

Postoperative quality and safety using Efficacy Safety Score (ESS) and a wireless patient monitoring system at the ward: A randomised controlled study

Erlend Johan Skraastad^{1,2} | Petter Christian Borchgrevink^{2,3} | Tom Ivar L. Nilsen^{1,4} | Johan Ræder^{5,6}

¹Clinic of Anaesthesia and Intensive care, St. Olavs hospital, Trondheim University Hospital, Trondheim, Norway

²Department of Circulation and Medical Imaging, Norwegian University of Science and Technology, Trondheim, Norway

³Unit on Complex Symptom Disorders, St. Olavs hospital, Trondheim University Hospital, Trondheim, Norway

⁴Department of Public Health and Nursing, Faculty of Medicine and Health Sciences, Norwegian University of Science and Technology, Trondheim, Norway

⁵Department of Anaesthesia and Intensive Care Medicine, Oslo University Hospital, Oslo, Norway

⁶Institute for Clinical Medicine, Medical Faculty, University of Oslo, Oslo, Norway

Correspondence

Erlend Johan Skraastad, Clinic of anaesthesia and Intensive Care, St.Olavs Hospital, Pb 3250 Torgarden, NO-7006 Trondheim, Norway.
Email: Erlend.Johan.Skraastad@stolav.no

Background: Postoperative pain, side-effects and time to mobilisation are indicators for the quality of postoperative recovery. The aim of this randomised controlled study was to investigate if efficacy safety score (ESS) combined with a wireless patient monitoring system would improve these clinical outcomes for patients at a general surgical ward.

Methods: The trial included 195 patients randomised to a standard care group (SC-Group) or intervention group (INT-Group) receiving continuous wireless monitoring of vital signs combined with ESS during the first 24 postoperative hours. The primary outcome was time to mobilisation. Secondary outcomes were average pain, doses of postoperative opioids, unscheduled interventions, side-effects, patient satisfaction and length of hospital stay (LOS).

Results: Mean time to postoperative mobilisation was 10.1 hours for patients in the INT-Group compared to 14.2 hours in the SC-Group; this corresponds to an adjusted hazard ratio of 1.54 (95% confidence interval 1.04-2.28). INT-Group patients received a higher dose of oral morphine equivalents; 26 mg vs 15 mg, $P < .001$; reported lower intensity of pain on a 0-10 scale; 2.1 vs 3.3, $P < .001$; and had higher patient satisfaction on a 5-point scale; 4.9 vs 4.3, $P < .001$. The LOS was similar between the groups; 71 hours in INT-Group vs 77 hours in SC-Group, $P = .58$. No serious side-effects were registered in INT-Group, whereas two were registered in SC-Group.

Conclusions: Introducing ESS as a decision tool combined with a wireless monitoring system resulted in less pain, increased satisfaction and more rapid mobilisation for patients in this study.

Trial Registration: clinicaltrials.gov Identifier: NCT03438578.

1 | INTRODUCTION

Judgement of quality of postoperative recovery has changed from single physiological variables to a broader assessment of patient outcome, for example, ability to drink, eat and mobilise.¹ To achieve this,

adequate and safe treatment of acute postoperative pain is important.^{2,3} Despite increased attention, postoperative pain is still undertreated.⁴ A Dutch study showed that 30% of patients had moderate or severe postoperative pain at rest,⁵ and in a Norwegian study, 38% reported a mean pain intensity ≥ 4 on an 11-point numeric scale.⁶

This is an open access article under the terms of the Creative Commons Attribution License, which permits use, distribution and reproduction in any medium, provided the original work is properly cited.

© 2019 The Authors. *Acta Anaesthesiologica Scandinavica* published by John Wiley & Sons Ltd on behalf of Acta Anaesthesiologica Scandinavica Foundation

Opioids are still standard care for management of acute postoperative pain, but the risk of severe adverse events can limit optimal dosing for analgesia.⁷ Although over-dosing of analgesics after non-complicated anaesthesia and surgery is rare, it still represents a major safety challenge.^{8,9} In a post-anaesthesia care unit (PACU) there are staffing and monitoring available to ensure quality and safety of the treatment. After discharge to an ordinary ward, there is less available capacity for frequent patient observation.

Postoperative patient side-effects, such as pain, nausea and vomiting, are often not documented in a standardised manner at the ward or put into a comprehensive overall evaluation or overview.^{6,10} Early warning scores, such as the National Early Warning Score (NEWS), have been developed to standardise surveillance of vital functions,¹¹ but do not include patient's quality parameters. At the project hospital, NEWS was based on cumbersome registration using pen and paper.

Efficacy Safety Score (ESS) is a validated clinical decision tool for the first 24 postoperative hours including both the PACU and the ward periods.¹² It covers multiple components of patient safety and quality status while monitoring the patient's experiences of the quality of care, including pain at rest and at movement. The Patient Status Engine (PSE) from Isansys Lifecare Ltd. is a wireless, semiautomatic registration system of vital patient parameters from wearable medical sensors.¹³

The aim of this study was to test the hypothesis that quality of care could be improved by combining ESS and PSE during the ward period of the first 24 hours after surgery, with reduced time to mobilisation and improved pain management, while ensuring patient safety.

2 | METHODS

2.1 | Design and setting

This single-centre, randomised controlled trial, with two parallel groups, was conducted at the Orkdal Department, St. Olavs Hospital, Trondheim University Hospital, Norway. Design and description of the study adhered to the Consolidated Standards of Reporting Clinical Trials statement (CONSORT).¹⁴ The study was approved by the Regional Committee for Medical and Health Research Ethics (reference number 2017/1903/REK South East A) and registered at clinicaltrials.gov (NCT03438578).

2.2 | Eligible patients for the study

Eligible patients were identified from operating theatre lists of mixed surgery at a medium-sized surgical unit and recruited during pre-admission clinic or when prepared for surgery. Inclusion criteria were patients undergoing acute or elective surgery expected to be hospitalised more than 24 hours postoperatively. Exclusion criteria were patients <18 years of age, poor communication capabilities or when planned surgery was incompatible with mobilisation during the first 24 hours. All the patients were subjected to the same post-operative

Editorial Comment

Despite improved postoperative pain treatment regimes on the hospital wards, variable and most often manual collection of routine clinical status of patients still poses a challenge. In this randomized clinical trial examining the post-operative period, introduction of an automated monitoring system enabled better pain relief, higher patient satisfaction, and slightly shorter post-operative hospital stay

prescriptions and PACU discharge criteria, according to the hospital protocols.

The intervention and study observation period started when patients returned to the ward from the PACU.

The ward nurses obtained patients' written informed consent pre-operatively and performed study enrolment. The patients were then randomly assigned to one of two groups—a standard care group (SC-Group) or an intervention group (INT-Group)—using a random number generator and sequentially numbered, opaque sealed envelopes set up a priori by the study personnel.¹⁵ The ward nurses had to pick up the envelope at a restricted office after enrolment. Due to the clinically obvious monitoring system, neither the staff nor patients could be blinded to group allocation at the ward.

2.3 | Intervention group

In the INT-Group, the ward nurses assessed ESS in parallel with electronic automatic retrieved vital signs from the wireless monitoring platform PSE. The PSE is a class IIa CE-marked medical device (Isansys Lifecare Ltd.) for hospital use monitoring heart rate, ECG, ventilation rate, axillar skin temperature, blood pressure and finger pulse oximetry; all from wireless and wearable sensors.¹³ The PSE gives an updated NEWS every minute which is calculated from the sensors, except for blood pressure measurements which are initiated manually. Registration of ESS was recorded for storage on the bedside PSE device, done hourly during the first 4 hours after PACU discharge and then every second hour except when the patient was confirmed sleeping. In this study, we used bedside monitoring and visual warnings were displayed on the bedside device. Information on given medication was extracted manually from the patients' charts.

2.4 | Standard care group

In the SC-Group, NEWS was documented on paper formularies at least every 12 hours or with increased frequency in the presence of increased symptom severity. The hospital's clinical guidelines for ward postoperative pain assessment were to evaluate pain upon arrival, and then regularly and at least every 8 hours. For patients receiving continuous epidural—or peripheral nerve block analgesia—evaluation was to be done every 3 hours. Frequency of postoperative pain evaluation and notes about pain assessment and management

were registered together with given medication, extracted from the patients' charts.

2.5 | Ordinary postoperative protocol

Both groups followed the same protocols and indications for medication according to the hospital's clinical guidelines. At the study hospital, post-operative pain management is provided by prophylactic multimodal regular prescriptions according to instructions for the individual procedure: paracetamol, non-steroidal anti-inflammatory drugs, steroids, opioids, local anaesthesia in the wound, perineural blocks and regional anaesthesia. Extra medications beyond these are mainly intravenous or oral administration of oxycodone 2.5-5 mg. According to hospital guidelines, extra opioid medication may be administered when pain is >3 on an 11-point verbal numeric rating scale (VNRS) based on nurse judgement. Further, the guideline is to provide supplementary oxygen if saturation is <94% on pulse oximetry for patients not having chronic obstructive pulmonary disease and/or when needed as judged by the nurse.

2.6 | Outcomes

The primary endpoint of this study was time to full mobilisation, defined as being able to walk more than one step with or without support.¹⁶ For both groups, mobilisation was attempted as early as possible after surgery, following the protocols for nursing plan and physiotherapy plan.

Secondary endpoints were average postoperative pain for the first 24 hours evaluated by an 11-point VNRS, milligrams of postoperative administered opioids, overall patient satisfaction on a 5-point scale, number of documented NEWS and pain assessments, presence of postoperative nausea and vomiting, unscheduled postoperative interventions, postoperative complications and length of hospital stay (LOS). For comparison of opioid medications, we used the conversion calculator for oral morphine milligram equivalents (MME) provided by the Norwegian Health Economics Administration (<http://www.helfoweb.com/morfinekvivalen-ter/>). Opioid additives to epidural anaesthesia are not part of this.

All the patients answered a questionnaire (see attachment) 24 hours postoperatively. This was performed by the study personnel and included questions about mobilisation, average pain, postoperative nausea and retching/vomiting, sleep, anxiety and worry, patient self-reported safety and security, mental function and satisfaction. We also registered unscheduled visits from physicians due to postoperative clinical issues or need for supplementary oxygen. Finally, we registered readmissions to the PACU or intensive care unit from the ward.

2.7 | Sample size calculations

A validation study addressing ESS in a total of 207 patients¹² was used for sample size calculations of the trial. A sample size of 130 patients (65 in each group) was required to show a 25% difference in mean time until full mobilisation from 12.6 (95% CI 10.6-14.6) hours with a power of 80% and an alpha level of 0.05 (Kane SP. SampleSizeCalculator.

<http://clincalc.com/Stats/SampleSize.aspx>). A sample size of 200 (100 in each group) included patients was considered sufficient to identify meaningful effect of the intervention on the primary outcome, allowing for some dropouts and missing data.

2.8 | Statistical methods

The Kaplan-Meier method and a log-rank test were used to analyse time to mobilisation, and group differences were analysed using the Mann-Whitney test. Additionally, Cox-regression was used to estimate hazard ratios for time to mobilisation between the intervention and control group, adjusting for age, American Society of Anesthesiologists (ASA) classification and sex. We used linear regression to estimate mean differences between the groups for opioid medication doses, numbers of pain assessments, NEWS performed and pain intensity assessments adjusting for age, ASA classification and sex. The precision of estimated effects is given by a 95% confidence interval. Categorical variables, such as reported oxygen therapy, postoperative nausea and retching/vomiting, were analysed using Chi-square tests. Patient satisfaction was analysed with Fischer's exact test based on a Chi-square test, due to low numbers of expected patients in some groups.

All collected data were registered in Microsoft® Excel® for PC, version 16. Data were analysed using SPSS version 25.0 (SPSS, Chicago, IL, USA).

3 | RESULTS

3.1 | Study groups

From 5 March 2018 to 18 October 2018, 201 patients were consecutively asked to participate; 200 were included and randomly assigned to two groups. As shown in the flow diagram (Figure 1), a total of 485 patients were potential candidates (ie planned in-hospital overnight stay and adequate communication skills) for the study. We were not able to attempt inclusion of all, due to limitations such as number of nurses and equipment available for study. Five patients were excluded, see Figure 1, resulting in data from 195 patients in the final analysis. Pre- and peroperative characteristics, length of stay and milligram equivalents of opioids given in the PACU, were similar between the groups (Table 1).

3.2 | Primary outcome

As the study progressed, it turned out to be a high number of prostatectomy patients (40 and 41 in the INT-Group and SC-Group respectively) who were instructed by the surgeon to not mobilise until the next day, making a cluster of mobilisation times for these patients in the data set within the 14-20 hour interval. After removing these radical prostatectomy patients from the analysis, the difference in mean time to mobilisation was 4.0 (95% CI 1.1-7.0) hours, with 10.1 (95% CI 8.1-12.2) hours for the INT-Group vs 14.2 (95% CI 12.0-16.3) hours for the SC-Group, $P = .008$.

The rate of mobilisation was 54% higher for INT-Group compared to SC-Group at any given time-point studied, when adjusted for age, ASA classification and sex: Hazard ratio 1.54 (95% CI 1.04-2.28).

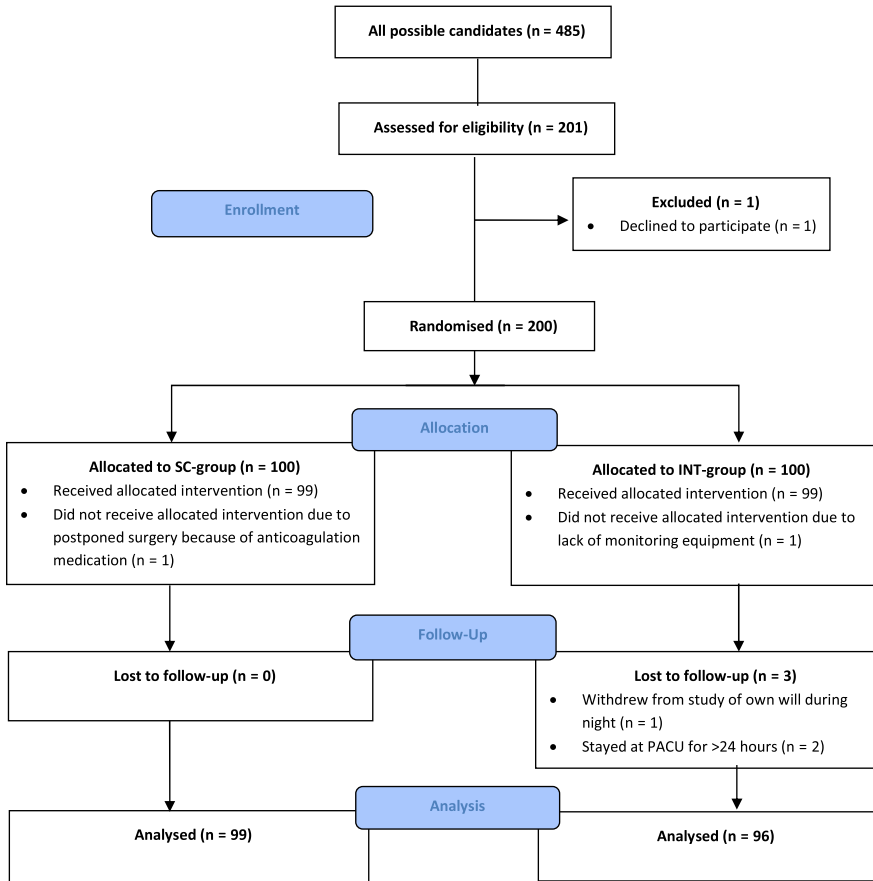


FIGURE 1 CONSORT 2010 flow diagram [Colour figure can be viewed at wileyonlinelibrary.com]

3.3 | Secondary outcomes

The difference in mean average intensity of pain on a 0-10 VNRS was 1.2 (95% CI 0.8-1.7), $P < .001$, with 2.1 (95% CI 1.8-2.9) for the INT-Group vs 3.3 (95% CI 2.9-3.7) for the SC-Group. The distribution of average pain is shown in Figure 2. An average pain intensity ≥ 4 on 0-10 VNRS was reported for 16% of the patients in the INT-Group and for 43% in the SC-Group.

The difference in mean opioid dose in MME provided at the ward was 10.3 (95% CI 4.2-16.4) mg, $P = .001$, with 25.5 (95% CI 20.9-30.0) mg in the INT-Group compared to 15.2 (95% CI 11.1-19.3) mg in the SC-Group. The distribution range is shown in Table 2. Figure 3 shows the relation of mean administered MME at the ward and average pain.

The difference in mean reported patient satisfaction on a 1-5 scale was 0.6 (95% CI 0.39-0.79), $P < .001$, with 4.9 (95% CI 4.9-5.0) for the INT-Group compared to 4.3 (95% CI 4.2-4.5) for the SC-Group. See Table 3 for distribution.

The difference in mean number of documented evaluations of pain was 5.3 (95% CI 4.7-5.9), $P < .001$, with 6.7 (95% CI 6.1-7.29) times for the INT-Group vs 1.4 (95% CI 1.1-1.6) times for the SC-Group. For 17 patients in the SC-Group, there was no documentation about pain for the study period.

Mean number of performed NEWS differed by 4.8 (95% CI 4.0-5.5), $P < .001$, with 8.2 (95% CI 7.4-9.0) in the INT-Group compared to 3.4 (95% CI 3.1-3.6) in the SC-Group.

Postoperative nausea and retching/vomiting were reported for 41 and 12 patients in the INT-Group, respectively, vs 45 and 21 patients in the SC-Group. This results in differences in proportions of 5.2% (95% CI -8.9-19.0), $P = .48$, and 9.3% (95% CI -2.0-20.5), $P = .10$, for nausea and retching/vomiting respectively.

Supplementary oxygen at the ward was provided to 57 patients in the INT-Group compared to 32 patients in the SC-Group, a difference in proportions of 25.6% (95% CI 11-59-38.25), $P < .001$.

Serious complications were not observed in INT-Group, but in two patients in SC-Group: One patient was accidentally found in a state of unconsciousness and seizure 6 hours after surgery. This happened again, and telemetrically ECG monitoring was established. An asystole alarm call went off, and the patient was treated for severe bradycardia at an intensive care unit. Another patient in the SC-Group was treated for having a stroke after mobilisation at the ward.

Minor complications were not reported in the SC-Group. Five patients in the INT-Group were identified by the nurses in need of extra treatment and follow-up: Two for pain treatment (nerve blocks established), two for treatment of hypotension and one for treatment of atrial fibrillation.

Mean LOS for the INT-Group was 70.9 (95% CI 63.1-78.7) hours compared to 76.6 (95% CI 61.0-92-3) hours for the SC-Group, a difference of 5.8 (95% CI -23.5 -12.0) hours, $P = .58$.

TABLE 1 Patient characteristics. Data are numbers or mean (\pm SD)

	INT-Group	SC-Group
Number of patients (n)	96	99
Age (years)	61 (\pm 12.5)	62 (\pm 13.3)
Height (m)	1.74 (\pm 0.10)	1.71 (\pm 0.10)
Weight (kg)	88.7 (\pm 18.8)	84.2 (\pm 19.0)
Body Mass Index (kg/m ²)	29.3 (\pm 6.9)	28.2 (\pm 6.1)
Sex (female/male)	36/60	37/62
Duration of anaesthesia (min)	177 (\pm 42)	182 (\pm 40)
American Society of Anesthesiologists Status (n)		
ASA I	1	2
ASA II	40	38
ASA III	52	56
ASA IV	3	3
Type of surgery performed (n)		
Urology		
Robot assisted radical prostatectomy (RARP)	40	41
Gastric surgery (n)		
Hemicolectomy laparoscopic/-open	9/3	4/3
Bariatric surgery (Gastric sleeve)	12	7
Stoma reversal	9	8
Laparoscopic small bowel resection/stoma	4	5
Total colectomy	1	2
Other (diagnostic laparotomy, acute cholecystectomy, proctectomy)	1	4
Orthopaedic surgery (n)		
Shoulder joint replacement	10	11
Ankle arthrodesis	2	4
Hip-/knee joint replacement	2	2
Fracture fixation	3	5
Shoulder joint stabilisation/reconstruction	0	2
Type of anaesthesia performed (n)		
Gas anaesthesia: Propofol induction. Desflurane and fentanyl/remifentanil	59	60
Gas anaesthesia + Epidural Anaesthesia/Regional block	30	33
Spinal anaesthesia \pm propofol sedation	7	6
Premedication (n)		
Paracetamol	96	99
Dexamethasone	93	98
Opioids	84	81
Non-steroidal inflammatory drugs	33	27
Fentanyl provided for surgery (mg)	0.25 (\pm 0.11)	0.25 (\pm 0.12)
Remifentanil provided for surgery (mg)	1.23 (\pm 0.85)	1.27 (\pm 0.89)
Morphine Milligram Equivalents provided at PACU (mg)	18.6 (\pm 22.9)	18.0 (\pm 21.5)
Time from end of surgery to discharge from PACU (min)	195 (\pm 81)	201 (\pm 80)

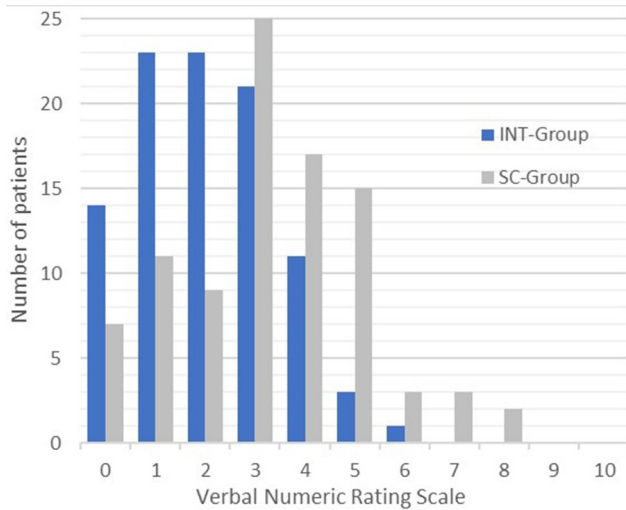


FIGURE 2 Distribution of patient-reported average pain for the first post-operative 24 hours on an 11-point verbal numeric rating scale (VNRS). Difference in mean average intensity of pain between the groups VNRS was 1.2, $P < .001$ [Colour figure can be viewed at wileyonlinelibrary.com]

4 | DISCUSSION

We report the results of the first randomised trial of postoperative use of the validated,¹² novel decision tool ESS integrated with wireless patient monitoring at a surgical ward. The results were earlier mobilisation, less pain, increased use of opioids and more satisfied patients during the ward part of the first 24 hours, by providing these clinical tools compared to standard care.

Mobilisation is a suggested golden goal for anaesthesia outcome because it encompasses the return of a spectre of physical capabilities.¹ Benefits from early mobilisation are shown for various types of postoperative patients.¹⁷ In our study, it turned out that the prostatectomy patients got restrictions on early mobilisation. To avoid the results getting biased from this, we excluded these patients from the analysis for time to mobilisation.

Our data on pain may be compared with a previous Norwegian study, the mean intensity of postoperative pain was then 3.0 on an 11-point numeric scale during the first 24 hours, and 38% of the patients reported a mean intensity of pain ≥ 4 .⁶ Compared to this, our results are better for the INT-Group, whereas for the SC-Group they are similar. The same authors recommended that postoperative on-demand medication should be given if pain intensity is over 3 on an 11-point scale, which also was determined as a cut-off for moderate-to-severe pain.¹⁸

The reason for less pain in the INT-Group may both be more attention and more opioid medication. The nurses performed a higher

number of NEWS and pain documentations in the INT-Group, and hence probably gave more attention to these patients. They also gave more opioids to patients in this group. This suggests improved communication and that the nurses were comfortable in giving a higher opioid medication.⁷ The association between more opioids used and less subsequent pain is to be expected.

Not all patients in the INT-Group got opioids. The nurses identified those in need of more on an individual basis and provided these patients efficient on-demand pain relief, with maintained safety. Table 2 shows that some of these patients needed, and were given, far above-average opioid doses. The INT-Group was four times as likely to get opioid dosing within the three highest dose intervals. Extra opioids were given at lower VNRS score compared to patients in the SC-Group (Figure 3). The situation for the patients in the SC-Group with the highest average VNRS represents a major quality concern. More opioid treatment in the INT-Group did not result in any increase in emetic symptoms or respiratory problems. Further, potential more drowsiness from more opioids in the INT-Group was not shown. In fact, the opposite seemed to be the situation, as these patients had earlier mobilisation and a tendency of shorter hospital stay.

Our interpretation is that the frequent surveillance with the ESS tool made the nurses able to pick out and surveil those patients with an individual higher need of opioids, and to treat them accordingly with better pain results and no increase in side-effects.

All our patients got optimal non-opioid multimodal premedication analgesic regimes, but despite this, most needed opioid pain medication, as will be expected for major surgical procedures staying overnight.¹⁹ Opioid analgesic is still a cornerstone in postoperative pain treatment and best controlled in the early phase in the PACU with titrated intravenous agents for reliable and rapid action.²⁰ Adequate early pain management may be associated with a lower incidence of persistent postoperative pain.²¹ Early appropriate treatment with higher opioid dosages of short duration which maximises analgesia, while minimising the risk of later abuse, has been advocated.²²

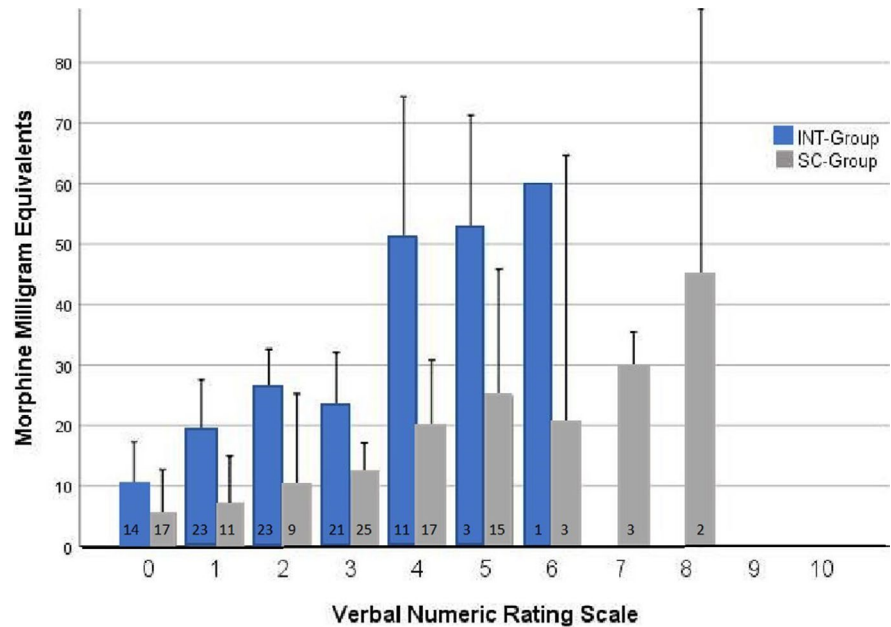
The pain assessment protocol in the INT-Group was more frequently scheduled and the documentation process itself was easier when compared to the hospital's standard protocol. This may explain some of the difference in the number of documented pain assessments.

The probability of receiving extra opioids for postoperative pain relief is significantly larger if a pain score is documented.²³ Absence of pain assessment and documentation were identified in a European survey report, which concluded with postoperative pain management being suboptimal.²⁴ The bedside documentation of ESS and automated NEWS by the PSE system is easier than manually performed NEWS, with subsequent documentation into patient

TABLE 2 Distribution range of total morphine milligram equivalents (MME) given at ward during the first 24 post-operative hours, n (per cent). Difference of mean provided MME between the groups was 10.3 mg, $P = .001$

	0 mg	1-19 mg	20-39 mg	40-59 mg	60-79 mg	>80 mg
INT-Group (n = 96)	12 (12.5%)	36 (37.5%)	24 (25.0%)	14 (14.6%)	8 (8.3%)	2 (2.1%)
SC-Group (n = 99)	34 (34.4%)	37 (37.4%)	22 (22.2%)	3 (3.0%)	2 (2.0%)	1 (1.0%)

FIGURE 3 Mean distributed morphine milligram equivalents (MME) at the ward related to average pain on an 11-point verbal numeric rating scale (VNRS) (95% CI). Number of patients in respective columns. Differences between the groups were 10.3 mg for MME, $P = .001$, and 1.2 on the VNRS, $P < .001$ [Colour figure can be viewed at wileyonlinelibrary.com]



records at another location. The total lack of documentation on pain in the SC-Group for 17 of 99 patients is similar to earlier reports of no documentation in 9%-13%.^{23,25}

It may be argued that simply enforcing the implementation of better pain and analgesia protocols may be as useful as the ESS + wireless monitoring system. Although this simple advice has been known for some time, documentation show that postoperative pain care has not improved to any major extent during the last years.⁴⁻⁶ Also, if a better and more rigorously applied pain protocol results in individualised use of more opioid analgesics, it will be necessary to have protocols on monitoring safety and side-effects.⁷⁻⁹ The ESS combined with wireless monitoring, as in our study, may be a way for systematic implementation of better overall care, including pain care.

The increased satisfaction in the INT-Group may be explained by improved pain relief, but other factors like being continuously monitored, regularity in follow-up and interactions with health care providers are probably also important. When patients become active participants in their own care it is shown that they become more comfortable and able to function.²⁶ However, the difference in satisfaction in our patients was mainly in the scaling of being 'satisfied' vs 'very satisfied', and this nuance may not be clinically significant outside a study setting.

Clinical outcomes are shown to be improved by the deployment of automated notification systems for vital signs monitoring in hospital wards.²⁷ The finding of increased use of oxygen therapy for the INT-Group reflects an expected effect of continuous monitoring.

Patients in the INT-Group with hypotension and atrial fibrillation were identified by the monitoring system, and the call-out algorithm initiated by a high ESS was used. The same algorithm was used for the two patients given nerve blocks due to insufficient pain control. This contrasts the SC-Group patient who was accidentally found unconscious with seizures. We think this would have been discovered earlier with continuous monitoring. However, this study was not designed to have the power to make any conclusions about patient safety issues, but the case reports are noteworthy.

A strength of this study is that ESS is validated and easy to perform in daily clinical work. Also, we had two large and similar groups without major differences in baseline variables. The groups showed internal diversity in age, sex and surgery performed, but we chose this design with mixed patient characteristics to achieve good generalisability.

A weakness is that we did not test the two components of the intervention separately. We chose a pragmatic approach with a combination of two possible favourable interventions to maximise patient satisfaction and safety. Moreover, due to the monitoring system, neither the staff nor the patients could be blinded to group allocation. However, the possible influence from the study induced focus on post-operative care may have resulted in better care also in the SC-Group, with potentially better results than in everyday care.

The relatively restricted observation period is another limitation. Whereas the ESS is designed also to be used in the PACU,¹² we

TABLE 3 Overall patient satisfaction for first 24 post-operative hours on a 1-5 scale, n (per cent). The difference in mean between the groups was 0.6 (95% CI 0.39-0.79), $P < .001$

	1 Very dissatisfied	2 Dissatisfied	3 Neutral	4 Satisfied	5 Very satisfied
INT-Group, n = 89	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (6.7%)	83 (93.3%)
SC-Group, n = 90	2 (2.2%)	3 (3.3%)	6 (6.7%)	30 (33.3%)	49 (54.4%)

chose to have a totally similar non-ESS protocol for all patients in the PACU period, in order to tease out the true benefit during the first day on the ward. This is a period when the patients have pain, side-effects and need for frequent surveillance, more so than later in the postoperative course. Outcomes further on, for the next day and for clinical endpoints after discharge, will definitely be of interest, but were beyond the scope of this study.

Also, as the benefit of using ESS and wireless monitoring has been established, a further step will be to look at the time consume, nurse satisfaction and cost-benefit of using these methods in a daily routine, and also to look for potential simplifications in order to minimise the extra workload.

This study shows that important postoperative issues, such as pain and early mobilisation, were significantly improved with the use of the clinical tool ESS and PSE wireless monitoring at the ward.

ACKNOWLEDGEMENTS

We thank study nurse Lillian A. Opøyen. for help conducting the study. We also thank all health care professionals at ward B3, St Olavs hospital, Orkdal for their assistance in this study.

CONFLICT OF INTEREST

The authors have no conflict of interest. Isansys Lifecare Ltd. (UK) lent us the monitoring hardware and provided supplies at a reduced price.

AUTHOR CONTRIBUTIONS

E.S.: Study design, conduct, analysis and manuscript preparation.
PCB, TILN, JR: Study design, analysis and manuscript preparation.

REFERENCES

- Levy N, Mills P, Mythen M. Is the pursuit of DREAMing (drinking, eating and mobilising) the ultimate goal of anaesthesia? *Anaesthesia*. 2016;71:1008-1012.
- Liu SS, Wu CL. Effect of postoperative analgesia on major postoperative complications: a systematic update of the evidence. *Anesth Analg*. 2007;104:689-702.
- Jones J Jr, Southerland W, Catalani B. The Importance of Optimizing Acute Pain in the Orthopedic Trauma Patient. *Orthop Clin North Am*. 2017;48:445-465.
- Meissner W, Coluzzi F, Fletcher D, et al. Improving the management of post-operative acute pain: priorities for change. *Curr Med Res Opin*. 2015;31:2131-2143.
- Sommer M, de Rijke JM, van Kleef M, et al. The prevalence of postoperative pain in a sample of 1490 surgical inpatients. *Eur J Anaesthesiol*. 2008;25:267-274.
- Fredheim OM, Kvarstein G, Undall E, Stubhaug A, Rustoen T, Borchgrevink PC. [Postoperative pain in patients admitted to Norwegian hospitals]. *Tidsskr Nor Laegeforen*. 2011;131:1763-1767.
- Gan TJ. Poorly controlled postoperative pain: prevalence, consequences, and prevention. *J Pain Res*. 2017;10:2287-2298.
- Benjamin (22) died after bone fracture. VG. <https://www.vg.no/forbruker/helse/i/Rv465/benjamin-22-doede-etter-benbrudd>. (19.05.2019), 2011.
- Got to strong medications - Davoud (23) died. Nettavisen. <https://www.nettavisen.no/nyheter/fikk-for-sterke-medisiner--davoud-%2823%29-dode/3257721.html>. (19.05.2019), 2011.
- Franck M, Radtke FM, Apfel CC, et al. Documentation of post-operative nausea and vomiting in routine clinical practice. *J Int Med Res*. 2010;38:1034-1041.
- Downey CL, Tahir W, Randell R, Brown JM, Jayne DG. Strengths and limitations of early warning scores: A systematic review and narrative synthesis. *Int J Nurs Stud*. 2017;76:106-119.
- Skraastad E, Raeder J, Dahl V, Bjertnaes LJ, Kuklin V. Development and validation of the Efficacy Safety Score (ESS), a novel tool for postoperative patient management. *BMC Anesthesiol*. 2017;17:50.
- Michard F, Sessler DI. Ward monitoring 3.0. *Br J Anaesth*. 2018;121:999-1001.
- Moher D, Schulz KF, Altman DG; CONSORT Group. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. *J Am Podiatr Med Assoc*. 2001;91:437-442.
- Doig GS, Simpson F. Randomization and allocation concealment: a practical guide for researchers. *J Crit Care*. 2005;20:187-191:discussion 91-3.
- Chua MJ, Hart AJ, Mittal R, Harris IA, Xuan W, Naylor JM. Early mobilisation after total hip or knee arthroplasty: A multicentre prospective observational study. *PLoS ONE*. 2017;12:e0179820-e179920.
- Epstein NE. A review article on the benefits of early mobilization following spinal surgery and other medical/surgical procedures. *Surg Neurol Int*. 2014;5:S66-73.
- Gerbershagen HJ, Rothaug J, Kalkman CJ, Meissner W. Determination of moderate-to-severe postoperative pain on the numeric rating scale: a cut-off point analysis applying four different methods. *Br J Anaesth*. 2011;107:619-626.
- Meissner W, Mescha S, Rothaug J, et al. Quality improvement in postoperative pain management: results from the QUIPS project. *Dtsch Arztebl Int*. 2008;105:865-870.
- Kaye AD, Ali SI, Urman RD. Perioperative analgesia: ever-changing technology and pharmacology. *Best Pract Res Clin Anaesthesiol*. 2014;28:3-14.
- Wu CL, Raja SN. Treatment of acute postoperative pain. *Lancet*. 2011;377:2215-2225.
- Brat GA, Agniel D, Beam A, et al. Postsurgical prescriptions for opioid naive patients and association with overdose and misuse: retrospective cohort study. *BMJ*. 2018;360:j5790.
- Ene KW, Nordberg G, Bergh I, Johansson FG, Sjöström B. Postoperative pain management - the influence of surgical ward nurses. *J Clin Nurs*. 2008;17:2042-2050.
- Benhamou D, Berti M, Brodner G, et al. Postoperative Analgesic Therapy Observational Survey (PATHOS): a practice pattern study in 7 central/southern European countries. *Pain*. 2008;136:134-141.
- Coyne ML, Smith JF, Stein D, Hieser MJ, Hoover L. Describing pain management documentation. *Medsurg Nurs*. 1998;7:45-51.
- McGuire DB. Comprehensive and multidimensional assessment and measurement of pain. *J Pain Symptom Manage*. 1992;7:312-319.
- Subbe CP, Duller B, Bellomo R. Effect of an automated notification system for deteriorating ward patients on clinical outcomes. *Crit Care*. 2017;21:52.

How to cite this article: Skraastad EJ, Borchgrevink PC, Nilsen TIL, Ræder J. Postoperative quality and safety using Efficacy Safety Score (ESS) and a wireless patient monitoring system at the ward: A randomised controlled study. *Acta Anaesthesiol Scand*. 2020;64:301-308. <https://doi.org/10.1111/aas.13492>