of patients who required assistance of the intensive care team or transfer to the intensive care unit. Other outcomes assessed included the number of patients who developed abnormal vital signs or had any adverse complications, eg, haemorrhage.

Patients frequently exhibit abnormal vital signs during recovery from general anaesthesia and in only a minority of cases does this progress and require intervention. Therefore statistical analysis was undertaken on the number of abnormal vital signs documented in each group, rather than the number of patients who developed the abnormal vital signs.

The incidence of abnormal vital signs in the first 24 hours following return to the ward from the recovery unit was 3%. Although not statistically significant, a greater number of abnormal vital signs (n=21) were identified in the experimental group compared to the control group (n=12) in the first four hours. This could be due to the fact that patients in the experimental group were monitored more frequently than those in the control group, thus increasing the likelihood of detection of abnormal vital signs.

This study supports the findings of other researchers (Harley and Tsamassiros 1997) that following return to the ward from the recovery unit if abnormal vital signs have not occurred in the first two and a half hours it is unlikely they will occur within the first four hours. The results also demonstrated no statistically significant difference in the incidence of abnormal vital signs in the first 24 hours, thus supporting the feasibility and safety of reduced frequency of monitoring vital signs following a patient's return to the ward from the recovery unit.

In this study, the incidence of abnormal vital signs may be underestimated due to poor compliance by nurses to the monitoring schedules. Although the monitoring regimes for both the experimental and control groups included monitoring of the oxygen saturation, it was interesting to note that this observation was monitored in less than 80% of all patients. One would assume that the patients who did not have their oxygen saturation monitored would have their respiratory rate monitored. However, this was not the case as there were patients who had neither observation recorded.

In this study bradycardia and hypotension were the most commonly occurring abnormal vital signs in the first 24 hours which supports the findings of other researchers. However, it should be noted that for the purpose of this study, bradycardia was defined as a pulse rate of less than 60 beats/minute. The majority of the patients who had bradycardia postoperatively also had a baseline pulse rate of under 60 beats/minute.

The majority (78%) of abnormal vital signs occurred after the first four hours indicating that all patients following surgery are at risk, hence pertinent observations

are critical and nursing staff should be vigilant as complications can occur at any point along the postoperative continuum.

None of the patients in either group demonstrated any serious or potentially life threatening events after returning to the ward. In the three patients who developed untoward events, there was no association between the time of occurrence of the abnormal vital sign, and the time since return to the ward.

These results indicate that there is no association between the frequency of observations in the first four hours and outcomes for the type of patients included in this study. However, as no adverse events were reported, it is unclear whether monitoring the patient frequently in the first four hours assists in the early identification of patients at risk of postoperative complications.

The results from this study have implications for clinicians and administrators and provide a platform for the rational use of services aimed at optimising patient care post surgery. The regimes for postoperative monitoring should be based upon the condition of the patients, the nurse's clinical judgement and with consideration of existing guidelines within the facility. Monitoring regimes should include appropriate vital signs to identify the complications that have been commonly reported to occur following surgery. Diligent visual observation and communication with the patient is also important as part of the patient's postoperative care.

Monitoring appropriate vital signs based on clinical judgement will provide nursing staff with valuable time and added flexibility to prioritise other nursing interventions. As the nurses' role expands to include more assessments, planning, teaching and evaluation, it is imperative that clinical practice is based on evidence rather than tradition. This research study reports on one clinical practice that can be changed to achieve that goal.

A major limitation of the study is the sample size, therefore the findings of this study cannot be generalised beyond the population and setting where this study was conducted. Potential confounders of early postoperative untoward events include the type of surgery, type of anaesthesia and ASA classification of the patients. However, as all the patients in the study had general anaesthesia and were classified as ASA class 1 or 2 and most of them had general surgery it can be concluded that the findings are only applicable to this population and cannot be generalised to other types of patients.

Replication of this study in other settings with patients classified as ASA 3 and with other surgical procedures will provide an evidence-based protocol for monitoring patients in the postoperative unit.

CONCLUSION

The research, including this study, demonstrates that current regimens for monitoring patients in the immediate postoperative period may in fact be more intensive than is indicated by patient outcomes. The data presented fails to provide justification for routine, frequent monitoring of vital signs in the postoperative period following return to the ward from the recovery unit. However, the results cannot be generalised to all patients following surgery. Clinicians, however, must utilise clinical judgement to determine which patients require close monitoring during the postoperative period. Further research needs to be undertaken to assess patient satisfaction with reduced monitoring.

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