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Title:

Agreement Between Standard and Continuous Wireless Vital Sign Measurements After Major Abdominal Surgery: A Clinical Comparison Study

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Abstract

Objective

Continuous wireless monitoring outside the post-anesthesia or intensive care units may enable early detection of patient deterioration, but good accuracy of measurements is required. We aimed to assess the agreement between vital signs recorded by standard and novel wireless devices in postoperative patients.

Approach

In 20 patients admitted to the post-anesthesia care unit, we compared heart rate (HR), respiratory rate (RR), peripheral oxygen saturation (SpO_2), and systolic and diastolic blood pressure (SBP and DBP) as paired data. The primary outcome measure was the agreement between standard wired and wireless monitoring, assessed by mean bias and 95% Limits of Agreement (LoA). LoA was considered acceptable if within ±5 beats min^{-1} (bpm), while RR, SpO2, and BP were deemed acceptable if within ±3 breaths min^{-1} (brpm), ±3%-points, and ±10 mmHg, respectively.

Main results

The mean bias between standard vs. wireless monitoring was -0.85 bpm (LoA -6.2 to 4.5 bpm) for HR, -1.3 mmHg (LoA -19 to 17 mmHg) for standard vs. wireless SBP, 2.9 mmHg (LoA -17 to 22) for standard vs. wireless DBP, and 1.7% (LoA -1.4mmHg to 4.8mmHg) for SpO_2, comparing standard vs. wireless monitoring. The mean bias of arterial blood gas analysis vs. wireless SpO_2 measurements was 0.02% (LoA -0.02% to 0.06%), while the mean bias of direct observation of respiratory rate compared to wireless measurements was 0.0 brpm (LoA -2.6 brpm to 2.6 brpm). 80% of all values compared were within predefined clinical limits.

Significance

The agreement between wired and wireless HR, RR, and PR recordings in postoperative patients was acceptable, whereas the agreement for SpO_2 recordings (standard vs. wireless) was borderline. Standard wired and wireless BP measurements may be used interchangeably in the clinical setting.

Introduction

Current clinical standards involve continuous monitoring of patients' vital signs in the operating theater, post-anesthesia care unit (PACU), and intensive care unit (ICU) to detect physiological deterioration and allow timely intervention [1], [2]. However, patients admitted to general wards are only assessed and monitored approximately every 6–8 hours [3], [4], potentially resulting in undetected patient deterioration and subsequent worsening of complications. Furthermore, patients admitted to the ICU from general hospital wards have a higher mortality than those admitted from the operating theater and emergency departments [5], implying that particular general ward patients would benefit from increased monitoring, enabling earlier intervention if needed.

Recent technological advances in the form of small wearable and wireless devices now make it possible to continuously record vital signs. These advancements are likely to improve patient safety because continuous monitoring has proven superior to manual measurements in identifying changes in vital signs, due to continuous, non-person-dependent monitoring [6], [7], [8]. In addition, wireless continuous monitoring devices have obvious advantages compared to continuous wired monitoring. For example, wearable devices do not restrict early postoperative mobilization but accommodate it by not keeping the patients in bed with cables, thereby improving patient comfort.

However, while continuous monitoring in combination with automated alerts may improve patient outcomes, numerous factors must be addressed to minimize the frequency of alerts and the imminent risk of alarm fatigue [9], [10], [11]. This involves ensuring that device measurement variation is within clinically acceptable limits.

Although many wearable devices are found to be accurate in the standardized settings required for clinical use and thus approved by the Food and Drug Administration and/or have received the European Conformity mark, they must be evaluated in a clinical setting and compared to standard equipment before being implemented in general hospital wards. Few of the marketed devices are thoroughly validated in well-designed clinical studies in the real-life clinical setting they are aimed for, and if conducted, some have yielded disappointing results [12]. Conversely, some studies have shown promising results in the accuracy of different devices measuring HR, but some need improvement in the precision of agreement of the test methods [13]–[17].

This study assessed the agreement between vital signs measured in a clinical setting by standard wired and new wearable wireless devices. We hypothesized that the agreement between standard and wearable devices would be within clinically acceptable limits.

Methods

This study was approved by the Regional Ethics Committee (H-17033535) and the Danish Data Protection Agency (2012-58-0004) before patient inclusion. The study is registered at https://clinicaltrials.gov (NCT05325814).

Participants

Patients were eligible for inclusion if they were ≥60 years, scheduled for major abdominal cancer surgery with planned PACU admission, and had an estimated surgical intervention duration of ≥2 hours. Exclusion criteria were implanted cardioverter defibrillator or pacemaker, allergy to study devices, severe cognitive impairment assessed by Mini-Mental State Examination, or inability to cooperate in wearing the wireless monitoring equipment.

Variables

We compared heart rate (HR), pulse rate (PR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and peripheral oxygen saturation (SpO_2) recorded by standard PACU equipment, with data collected by continuous wearable devices. In addition, we compared standard (visually observed) and wearable automated respiration rates (RR). Finally, we compared invasive arterial blood pressure (aBP) measured in the radial artery to wearable and standard monitoring and wearable peripheral SpO_2 to arterial oxygen saturation derived from arterial blood gas (ABG). Due to ethical considerations, the latter two assessments were only conducted if patients had an arterial line or ABG was assessed for clinical reasons, and therefore, they were not performed in all patients.

Equipment

In the PACU, patients were monitored using the standard clinical monitoring system, Philips IntelliVue MP50 and IntelliVue X2 (Philips, Amsterdam, the Netherlands). These systems measure the HR and RR using ECG leads (Philips M1672A), and the BP with a standard oscillometric cuff (Welch Allyn Flexiport, Reusable Blood pressure Cuff) on the upper arm. We determined peripheral saturation using a fingertip pulse oximeter (Philips M1191BL), with SpO_2 and PR values averaged over a 10-second period.

The wearable devices (table 1) were chosen due to their FDA- and CE-marks and the fact that they all communicate real-time with a bedside gateway: 1) Isansys Lifetouch (Isansys Lifecare, Oxfordshire, UK), a wireless, lightweight single-lead electrocardiogram patch placed over the 4th intercostal space on the left side of the thorax. This device records a single-lead ECG continuously,

1000 samples per second. The HR is estimated using the R-peak interval, sampled once per minute. RR is derived from changes in the amplitude of the QRS complex when the lungs contract and expand, thereby changing the thorax impedance during the respiratory cycle. The manufacturer states that the device has an HR accuracy of ±5 beats per minute (bpm) or 10% maximum error. 2) Meditech BlueBP-05 (Meditech Ltd., Budapest, Hungary), a compact wireless oscillometric cuff-based BP device used on the arm, which the manufacture states has an accuracy of ±3 mmHg or 2% of the measured values. 3) Nonin WristOx$_2$ 3150 (Nonin Medical inc., Minnesota, USA), a wireless wrist-born wearable finger pulse oximeter connected to a soft finger sensor (8000SM-WO2). This device measures SpO_2 and PR acquired by photoplethysmography at a rate of 1 Hz based on the average of the last four beats. The device has a product accuracy measuring SpO_2 of ±3% points when validated against the arterial oxygen saturation cannula, according to the manufacturer. 4) All data were sent to a patient gateway (Isansys Lifecare, Oxfordshire, UK) by Bluetooth and instantly transferred to the study database. A photo of the wireless monitoring devices is seen in Figure 1.

Monitoring procedure

Data collection began after a minimum of 12 hours after admittance to the PACU to reflect the situation closest to PACU discharge and hence a physical condition similar to that of patients on a general ward. All measurements were conducted in a standard clinical setting, including patient movements in the bed and caregivers intervening.

Data acquisition was completed with a study investigator at the bedside performing measurements every 15 minutes, and both wireless and standard monitoring sensors were used according to device manuals. Thus, HR, PR, BP, SpO_2 were assessed as paired vital signs seven times for each patient.

HR and RR measurements were taken by simultaneously recording the value from the patient gateway (sampled at one per minute from the previous 60 seconds) and the value from the standard device.

To obtain valid blood pressure recordings, we began by selecting the appropriate cuff size after measuring the upper arm circumference[18]. SBP and DBP (standard, wireless, and aBP) were measured on the same arm with a 2-minute rest interval between each measurement, rotating which device measured first, and adhering to the protocol for validating blood pressure measurements[19].

The pulse oximetry sensors of the standard and wireless monitoring systems were applied simultaneously on the same hand, switching between the second and third fingers, and performed concurrent recordings of SpO_2 and PR. We intended to compare RR measures by inducing bradypnea and tachypnea using a metronome, but this proved impossible due to the patients' clinical conditions.

Consequently, we measured the RR by visually inspecting and counting chest movements for one minute, twice in each patient, which is considered the most valid clinical standard. Simultaneously, the wearable device automatically recorded the RR.

Statistical analysis and outcomes

The primary outcome was the mean bias of the measurements, described as the accuracy of the measurements and 95% limits of agreement (LoA) with 95% confidence intervals (CI), defined as the precision between the reference devices and the wireless devices. A review of the literature revealed that no previous studies could be used to form the basis for a power calculation. Therefore, we pragmatically chose 20 patients as our sample size with an expected seven paired measurements per vital sign, with up to 140 comparisons for each parameter. We used the Bland-Altman method to compare the two methods with replicate measurements of each method for repeated measurements because this method compensates for multiple measures taken from the same subject[20]. The confidence interval variation of LoA was determined as suggested by Zou et al., using the Method of Variance Estimates Recovery (MOVER) method[21], and we calculated the root mean square deviation (RMSD) to report accuracy as a function of precision and bias. We used single values from each measurement and results were visualized with Bland-Altman plots. A priori, we defined conservative clinically acceptable limits as: HR and PR ±5 bpm, SpO_2 ±3% points, RR ±3 breaths per minute (brpm)), and SBP and DBP ± 10 mmHg, respectively, inspired by other method comparison studies [17], [22].

All analyses were undertaken using the R Foundation Statistical Program (R v.3.6.0) and R studio (v.1.2.5001).

Results

We consecutively enrolled 20 consecutive patients in the study. No patients declined to participate. Table 2 summarizes the demographic characteristics of the patients: 75% were male with median age of 69 years and had an average BMI of 25 kg/m^2 and a median surgery duration of 4 h. 15 min. Missing data were due to patient mobilization, PACU discharge, and other interventions by caregivers that made it difficult to obtain a measure. The missing data for pairs of measurements ranged between 9% for standard vs. wireless SpO_2 monitoring to 25% for arterial diastolic blood pressure (aDBP) vs. standard DBP monitoring (Table 3).

Agreement between circulatory parameters

The mean HR was 73 bpm for both devices, values ranging from 50 bpm to 108 bpm, a mean bias of −0.85 bpm, and LoA from −6.2 bpm (95% CI −8.6 to −5.5) to 4.5 bpm (95% CI 3.8 to 6.9) (TTable 3 and Figure 2a). The mean PR was 73 bpm for both devices, with values ranging from 48 bpm to 108 bpm, a mean bias of 0.15 bpm, and LoA −5.5 bpm (95% CI −8.0 to −4.8) to 5.8 bpm (95% CI 5.1 to 8.3) (Table 3 and Figure 2b). Approximately 95% of the paired measurements recording HR and PR were within the predefined acceptable clinical limits of ±5 bpm, with an equal root mean square deviation of 2.9.

The mean SBP was 113 mmHg (aBP), 108 mmHg (standard), and 110 mmHg (wireless monitoring), with values ranging from 79 mmHg to 181 mmHg. The mean bias was 4.5 with LoA −22 mmHg (95% CI −38 to −15) to 31 mmHg (95% CI 24 to 47) for arterial systolic blood pressure (aSBP) vs. wireless monitoring and mean bias -1.3 with LoA -19 mmHg (95% CI −28 to −16) to 17 mmHg (95% CI 13 to 26) for standard vs. wireless monitoring (Table 3 and Figure 2c + 2d). Overall, we found 74% of the paired measurements within the clinically acceptable limits of 10 mmHg when comparing aSBP with wireless monitoring, 67% when comparing aSBP with standard, and 79% when comparing standard with wireless monitoring, RMSDs of 11.6, 11.6, and 8.9.

The mean DBP was 50 mmHg (aDBP), 59 mmHg (standard), and 58 mmHg (wireless), ranging from 37 mmHg to 88 mmHg. The mean bias was −6.9 mmHg with LoA −28 mmHg (95% CI −39 to −24) to 14 mmHg (95% CI 10 to 25) for aDBP vs. wireless monitoring and mean bias 2.9 with LoA −17 mmHg (95% CI −26 to −13) to 22 mmHg (95% CI 19 to 32) for standard vs. wireless monitoring (Table 3 and Figure 2e + 2f). We found 48% of the paired measurements within clinically acceptable limits when comparing aBP with wireless monitoring and 85% within acceptable limits of ±10 mmHg when comparing standard with wireless monitoring.

Agreement between respiratory parameters

The RR records were equal in means and noted 14 brpm measured with direct observation and wireless monitoring, ranging from 7 to 20 brpm. The mean bias was 0.0 and LoA -2.6 brpm (95% CI −3.8 to −2.0) to 2.6 brpm (95% CI 2.0 to 3.8) (Table 3 and Figure 3a). Overall, all measurements were within the acceptable clinical limits of ±3 brpm.

Mean SpO_2 values were 96% and 95% with standard and wireless monitoring, values ranging from 86% to 100%. The mean bias was 1.7% and LoA −1.4% (95% CI −2.3 to −0.8) to 4.8% (95% CI 4.3 to 5.8). We found 91% of the measurements within clinically acceptable limits of ±3% points (Table 3 + Figure 3b).

The mean of ABG was 96%, and compared to wireless SpO_2, we recorded a mean bias of 0.02% and LoA −0.02% (95% CI −2.3 to 0.00) to 0.06% (95% CI 0.04 to 2.4) (Table 3 and Figure 3c). We found 100% of all measurements within acceptable clinical limits of ±3% points (Table 3 and Figure 3c).

Discussion

This study showed that continuous wireless devices have high accuracy and precision when measuring HR, PR and RR, using standard monitoring as a reference method. SBP and DBP comparisons exceeded predetermined acceptable clinical limits of agreement, and SpO_2 comparisons were within acceptable clinical limits in 91–100% of all measurements.

Despite the conservative, predefined acceptable clinical limits[12], our study confirms prior findings using the same device[17], [23], [24]. The RR measurements had a narrow LoA and a mean bias of 0.00. When comparing direct observations with wireless measurements, we found that 100% of the paired measurements were within acceptable clinical limits (±3 brpm). These are unexpected findings in light of the existing literature, where RR has been found to be highly variable and imprecise in studies examining both direct observations and wireless measurements[22], [25], [26], and that the inter-and intravariability of direct observations is substantial, implying that results should be interpreted cautiously. The fact that the majority of measured rates were within the normal or borderline normal respiratory range (7–20 brpm) may account for the good accuracy, which does not require us to challenge our equipment despite accepting no more than a difference of ±3 brpm.

Additionally, we had relatively few paired comparisons (31), indicating that a more extensive study is necessary to validate this device. The optimal reference standard for measuring RR has yet to be found, which is inexpedient because it is considered the most critical parameter for predicting clinical deterioration[27], [28]. This is coupled with the fact that RR is most often measured by nurses with preferences for specific digits. Thus a large database study with almost 3 Mio. EWS entries found that RR was often divisible by four, indicating that the nurses count for 15 seconds and then multiply by four to account for a minute [29]. The above makes the validation all the more significant.

The wireless blood pressure monitoring device lacked precision and accuracy, underestimating the recorded SBP values and overestimating the measured DBP values. This is consistent with the results obtained by comparing standard measurements with the aBP (Table 3). Thus, the standard vs. aBP comparison had the same wide LoA and low precision as the wireless BP vs. aBP comparison, with only 67% of paired SBP and 43% of paired DBP measurements being within clinically acceptable limits. Consequently, the results reveal that cuff-based standard blood pressure measurements are inaccurate, and previous studies have demonstrated that non-invasive devices tend to overestimate hypotensive BP values and underestimate hypertensive BP values. Nonetheless, the wireless monitoring device was as accurate as the standard equipment used in general wards. Hence, both approaches can be used interchangeably in the clinical setting but with awareness of their drawbacks.

When comparing the SpO_2 measurements, we found that wireless monitoring tended to underestimate the values compared to those obtained with standard wired devices by a mean bias of 1.7%. The results found by comparing standard and wireless devices are similar to those found in a recent study investigating the same device in a different population (patients with chronic obstructive pulmonary disease), suggesting that the interpretation of the SpO_2 measurements is challenging for both standard wired and wireless devices [17]. The accuracy of devices measuring SpO_2 is sensitive to their proper placement on the finger, the movement of the finger/arm, and the device's construction; for example, the diode that emits infrared light determining the accuracy deteriorates over time[30]. However, compared to the ABG, the mean bias of 0.02% was minimal, and the LoA was narrow, indisputably indicating good accuracy and precision. However, larger sample sizes are required to verify this assumption, and evaluating the impact of long-term sensor use, finger mobility, and the use of different fingers is essential.

Comparing different validation studies on wireless vital sign technologies is difficult because most studies validate other devices, have separate setups, and are often conducted in healthy or low-risk patients, thereby inducing falsely high accuracy[12],[31]. Moreover, there is no consensus or set of guidelines for conducting and analyzing validation studies of ward monitoring systems.

Our study has a number of strengths. First, the validation was carried out in a clinical setting. Second, a bedside investigator inspected and registered the data quality during the monitoring period, which is pivotal to ensure accuracy when devices are placed on patients moving in their beds, receiving treatment and care, as is the case in the PACU immediately before discharge to the general ward. Third, multiple measures were taken in a variety of patients.

The study has limitations as well. First, we compared wireless devices to clinical standard wired monitoring rather than to a “gold standard,” making it impossible to determine to which extent the observed discrepancies were due to the individual devices

However, the wireless and wired equipment performed relatively equally when the clinical setting allowed aBP to be used, and SpO_2 measurements were compared with ABG when possible. Second, the investigator was positioned near the patient throughout the 1.5-hour monitoring period, potentially influencing the dept of the respiration, which could have resulted in improved RR recordings. Last, while most recordings were within or near the normal range, the optimum range should encompass even more deranged vital signs. However, as illustrated in the Bland-Altman plots, no systematic bias related to the extreme values was seen, indicating that the findings are valid even in severe cases.

The quest for accurate monitoring should focus on performance in the physiological ranges of interest because these measurements must be reliable. However, exact measurement with inherent technological challenges may not be the only way forward. Thus, to monitor the effectiveness of interventions, it may be sufficient to have devices that accurately describe whether a threshold is crossed or have the ability to detect trends of deviating vital signs with relevance for clinical outcomes (normalization vs. further deterioration). Such an endeavor requests close collaboration between device manufacturers and clinicians who can define target outcomes and give advice regarding clinically irrelevant alerts and potential alert fatigue.

Conclusion

In our monitoring of postoperative patients, we found the agreement between wired and wireless HR, RR, and PR recordings to be acceptable, whereas the agreement with regard to SpO_2 recordings was borderline acceptable. Standard wired and wireless BP measurements may be used interchangeably in the clinical setting.

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Figure Legend

Fig. 1: Placement of wireless monitoring devices

The setup of wireless devices during comparison of recorded vital signs: Electrocardiograms measuring heart rate, blood pressure monitor, and peripheral oxygen saturation. All wireless and transmitting data via Bluetooth to a bedside gateway and a central server.

Fig. 2: Bland Altmann plots of agreement between measurements of various paired vital sign measurements (heart rate, pulse rate, systolic blood pressure, and diastolic blood pressure). Solid line presents mean bias; dotted lines equal upper and lower limits of agreements (LoA). The grey shaded areas illustrate predefined acceptable clinical limits.

Fig. 3: Bland Altmann plots of agreement between various vital sign measurements (respiratory rate and peripheral oxygen saturation). Solid line presents mean bias; dotted lines equal upper and lower limits of agreements (LoA). The grey shaded areas illustrate predefined acceptable clinical limits.

Figure 1.

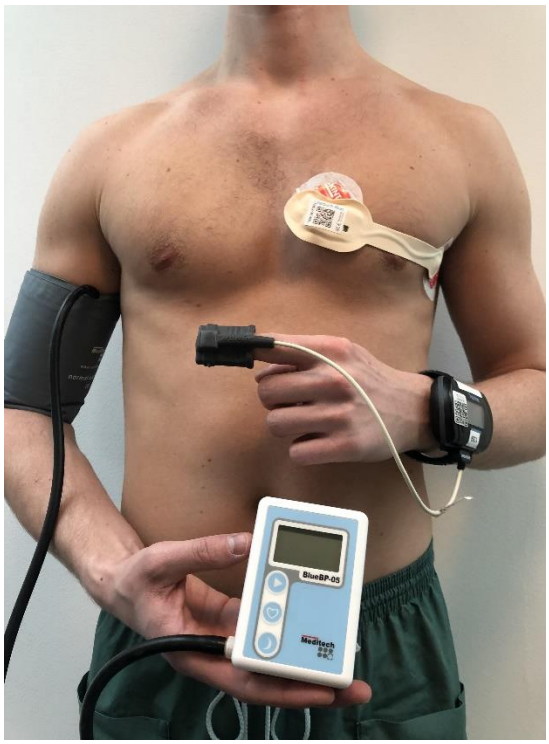

Figure 2

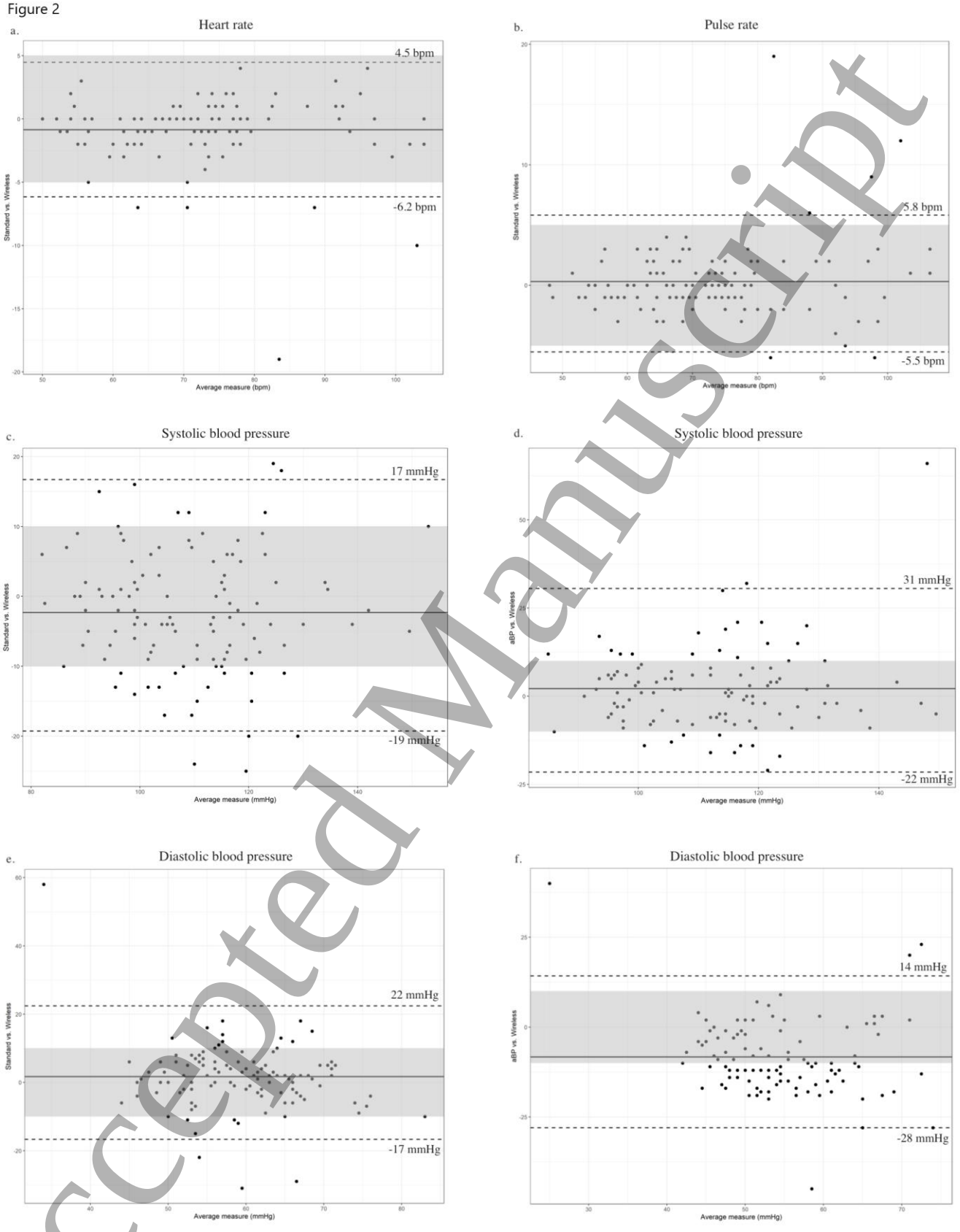

Figure 3

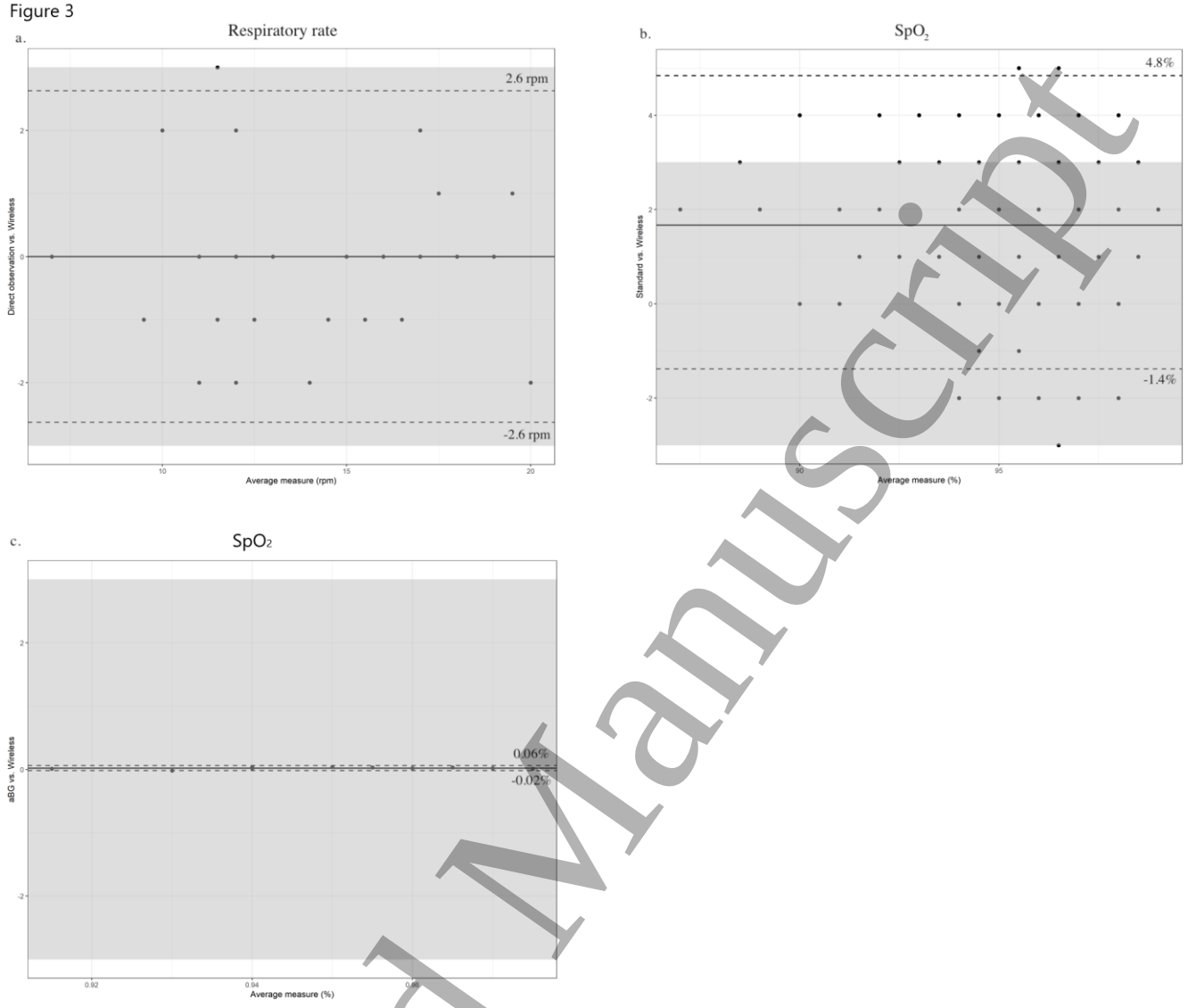

Table 1 Overview of the werable devices

	Isansys Lifetouch 	**Nonin WristOx 3150** 	**Meditech BlueBP-05** 
Parameter(s)	HR RR Single lead ECG	SpO_2 PR	Blood pressure
Placement	Intercostal four left side of the thorax	Wrist-worn unit connected to a soft finger sensor	Inflatable cuff, worn on the upper arm
Sampling frequency	One per minute 1000 samples per second	1 Hz averaged every four beats	Intermittent basis

Table 2. Baseline characteristics

Parameter	**n = 20**
Gender, male, female	15 (75%), 5 (25%)
Age, years	69 [67-73]
BMI	25 [22-28]
Smoking history current, former, never	1 (5%), 13 (65%), 6 (30%)
Excessive alcohol consumption	4 (20%)
ASA, I,II,III,IV	0 (0%), 7 (35%), 13 (65%), 0 (0%)
Baseline measurements before surgery	
SpO_2	99 [97-99]
Systolic Blood Pressure, mmHg	137 [127-146]
Diastolic Blood Pressure, mmHg	75 [68-83]
Primary operation	
Esophagus resection	11 (55%)
Pancreatoduodenectomy	6 (30%)
Total pancreatectomy	1 (5%)
Colangiojejunostomy	1 (5%)
Laparoscopy with biopsy	1 (5%)
Duration of surgery	4 h 15 m [3h 28 m – 4 h 46 m]

BMI: Body Mass Index; kg/(height in m)^2; Alcohol consumption: Excessive intake is alcohol consumption more than recommended by the Danish Health Authority, which is 12 g/day for women and 24 g/day for men; ASA: American Society of Anesthesiologist, Physical Status Classification; CCI: Charlson Comorbidity Index; TUG: Timed Up and Go test; SpO_2: Peripheral oxygen saturation; CI: Confidence interval; Values are given as numbers (percentage) or median of [IQR].

Table 3. Summary of agreement between standard and wireless devices

Parameter	N of paired measurements/ expected	Device name	Mean (95% CI)			Mean Bias	Lower LoA (95% CI)	Upper LoA (95% CI)	Root mean square deviation	Measurements within clinical thresholds (%)
Circulatory Parameters			**Standard invasive**	**Standard non-invasive**	**Wireless**					
Heart rate/bpm	110/140	Philips/Lifetouch		73 (70-75)	73 (71-76)	-0.85	-6.2 (-8.6 to-5.5)	4.5 (3.8 to 6.9)	2.9	105 (96%)
Pulse rate/bpm	126/140	Philips/Nonin		73 (71-75)	73 (70-75)	0.15	-5.5 (-8.0 to-4.8)	5.8 (5.1 to 8.3)	2.9	120 (95%)
Systolic blood pressure/mmHg	117/140	Philips/Meditech		108 (105-110)	110 (107-113)	-1.3	-19 (-28 to -16)	17 (13 to 26)	8.9	92 (79%)
	110/140	Philips invasive/Mediteh	113 (111-116)		111 (109-114)	4.5	-22 (-38 to -15)	31 (24 to 47)	11.6	81 (74%)
	105/140	Philips invasive/Philips	113 (110-116)	108 (105-110)		6.4	-17 (-31 to -11)	30 (24 to 44)	11.6	70 (67%)
Diastolic blood pressure/mmHg	117/140	Philips/Meditech		59 (58-61)	58 (56-60)	2.9	-17 (-26 to -13)	22 (19 to 32)	9.7	99 (85%)
	110/140	Philips invasive/Meditech	50 (48-52)		58 (56-60)	-6.9	-28 (-39 to -24)	14 (10 to 25)	13	53 (48%)
	105/140	Philips invasive/Philips	50 (48-52)	59 (58-61)		-9.1	-28 (-37 to -24)	9.4 (6.0 to 19)	14	45 (43%)
Respiratory parameters										
Respiratory rate/brpm	31/40	Counted/Lifetouch		14 (13-15)	14 (13-15)	0.00	-2.6 (-3.8 to -2.0.)	2.6 (2.0 to 3.8)	1.34	31 (100%)
Peripheral oxygen saturation/ %	10/10	Arterial oxyhemoglobin/Nonin	96 (94-98)		94 (93-95)	0.02	-0.02 (-2.3 to 0.00)	0.06 (0.04 to 2.4)	0.03	10 (100%)
	127/140	Philips/Nonin		96 (96-97)	95 (94-95)	1.7	-1.4 (-2.3 to -0.8)	4.8 (4.3 to 5.8)	2.3	116 (91%)

Bpm, beats per minute; mmHg, millimeters of mercury; brpm, breaths per minute