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Original article

Continuous remote monitoring in post–bariatric surgery patients: development of an early warning protocol

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Abstract

Background: Continuous monitoring of vital parameters after bariatric surgery can detect postoperative bleeding or anastomotic leakage.

Objectives: This report describes the development of a continuous remote early warning score (CREWS). This is an EWS-based notification protocol for deterioration detection in bariatric patients.

Setting: Catharina Hospital, the Netherlands.

Methods: Several CREWS protocols were developed by combining thresholds indicative of tachycardia and tachypnea using literature insights and expert sessions. These protocols were tested retrospectively using continuously measured vital signs in a cohort of 185 patients who underwent primary bariatric surgery. A wearable remote monitoring device (Healthdot, Philips) was used in hospital and at home up to 14 days after surgery. The outcomes included were demographics, use of beta-blockers, and complications necessitating reintervention.

Results: Thresholds of 110 beats per minute (bpm) and 20 breaths per minute (rpm) for heart rate and respiration rate, respectively, detected postoperative bleeding and anastomotic leakage with 75% (3/4 patients) sensitivity. The protocol was silent (no alarms/day) in 69.5% of patients and produced more than 1 alarm/day in 1.6% of patients. The average postoperative heart rate was unaffected by the use of beta-blockers.

Conclusions: A description of the steps in the development of an EWS protocol in bariatric patients based on continuous vital sign monitoring is useful. The most sensitive and silent protocol measured heart rate and respiratory rate with thresholds of 110 bpm and 20 rpm and appeared to be feasible for clinical use. There seemed to be no clinically relevant impact of beta-blockers. This CREWS protocol could be a starting point for future studies. (Surg Obes Relat Dis 2022;18:1298–1303.) © 2022 American Society for Metabolic and Bariatric Surgery. Published by Elsevier Inc. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/).

Keywords: EWS; Remote; Bariatric surgery; Vital parameters; Monitoring

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Complications after bariatric surgery are infrequent but could be life-threatening and require reintervention. Early detection of abnormal vital parameters indicating clinical deterioration due to postoperative complications could avoid delayed treatment and unfavorable outcomes [1,2]. In current clinical practice, vital parameter measurements are captured intermittently to identify patients who deteriorate and need escalation of care. This detection is based on exceeding thresholds using an early warning scoring (EWS) system [3–5]

Recent literature has shown the potential of continuous vital sign measurement to detect postoperative deterioration compared to intermittent measurements [6–10]. Unobtrusive wearable devices facilitate continuous monitoring more widely. However, no guidelines for developing protocols for the early detection of deterioration using continuously measured vital signs in post–bariatric surgery patients are currently available.

Several factors challenge the development of an EWS for post–bariatric surgery patients. First, the temporal course of vital parameters following uncomplicated post–bariatric surgery is poorly documented in the literature, hampering the identification of abnormal values [11,12]. Second, discharge criteria, including thresholds of vital parameters, vary between hospitals for this group. Furthermore, obesity itself can induce variations in cardiac and respiratory rates, which may alter the validity of standard EWS protocols.

The purpose of this report is to describe the process of the development of a continuous remote early warning score (CREWS) protocol. Such an EWS-based notification protocol for deterioration detection could be used for patients after bariatric surgery.

Methods

The CREWS protocols developed in this study were EWS-based, with preset thresholds of heart and respiratory rate. The score of each parameter ranged from 0 to 2. The sum of these scores resulted in 3 risk band zones (Fig. 1). A notification was generated if the CREWS remained elevated for a preset number of minutes ("reassurance time"). To obtain subsequent alarms, the score had to remain decreased for a preset number of minutes ("baseline reset time") before increasing again (Supplemental Fig. S1).

Score / Vital parameter	0	+1	+2	CREWS		
Heart rate	<X		≥X	0-1	2	3
Respiration rate	<X	≥X				

Fig. 1. CREWS scoring system and risk zones. Left = scoring system: distribution of scores in case of deviating vital parameters. Right = CREWS risk zone scores. CREWS = continuous remote early warning score.

Despite these mechanisms to mitigate alarm fatigue, the system needs to be calibrated to avoid missing critical patient deteriorations.

Monitoring device

Vital parameters were measured using Healthdot (Philips Electronics, Netherlands). Healthdot is a validated remote wearable sensor for continuous measurements of heart rate and respiration rate (RR) based on accelerometer measurements [13]. The device is attached under the lower left rib and can be worn for 14 days (Supplemental Fig. S2). The continuously measured data are averaged over 5-minute intervals and transmitted wirelessly using a low-power wide-area network (LoRa) to a backend server (Health Suite Digital Platform, Philips Electronics, Netherlands) for visualization in a software dashboard located at the hospital (Philips IntelliVue Guardian Software). This tool is designed to implement custom EWS-based protocols and notification schemes to alert clinical staff to deteriorating patients. The frequency and manner in which vital signs and notifications are delivered to the medical staff depend on the protocol the user establishes for integrating continuous and remote monitoring into the ward or hospital workflow.

Study population

For this study, a cohort of remotely monitored patients in 2019 and 2020 (PJ-013483 FLAGSHIP Transitional Care Study 3) was used. The patients underwent either laparoscopic sleeve gastrectomy or laparoscopic Roux-en-Y gastric bypass. The Healthdot device was applied postoperatively for 14 days. The monitoring system was not integrated in the clinical workflow. The data obtained were for retrospective use. In the surgical ward, vital parameters were measured every 8 hours. Discharge took place the day after the surgery when meeting the criteria: feeling well enough, no tachycardia according to the physician's judgment, or a decrease in hemoglobin of more than 2.42 g/dL points. The collected patient demographics included sex, age, body mass index (BMI), type of primary bariatric surgery, length of hospital stay, American Society Anesthesiologists classification, and the use of beta-adrenergic blocking medication. Follow-up took place up to 30 days after surgery. Data that defined the onset, end, clinical consequences, and outcome measurements of postoperative bleeding or anastomotic leakage were extracted retrospectively from the electronic health record medical professionals.

Step 1: Literature search

Supportive evidence for appropriate protocol thresholds was retrieved through a PubMed database search. The following medical subject headings terms were used: bariatric surgery, gastric bypass, gastrectomy, postoperative complications, anastomotic leakage, bleeding, vital signs, tachycardia, tachypnea, and beta-blockers. Studies with data on heart rate and RR related to postoperative complications after primary gastric sleeve and bypass were included.

Step 2: Expert sessions

A team consisting of a surgeon, anesthesiologist, intensivist, and a data scientist had a total of 3 work sessions. The literature was discussed, and optional thresholds for heart rate and RR were defined. Risk points were assigned on an empirical basis, using literature where possible. After comparing the results of the tested protocols in the final session, it was discussed which protocol was most suitable for the detection of postoperative bleeding or anastomotic leakage.

Step 3: Testing protocol performance

Step 3.1. Clinical deteriorations

A complication requiring reintervention (Clavien-Dindo 3b) was considered detected when $\geq$1 notifications were generated within 24 hours prior to the reintervention.

Step 3.2. Alarm time setting optimization

The reassurance and baseline time settings were optimized for each selected protocol specifically. The tested options were 0, 5, 15, 30, or 60 minutes. The reassurance time was defined as the longest possible time with vital sign abnormalities in the yellow or red risk zone, not leading to notifications, while preserving the best possible result for sensitivity to detect clinical deterioration.

Step 3.3. Protocol performance testing

Statistical analysis of the vital signs and influence of beta-blockade was carried out retrospectively. In clinical practice, the heart rate of patients on a beta-blocker is often regarded as an unreliable value. Despite numerous other factors and drugs that can affect the heart rate, beta-blockers are the most clinically relevant as they can negatively affect the physiological response of the heart through direct suppression of the sinus node.

A simulation tool was created to reproduce the CREWS and the notification system as present in the Philips IntelliVue Guardian Software. The output of the simulation tool was used to determine the ability of the CREWS and notification protocol to capture deteriorations due to bleeding or leakage and to produce a specific alarm burden to the clinical team. The most sensitive protocol with the fewest number of alarms was selected and applied to the clinical cases for illustration purposes. The data analysis and the simulation tools were produced using Python 3.6.

Results

In total, 15 studies were included following the literature search. An increased heart rate and respiratory rate are the most common and important clinical findings for the detection of deterioration in hospital [14,15] and specifically after bariatric surgery [11,12,16–19]. There was more focus on anastomotic leakage rather than bleeding events.

The average heart rate range is between 50 and 110 beats per minute (bpm) in a general emergency department [20]. Although hospital mortality increases by 5% when the heart rate is above 120 bpm, a trend is seen above 100 bpm [21]. Therefore, the threshold for tachycardia is 100 bpm in the most currently used EWS.

The cardiovascular structure of patients living with obesity is altered compared to that of patients with a lean bodyweight. An example is an increased resting heart rate due to higher sympathetic and lower vagal activity [22,23]. Additionally, the metabolic and physiological response to a complication can be different [14,24]. Specifically, after bariatric surgery, it has been suggested that sustained tachycardia that exceeds 120 bpm [11,12,25] and occurs within 20 hours after surgery [11] can indicate anastomotic leakage. A rate between 100 and 120 bpm [11,16,17] within 8 hours [11] is related to a bleeding event.

The respiratory rate is an often underexposed but no less important vital parameter to measure [15], as a small increase from 20 to 24–28 breaths per minute (rpm) already increases hospital mortality by 5% [21]. The minimum RR is 20 rpm in most current protocols.

To compensate for smaller tidal volumes, the respiratory rate in patients with a BMI $\geq$40 was higher (15–21 rpm) than that in those with a BMI within the normal range (10–12 rpm) [26]. In complicated bariatric surgery, signs of respiratory distress (RR $\geq$24 rpm or increasing oxygen requirement) are shown to be an independent clinical indicator for anastomotic leakage with 90% specificity, as they often develop later in the postoperative course [12].

The second step in the development of the new protocol was the expert sessions. The two-tailored EWS protocol consisting of heart rate and RR was a literature and expert opinion–based decision. The tested protocols were heart rate versus RR: 100–18, 110–18, 110–20, and 120–18. Subsequent scores led to a color of CREWS risk zones (Fig. 1).

These protocols were tested in step 3 of the current study using a cohort of 184 patients. Additional home data from 162 patients were available. The majority were female (72%), the mean age was 46.4 years (standard deviation [SD] = 11.41), and the BMI was 40.23 kg/m^2 (SD = 4.13). The participants underwent either primary gastric bypass or sleeve gastrectomy (Supplemental Table S1). A total of 4 severe deteriorations were confirmed, of which 2 anastomotic leakages (Clavien-Dindo [CD] 4) and 1 bleeding event (CD 3) occurred. The last event, bleeding, occurred while the patient was still hospitalized (CD 3) (Supplemental Table S2).

In total, 2433.25 days of vital sign measurements were available for analysis. The average heart rate of participants without beta-blockers was significantly higher in the hospital than that at home (76 bpm [SD = 10.66] and 72 bpm [SD = 9.18], $P < .0011$). The average RR was the same at inside (16.8 rpm [SD = 2.81]) and outside (17.3 rpm [SD = 2.68] $P > .5$) of the hospital. Beta-blockers were used in 14.5% (n = 27) of the participants. Their average heart rate was significantly higher in the hospital (75.77 bpm [SD = 11.68]) versus home (69.48 bpm [SD = 9.89] $P < .05$). Their average RR was 15.57 rpm (SD = 1.84) in the hospital and 16.41 rpm (SD = 2.16) at home, which was comparable ($P > .5$). None of these participants had a complicated postoperative course.

Regardless of whether a patient did or did not use beta-blockers, no difference was seen in their average heart rate in the hospital or at home ($P = .8$ and $P = .145$, respectively) (Supplemental Table S3).

The performance of the different notification protocols, including the optimized reassurance and baseline reset times, is summarized in Table 1.

Most protocols resulted in an overall sensitivity of 75%: 100% in hospital and 66% at home. The protocol with a threshold for the heart rate of 110 bpm was also the most silent: 69.7% of the patients had no alarm at all, and 1.6% of the patients received >1 alarm per day. The protocol with a threshold for the heart rate of 100 bpm was equally sensitive, however less silent as 45.5% of the patients had no alarm and 11.4% of the patients >1 alarm per day. Figure 2 visualizes the performance of the 110–20 protocol, excluding the reassurance and baseline reset time. All available vital sign measurements were plotted against the 3 risk zones. In 26.26% of the measurements from patients with a complication (total of 693 red dots), obtained within 24 hours before the complication, the total score resulted in an increased risk zone (24.53% red risk zone and 1.73% yellow risk zone). The exact time to complication of the measurements in the red- and green-risk areas could not be determined. More detailed information of the complications is available in the Supplemental Appendix.

Discussion

Current EWS protocols have not been investigated widely in continuous remotely monitored vital parameters, and threshold values are poorly defined. This paper showed the steps toward the development of such a protocol to detect postoperative deterioration in a bariatric population. A two-tailored protocol consisting of heart rate and RR with thresholds of 110 bpm and 20 rpm, respectively, seemed to be most suitable to detect deterioration due to postoperative bleeding or anastomotic leakage. The effect of beta-blockers on postoperative vital signs appeared to be negligible, not necessitating an adjustment in protocol settings.

The thresholds of 110 bpm and 20 rpm are consistent with values found in the literature and fit the found mean postoperative vitals. Although it has been shown that in anastomotic leakage, the heart rate exceeds 120 bpm in most cases [11,12,25], these measurements were performed at the moment of readmission or reintervention. Using 120 bpm as the threshold in the notification protocol will lead to a delay in the detection and treatment of anastomotic leakage. In cases of postoperative bleeding, the heart rate remains within the 100–120 bpm range [11]. Lowering the alarm threshold to 100 bpm, the number of alarms that need follow-up increased considerably without improving the detection performance. This results in an unnecessary increase in workload and associated alarm fatigue.

Concerning the respiratory rate, the literature shows that respiratory distress (RR ≥24 rpm or increasing oxygen requirement) is an independent indicator for anastomotic leakage with 90% specificity. Again, these values are related to signs of advanced disease. For earlier detection and results of performance of the protocol, a threshold of 20 rpm seemed to be justified.

Notably, tachycardia will not always be present in cases of complications, specifically in patients with postoperative bleeding [16,18,27]. These interindividual differences can indicate that the detection of deterioration based on a generic predefined threshold will not be sufficient. Of course, patients' symptoms and the clinical view including trend analysis should be taken into account. Recently, van Rossum showed that adjusting thresholds to personal or situational factors can increase the detection of events in the surgical ward, but combining more adaptive protocols also improved the protocol performance [28]. However,

Table 1
CREWS protocols

HR (bpm)	RR (rpm)	Reassurance time (min)	Baseline time (min)	Overall sensitivity (%)	Sensitivity hospital (%)	Sensitivity home (%)	>1 alarm/day	Alarm silence (%)
100	18	15	15	75%	100%	66%	11.4%	45.5%
110	18	15	15	75%	100%	66%	1.6%	69.7%
110	20	15	15	75%	100%	66%	1.6%	69.7%
120	18	30	15	33%	0%	33%	0.5%	95.5%

CREWS = continuous remote early warning score; HR = heart rate; bpm = beats per minute; RR = respiration rate; rpm = breaths per minute; 4 different threshold combinations.

Reassurance and baseline reset times are predefined and optimized per the included protocol sensitivity: % of patients in hospital N = 184 and home N = 162. >1 alarm/day: % of N = 162 patients receiving >1 alarm/day for a duration of 14 d. Alarm silence: % of N = 162 patients having no alarms at all during 14 d.

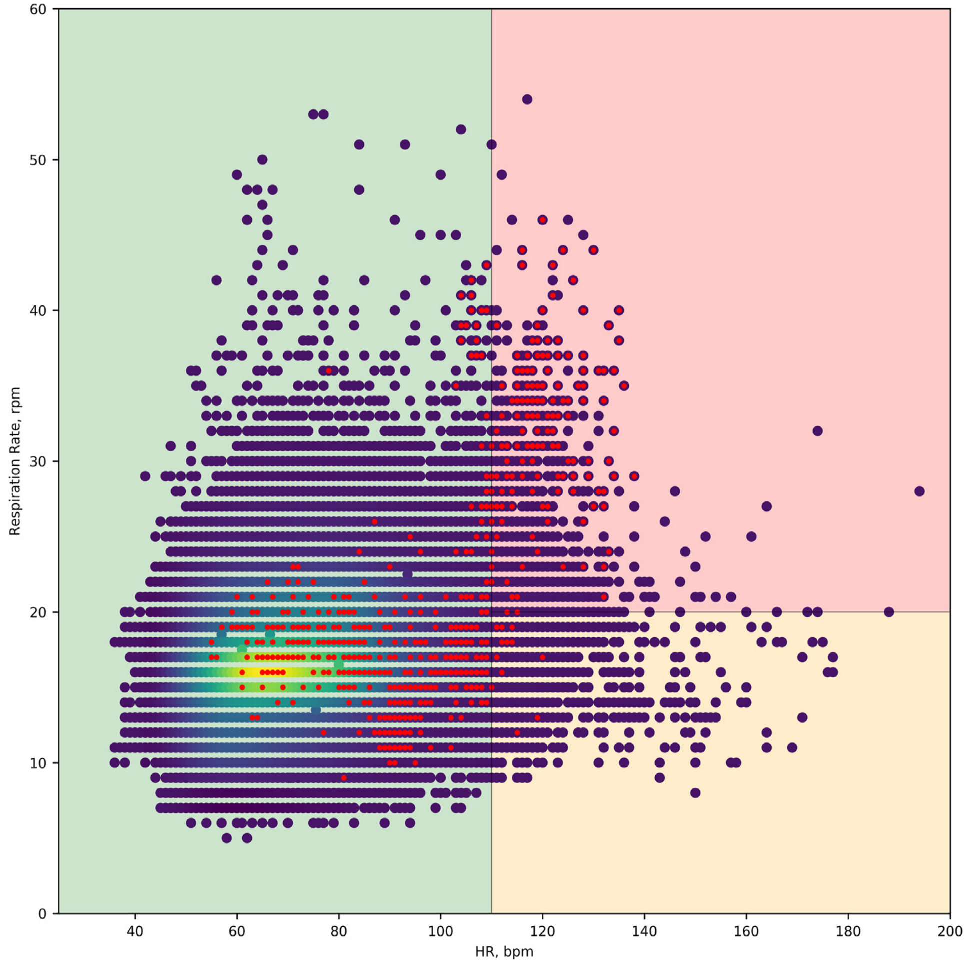

Fig. 2. Continuous vital sign measurements plotted against the 110–20 CREWS protocol. Vital sign measurements plotted against the 110–20 protocol. Purple dots = all available vital sign measurements, heart rate and respiration rate, obtained over the 14 days postoperatively. The measurement density increases as the dots turn yellow. The red zone = CREWS risk score 3, yellow zone = score 2, green = score 0–1. Red dots = all measurements, heart rate and respiration rate, within 24 hours before complication (all complications together). CREWS = continuous remote early warning score; HR = heart rate; bpm = beats per minute; rpm = breaths per minute.

individualized thresholds based solely on preoperatively measured values contributed the least to the improvement in alarm performance. Assessment of the added value of other individual factors (age, gender, co-morbidities) and vital signs (e.g., temperature) can be considered for future studies with larger data sets.

In clinical practice, it is suggested that the ability to increase the heart rate during physical stress is impaired by beta-blockers, causing late or even undetectable deterioration. Sepsis and infection as the sole cause of death after noncardiac surgery were seen more commonly in patients using beta-blockers in one study [29]. On the other hand, limited effects of these blockers have been shown on postoperative outcomes after laparoscopic gastric bypass [30] which is in accordance with the findings in the current study. However, limited by the number of events and the low amount of beta-blocker use, this finding cannot yet be extrapolated to clinical application. Other limitations were the large influence of experts and less on data for composing the protocol, as the literature was limited.

One should be aware that the implementation of a device for the use of telemonitoring of postbariatric patients leads to a change in the current postoperative infrastructure. Next to the development of a notification protocol, the timing and frequency of patient monitoring should be established, and a follow-up protocol in case of abnormal vital signs is critical. Clinical personnel should be trained in the use of remote monitoring devices and associated software. Also it is necessary to inform the patient about the device and what to do in case of medical or technical problems as this increases compliance and safety. Such decisions may differ between centers, depending in part on available materials and finances. This report can be a stepping stone for future postoperative care in which telemonitoring will be an important part and not limited to bariatric surgery alone.

Conclusion

The process of the development of an EWS-based notification protocol for remote and continuous monitoring (CREWS) to detect postoperative bleeding or anastomotic leakage after bariatric surgery is reported. Implementation of a protocol with a threshold of 110 bpm for heart rate and 20 rpm for RR may be feasible, while the use of beta-blockers seemed not to necessitate a protocol setting. These results could be taken into account in future studies.

Disclosures

The authors have no commercial associations that might be a conflict of interest in relation to this article.

Supplementary data

Supplementary material associated with this article can be found, in the online version, at https://doi.org/10.1016/j.soard.2022.06.018.

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