Continuous versus intermittent vital signs monitoring in patients admitted to surgical wards: a cluster-randomised, controlled trial

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Abstract

Background

Vital signs monitoring is a universal tool for the detection of postoperative complications, but unwell patients can be missed in between traditional observation rounds. New remote monitoring technologies promise to convey the benefits of continuous monitoring to patients on general wards.

Objective

The aim of this study was to evaluate whether continuous remote vital signs monitoring is a practical, acceptable and effective way of monitoring surgical patients.

Methods

A prospective, cluster-randomised, parallel-group, controlled study was performed. Patients admitted to two surgical wards at a large tertiary hospital received either continuous and intermittent vital signs monitoring, or intermittent monitoring alone. The primary outcome measure was time to administration of antibiotics in sepsis. Secondary outcome measures included length of hospital stay, 30-day readmission rate, mortality and patient acceptability.

Results

350 patients were recruited between January and June 2017. 140 patients received continuous remote monitoring and 210 received intermittent monitoring alone. On average, patients receiving continuous monitoring were administered antibiotics faster after evidence of sepsis, had a shorter average length of hospital stay and were less likely to require readmission within 30 days of discharge. Wide confidence intervals suggest these differences are not statistically significant. Patients found the monitoring device to be acceptable in terms of comfort and perceived an enhanced sense of safety.

Conclusions

Remote continuous vital signs monitoring on surgical wards is practical and acceptable to patients. Large, well-controlled studies in high-risk populations are required to determine if the observed trends translate into a significant benefit for continuous over intermittent monitoring.

Trial registration:

The study was prospectively registered on the ISRCTN registry on 19th December 2016 under registry number ISRCTN60999823; URL: https://doi.org/10.1186/ISRCTN60999823.
Introduction

Perioperative complications are unfortunately common following surgical procedures. Postoperative mortality is the third leading cause of death in the USA[1]. The International Surgical Outcomes Study (ISOS) found that 17% of patients undergoing inpatient surgery developed at least one complication[2]. This figure rose to 27% in patients undergoing major surgery. In addition, 2.8% of patients who developed a postoperative complication died before discharge from hospital. Monitoring patients beyond the operating room is important to allow early detection of clinical deterioration and timely intervention[3].

The early warning score system is predicated on the idea that derangements in simple physiological observations can identify hospital inpatients at high risk of deterioration[4]. Prodromal warning signs, such as increased respiratory rate or decreased blood pressure, precede critical illness[5] allowing early recognition and management of the patient to reverse the abnormal physiological decline or prompt admission to a critical care area.

A significant limitation of early warning score systems is their intermittent nature[6]. Clinical deterioration on general wards may remain undetected for hours before clinicians are alerted[3]. One solution may be continuous vital signs monitoring, which until now has been limited to use on critical care wards due to prohibitive cost and implications for patient mobility and recovery.

The development of wireless and wearable sensors allows continuous monitoring of ambulatory patients. A number of such tools have already received the Food and Drug Administration (FDA) clearance, but clinical studies are required to demonstrate their clinical utility in the post-surgical setting[3,7].

A recent systematic review identified nine studies assessing the effect of continuous vital signs monitoring on general wards[8]. The authors found no evidence of a significant reduction in ICU transfers or other adverse events with continuous monitoring, but recognised heterogeneous methods, study populations and outcome measures.

The aim of this study was to evaluate whether continuous remote vital signs monitoring is a practical way of monitoring surgical patients outside of the critical care setting, if it enables earlier treatment of septic complications, and if its use is acceptable to patients.

Methods

The study was designed as a cluster-randomised, prospective, parallel-group, controlled single-centre study, comparing remote continuous vital signs monitoring and intermittent monitoring with intermittent monitoring alone.

Ethical approval was granted on 30th November 2016 by the Yorkshire & The Humber - Bradford Leeds Research Ethics Committee, ref: 16/YH/0426. The study was prospectively registered on the ISRCTN registry (ISRCTN60999823). No changes were made to the registered protocol. The trial was performed in accordance with Good Clinical Practice guidelines and the Declaration of Helsinki, and is presented according to the CONSORT statement principles[9].
The study population were patients admitted to two elective general surgery wards (male and female) at a single tertiary centre in Leeds, United Kingdom. The inclusion criteria included patients 18 years of age or older who were able to provide informed consent to participate. Exclusion criteria included those with a known allergy to the electrode adhesive, and those with a cardiac pacemaker in situ. Patients were approached as soon as practical after their admission onto the wards.

**Randomisation**

Consenting participants were allocated to one of two monitoring arms for the length of their admission, according to the ward bay they were first arbitrarily admitted to. Each ward has 4 bays containing 6 beds each.

Of the 4 bays on each ward, 3 were randomly allocated to one of the monitoring arms; two bays were allocated to receive the patch and one to receive usual intermittent monitoring. Each bay was independently block randomised to an intervention arm by the primary investigator (CD) using online software: Sealed Envelope Ltd. 2016, available from https://www.sealedenvelope.com/simple-randomiser/v1/lists [Accessed 12 Jan 2017].

The two remaining bays (one on each ward) could not be randomised because they did not have the required hardware installed. Patients in these bays were therefore allocated to receive usual intermittent monitoring alone.

The allocation of patients to each bay was performed by hospital bed managers, who were independent of the trial and unaware of the bay allocations. Due to the nature of the intervention, neither the patient nor their nurse were blinded to the allocated monitoring arm.

**Control**

All patients in the study received usual intermittent vital signs monitoring. In our institution, this is the National Early Warning Score (NEWS), which involves intermittent manual charting of vital signs and the calculation of a combined score, giving an indication of patient status. The control arm received NEWS monitoring alone. For postoperative patients, this typically consisted of hourly recording of blood pressure, pulse, temperature, respiratory rate, and oxygen saturation until the patient’s condition was stable when the frequency of observations was decreased to two-hourly and then four-hourly. For patients not undergoing an operation, the frequency of monitoring was tailored to their condition.

**Intervention**

Patients admitted to an intervention bay received usual intermittent NEWS monitoring, in addition to continuous vital signs monitoring via the SensiumVitals® (Sensium, Abingdon, UK) system. This system consists of a CE-marked wireless patch (see Figure 1) worn on the chest of the patient, which continuously monitors heart rate, respiratory rate and temperature. The data is transmitted wirelessly every two minutes to a central monitoring station or a mobile device carried by the patient’s nurse. The nurse is alerted when there is deviation from pre-set physiological norms. The alert prompts an acknowledgement of the notification, after which the nurse is free to act according to their clinical discretion. All other clinical care remained as normal in the intervention group.
Primary outcome measure

The primary outcome measure was time to antibiotics after the first evidence of sepsis, defined according to a revised consensus conference definition in 2001 by the presence of a likely source of infection and 2 or more of the following criteria[10]:

- Temperature >38.3°C or <36.0°C
- Tachycardia >90 beats per minute
- Tachypnoea >20 breaths per minute
- pCO2 <4.3 kPa
- Hyperglycaemia (blood glucose >6.6 mmol/l) in the absence of diabetes mellitus
- Acutely altered mental status
- WBC count >12×10⁹/L or <4×10⁹/L

The decision to prescribe antibiotics was usually made by the junior doctor on the ward, based on local protocols and clinical discretion. The time to antibiotics was determined by review of the observations chart, the SensiumVitals® data, the electronic medications record and the medical notes of the patient during their hospital admission.

Secondary outcome measures

- In-hospital mortality
- Length of hospital stay
- Number of admissions to Level II/III care
- Readmission to hospital within 30 days of discharge
- Patient acceptability and compliance

To assess acceptability, patients in the continuous monitoring group were asked to complete a short questionnaire. The patients were asked to rank the comfort and sense of safety they perceived from wearing the patch on a scale from ‘Strongly Agree’ to ‘Strongly Disagree’.

Statistical analysis

A formal sample size calculation was not possible given the lack of data surrounding the primary outcome measure, and so assumptions were used to calculate an appropriate sample size. A sample size of 325-625 was suggested as an appropriate target based on
assumed eligibility rate (90%), consent rate (30-50%) and patient turnover (4 patients per
bed per calendar month).

Analysis was on an intention-to-treat basis at the individual patient level. The primary
analysis included only the 6 randomised bays. The two non-randomised bays were included
in a separate exploratory analysis. Each of the outcome measures was summarised by
intervention or control group using descriptive statistics. As there was no formal sample size
calculation, no statistical comparison between trial arms was made.

Study set-up

The monitoring system was set up in the wards over a period of six weeks, during which a
number of stakeholders were engaged with the project. Early on, permission from the
Estates and Information Technology departments was obtained. The ceiling-mounted
bridges were installed by the hospital Estates department using existing electrical wiring
circuits to ensure compliance with local policies. The monitoring software was integrated
with the hospital admissions data system, so that patients could easily be added to the
remote monitoring system. All data are stored and retained on the hospital network,
alleviating initial concerns about data security by inheriting all hospital security procedures
and data backup policies.

General surgeons were informed of the project at local audit meetings. Nursing staff were
trained face-to-face to use the system over a period of one week, after which ad hoc
refresher training was available on request.

Results

350 patients were included in the study between January and June 2017. A patient flow
chart is presented in Figure 2, and patient characteristics in Table 1.

140 patients were allocated to receive continuous monitoring alongside standard care. 210
patients were allocated to the control group. 86 of these patients were admitted to
randomised bays.

Two patients in the control arm (both from randomised bays) were given the continuous
monitoring intervention at the request of the direct care team.
73% of patients (n=257) underwent a surgical intervention during their admission. These were mostly colorectal resections (n=132), stoma formations (n=23), stoma reversals (n=12), hernia repairs (n=20) and other colorectal laparotomies including fistula exploration (n=23). Less common procedures were hepatobiliary (n=14), urological (n=9), appendicectomy (n=7) and abdominal wall repair (n=5). 8 procedures were classified as Other.

There were a similar number of complications and sepsis events across both arms of the study (see Supplementary Material), indicating that both groups had similar baseline risk factors.

One patient died of alcoholic liver disease during their participation in the study. This patient was allocated to receive continuous monitoring.
Table 1: Baseline patient characteristics

<table>
<thead>
<tr>
<th></th>
<th>SensiumVitals®+NEWS (n=140)</th>
<th>NEWS alone (n=86)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Males</strong></td>
<td>76 (54.3%)</td>
<td>39 (45.4%)</td>
</tr>
<tr>
<td><strong>Females</strong></td>
<td>64 (45.7%)</td>
<td>47 (54.6%)</td>
</tr>
<tr>
<td><strong>Age (mean)</strong></td>
<td>65.2 years (range 24-94)</td>
<td>63.7 (range 21-92)</td>
</tr>
<tr>
<td><strong>ASA</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>9 (6.4%)</td>
<td>9 (10.5%)</td>
</tr>
<tr>
<td>2</td>
<td>62 (44.3%)</td>
<td>35 (40.7%)</td>
</tr>
<tr>
<td>3</td>
<td>42 (30.0%)</td>
<td>22 (25.6%)</td>
</tr>
<tr>
<td>4</td>
<td>3 (2.1%)</td>
<td>3 (3.5%)</td>
</tr>
<tr>
<td>Not documented</td>
<td>24 (17.1%)</td>
<td>17 (19.8%)</td>
</tr>
<tr>
<td><strong>Emergency admissions</strong></td>
<td>70 (50%)</td>
<td>44 (51.2%)</td>
</tr>
<tr>
<td><strong>Elective admissions</strong></td>
<td>70 (50%)</td>
<td>42 (48.8%)</td>
</tr>
<tr>
<td><strong>Surgical intervention</strong></td>
<td>103 (73.6%)</td>
<td>62 (72.1%)</td>
</tr>
<tr>
<td><strong>Medical outliers</strong></td>
<td>19 (13.6%)</td>
<td>14 (16.3%)</td>
</tr>
</tbody>
</table>

Primary outcome measure

The main results of the study are summarised in Table 2. Of the 36 sepsis events recorded in randomised bays, there was sufficient data to analyse the time to antibiotics in 34 cases. The average time from the first evidence of sepsis to the first administration of antibiotics was 626 minutes in the intervention group (n=22, 95% CI 431.7-820.3 minutes). The average time to antibiotics in the control group was 1012.8 minutes (n=12, 95% CI 425.0-1600.6 minutes)(see Figure 3).

Figure 3: Scatter graphs to show mean (x) and 95% confidence intervals between trial arms for Time to antibiotics in sepsis, Length of hospital stay and 30-day readmission rate.
<table>
<thead>
<tr>
<th></th>
<th>SensiumVitals +NEWS (n=140)</th>
<th>NEWS alone: incl non-randomised bays (n=210)</th>
<th>NEWS alone: only randomised bays (n=86)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Males</td>
<td>76 (54.3%)</td>
<td>77 (36.7%)</td>
<td>39 (45.4%)</td>
</tr>
<tr>
<td>Females</td>
<td>64 (45.7%)</td>
<td>133 (63.3%)</td>
<td>47 (54.6%)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean Range</td>
<td>65.2 years (24-94 years)</td>
<td>60.5 years (19-93 years)</td>
<td>63.7 years (21-92 years)</td>
</tr>
<tr>
<td>ASA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>9 (6.4%)</td>
<td>19 (9.0%)</td>
<td>9 (10.5%)</td>
</tr>
<tr>
<td>2</td>
<td>62 (44.3%)</td>
<td>97 (46.2%)</td>
<td>35 (40.7%)</td>
</tr>
<tr>
<td>3</td>
<td>42 (30.0%)</td>
<td>50 (23.8%)</td>
<td>22 (25.6%)</td>
</tr>
<tr>
<td>4</td>
<td>3 (2.1%)</td>
<td>5 (2.4%)</td>
<td>3 (3.5%)</td>
</tr>
<tr>
<td>Not documented</td>
<td>24 (17.1%)</td>
<td>39 (18.6%)</td>
<td>17 (19.8%)</td>
</tr>
<tr>
<td>Emergency admissions</td>
<td>70 (50%)</td>
<td>113 (53.8%)</td>
<td>44 (51.2%)</td>
</tr>
<tr>
<td>Elective admissions</td>
<td>70 (50%)</td>
<td>97 (46.2%)</td>
<td>42 (48.8%)</td>
</tr>
<tr>
<td>Surgical intervention</td>
<td>103 (73.6%)</td>
<td>154 (73.3%)</td>
<td>62 (72.1%)</td>
</tr>
<tr>
<td>Medical outliers</td>
<td>19 (13.6%)</td>
<td>27 (12.9%)</td>
<td>14 (16.3%)</td>
</tr>
<tr>
<td>Number of complications (all*)</td>
<td>102 (72.9%)</td>
<td>143 (68.1%)</td>
<td>57 (66.3%)</td>
</tr>
<tr>
<td>Number of major complications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Clavien-Dindo &gt;2**)</td>
<td>8 (5.7%)</td>
<td>17 (8.1%)</td>
<td>5 (5.8%)</td>
</tr>
<tr>
<td>Sepsis events</td>
<td>24 (17.1%)</td>
<td>33 (15.7%)</td>
<td>12 (14.0%)</td>
</tr>
<tr>
<td>Time to antibiotics in cases of sepsis</td>
<td>n=22</td>
<td>n=32</td>
<td>n=12</td>
</tr>
<tr>
<td>Mean (95% confidence interval)</td>
<td>626.0 minutes (95% CI 431.7-820.3)</td>
<td>900.0 minutes (95% CI 621.6-1178.4)</td>
<td>1012.8 minutes (95% CI 425.0-1600.6)</td>
</tr>
<tr>
<td>Level II/III admissions</td>
<td>3 (2.1%)</td>
<td>5 (2.4%)</td>
<td>2 (2.3%)</td>
</tr>
<tr>
<td>(95% confidence interval)</td>
<td>(95% CI 0%-4.54%)</td>
<td>(95% CI 0.319%-4.44%)</td>
<td>(95% CI 0%-5.51%)</td>
</tr>
<tr>
<td>Length of stay in hospital</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (95% confidence interval)</td>
<td>13.3 days (95% CI 11.3-15.3)</td>
<td>15.5 days (95% CI 10.1-20.9)</td>
<td>14.6 days (95% CI 11.5-17.7)</td>
</tr>
<tr>
<td>Readmissions</td>
<td>16 (11.4%)</td>
<td>38 (18.1%)</td>
<td>18 (20.9%)</td>
</tr>
<tr>
<td>(95% confidence interval)</td>
<td>(95% CI 6.16%-16.7%)</td>
<td>(95% CI 12.9%-23.3%)</td>
<td>(95% CI 12.3%-29.5%)</td>
</tr>
<tr>
<td>Inpatient deaths</td>
<td>1 (0.7%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

Table 1: Summary of patient characteristics in both patched and control arms
*All complications include any deviations from the normal post-operative course, from minor (such as nausea) to major (such as death).
** Clavien-Dindo is a scale for the severity of complications. A Clavien-Dindo score >2 indicates that the complication required critical care admission or a further surgical procedure, or resulted in death.

Table 2: Summary of outcome measures
Secondary outcome measures

There were very few inpatient deaths (n=1) and admissions to Level II/III care (n=5) across both arms of the study. Length of hospital stay was on average 1.3 days shorter in patients who had continuous monitoring (13.3 days, 95% CI 11.3-15.3 days versus 14.6 days, 95% CI 11.5-17.7 days). The rate of readmissions within 30 days of discharge was lower in the continuous monitoring group (11.4%, 95% CI 6.16%-16.7% versus 20.9%, 95% CI 12.3%-29.5%)(see Figure 3).

Exploratory analysis

When the two non-randomised bays were analysed alongside the 6 randomised bays, the results were very comparable with narrower confidence intervals (Table 2).

Patient acceptability and compliance

58 out of 140 (41%) patients in the continuous monitoring group returned a short questionnaire. The results are shown in Figure 4. 82% of patients found the patch to be comfortable. 82% of the patients reported feeling safer whilst wearing the patch.

Patients in the continuous monitoring group wore the patch for an average of 5 days (range 1-24 days). Of the 142 patients who wore the monitoring patch, 34 had the continuous monitoring discontinued early (see Figure 2); 23 of these were at patient request. Two patients developed a rash under the electrodes. Eighteen patients found it itchy or bothersome. Three patients did not offer a reason for removing the patch.

![Figure 4: Patient responses to Questionnaire](image)

Discussion

In this single-centre randomised controlled trial, surgical patients with evidence of sepsis tended to receive antibiotics faster if they received continuous vital signs monitoring when compared to those receiving usual NEWS monitoring alone. Patients receiving continuous
vital signs monitoring had a shorter average length of hospital stay and were less likely to require readmission within 30 days of discharge. Patients found the monitoring device to be acceptable in terms of comfort and perceived safety.

The findings must be interpreted within the limitations of the study. A formal sample size calculation was not possible given the lack of data surrounding the primary outcome measure and so the findings were limited to descriptive statistics; no formal statistical comparison was possible[11]. Although the wide, overlapping confidence intervals suggest that a statistically significant difference between the two groups is unlikely, with a larger sample size and increased study power it is possible that the observed trends might become statistically significant. In addition, the relatively small number of sepsis cases means there is likely to be imbalance in pre-randomisation variables, which would require adjustment in a formal analysis.

There were very few cases of inpatient mortality or admission to Level II/III care, making comparisons between the monitoring arms difficult. One explanation for this low event rate is that the population contained a high proportion of low-risk patients: medical outliers and those who did not undergo surgery during their admission. A more striking effect might be evident in a higher-risk population.

The limitations of the randomisation technique must also be taken into account. Ideally, the study data would have been analysed at cluster level, but small numbers of patients within each bay necessitated analysis at the individual level. The cluster-randomisation methodology led to differences in the baseline demographics of the treatment arms. One of the female bays allocated to receive continuous monitoring had a proportionally lower turnover of patients than the other bays. This led to an imbalance in the male: female ratio between the two arms. The fact that the control arm was, on average, 1.5 years younger than the treatment arm may have conferred an advantage to this group.

The potential benefits of continuous monitoring may have been underestimated in this study due to the exposure to the patch in the intervention arm. 24% of the patients who were allocated to receive continuous monitoring did not wear the patch for their entire admission. However, this may reflect what can be truly expected in the clinical environment. There were other challenges to implementing the technology. There was initially an unacceptably high number of alerts sent to nursing staff. These were reduced by 90% by adjusting the alarm thresholds to more clinically appropriate levels and increasing the intervals between reminder alerts. Engagement with the new system varied between nursing staff but was aided by support from senior ward nurses. Engagement was further increased with the implementation of changes suggested by the nursing staff themselves, such as smaller devices and louder alert tones.

There are few clinical evaluations of continuous vital signs monitoring in the literature[8]. The preponderance of observational studies means that causal associations between interventions and patient outcomes have to be interpreted with care. The three largest randomised controlled trials of continuous monitoring report conflicting results, illustrating the difficulties in evaluating such complex interventions. The potential benefit of the additional monitoring may be negated by inadequacies in other areas, such as staffing levels, escalation protocols and nursing compliance[12]. Demonstrating clinical benefit will likely require large, well-controlled studies in high-risk populations to find significant differences in clinical outcomes, such as critical care admissions. This is important as these systems are
not without financial cost. System prices are around $1500, and the cost of disposable patches varies.[7] Further research is required to determine with certainty whether continuous postoperative monitoring offers a significant benefit over intermittent monitoring and can be justified for routine care in terms of cost effectiveness.

In conclusion, this study has demonstrated the practicability and acceptability of implementing a remote continuous monitoring system in the general surgical ward setting. There is a trend towards clinical benefit. The findings of this study should be used to inform the protocols for further evaluations. Follow-up studies should be individually-randomised and stratified to minimise the baseline differences between the two treatment arms and include a high-risk population with a high rate of adverse events.

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Declaration of interests

There are no known conflicts of interest associated with this work and there has been no significant financial support for this work that could have influenced its outcome.
References


