

Wireless Continuous Arterial Blood Pressure Monitoring During Surgery: A Pilot Study

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Patient monitoring devices supporting wireless transmission can facilitate transport and ambulation of patients in hospitals. To replace wired sensors with wireless sensors, the accuracy and resistance to interference of the wireless sensors have to be documented. We compared the performance of a wireless arterial blood pressure biomedical sensor prototype with standard wired sensors in a clinical setting. Four patients undergoing laparoscopic abdominal surgery were recruited for testing of the device. Lines to a wireless arterial blood pressure sensor and standard wired sensor were connected to the same arterial cannula inserted in the right radial artery. Data from both systems were logged for postprocedure statistical comparison. During the

procedure, 13 other electric devices were used, either continuously or intermittently. A sample-by-sample comparison was performed for both wired and wireless data. Statistical tests showed mean difference of 0.71, standard deviation of 0.14, and confidence interval of -1.28 to 1.56 , indicating no significant electromagnetic interference on invasive arterial blood pressure monitoring caused by biomedical devices used during surgery. The wireless pressure biomedical sensor with Bluetooth wireless transmission of signals did not interfere with biomedical devices used in the operating room or *vice versa*.

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In the advanced surgical and critical care setting, biomedical sensors are routinely attached to the patient by invasive or noninvasive routes for continuous, uninterrupted monitoring of physiological variables such as electrocardiogram and arterial and venous blood pressures (1).

In the course of treatment, the patient is transported between various locations at the hospital for diagnostics or surgical interventions and postprocedure units or departments. In addition, early postprocedure ambulation of patients is an important element in the restitution strategy. Transportation of critically ill patients can be dangerous unless properly planned (2–

4). The basic biomedical sensor technology for invasive arterial blood pressure measurement has been used in advanced medical treatment and surveillance in the emergency room, operating room (OR), postanesthesia care unit, or intensive care unit and has remained virtually unchanged for several decades, except for a shift from disposable to nondisposable biomedical sensors. The use of wireless biomedical sensors for patient monitoring, with a reduction in numbers of wires attached to the patient, may ease transportation of patients and also facilitate early ambulation of the patient in the intensive care unit or intermediate care environment.

To replace wired sensors with wireless sensors, the accuracy and resistance to interference of the wireless sensors has to be documented. In this clinical study, a wireless, nondisposable biomedical sensor prototype was compared with a standard wired disposable biomedical sensor for invasive arterial blood pressure monitoring during abdominal surgical procedures under controlled conditions. The research hypothesis was that a difference between wired and wireless arterial blood pressure should be small and negligible. The possible effect of electromagnetic noise generated by the other biomedical devices in the OR was recorded and analyzed.

This paper is a result of studies made in the project Wireless Health and Care (WSHC) (Velmahos GC, Demetriades D, Ghilardi M, et al. Life support for trauma and transport: a mobile ICU for safe in-hospital transport of critically injured patients. *J Am Coll Surg* 2004;199:62–8). The WSHC project was established with 35 financial support from the Research Council of Norway. MemsCap is an industrial partner and the Interventional Centre is a clinical partner of the WSHC project, respectively carrying the rest of their project costs.

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Table 1. Patient Characteristics

Patient	Age	Sex	Operation	Duration of surgery
1	58	Female	Laparoscopic adrenalectomy dexter	1:05
2	36	Female	Laparoscopic adrenalectomy dexter	3:10
3	58	Female	Laparoscopic refundoplication	8:55
4	71	Female	Laparoscopic resection of pancreatic tumor	3:25

Methods

Four patients scheduled for various laparoscopic abdominal surgical procedures volunteered as test subjects and gave written informed consent. The protocol was approved by the Regional Ethical Committee. In the data processing, the patient data were made anonymous. Table 1 shows patient characteristics. The procedures were performed during general anesthesia.

The patients were positioned on the operating table in a supine position, with the right arm on an armrest attached to the side of the operating table. In all patients, arterial blood pressure was monitored simultaneously from arteria radialis by the wireless prototype biomedical pressure sensor and a standard wired biomedical pressure sensor.

Invasive arterial blood pressure was measured with a nondisposable wireless biomedical sensor prototype called WisMos (MemsCap; Skoppum, Norway) (5). WisMos is a high-sensitivity, gold-plated, piezoresistive, battery-driven biomedical sensor with a pressure range from -20 to 300 mm Hg. The sensor compensates for temperature alterations with an internal thermistor. It has an operating range programmed up to 20 m (Bluetooth power class 2) and is used with a line-set with a silicone dome diaphragm preventing liquid from entering between the biomedical sensor and the dome diaphragm. The wireless biomedical sensor was mounted on a bracket on an IV pole. A sterile 844-28 silicone dome was connected to the wireless biomedical sensor. Signals were sent from a built-in radio transmitter in the wireless biomedical sensor with a Bluetooth chip from Blue Giga (6) to a laptop with a radio receiver in the OR based on the Bluetooth 1.2 wireless standard (7).

Invasive arterial blood pressure was measured according to the unit's standard protocol. A catheter with an arterial line primed with NaCl 0.9% was positioned in the radial artery on the right wrist of all patients. A sterile line set with a disposable pressure biomedical sensor from Edwards Lifesciences (8), and a positive pressure flushing system was attached to a Siemens HemoPod with a 3-m wired connection to a Siemens SC 9000 patient monitor. The invasive arterial blood pressure measured by this method was regarded as the reference pressure. Invasive blood pressure signals transmitted with the wired solution were sampled at a sampling frequency of 100 Hz. Both

sensors were serially connected to the same line set leading to the arterial cannula (Fig. 1).

The digital pressure measurements were collected from a standard Siemens monitor, using a customized LabView (9) software application developed by Sensometrics (Oslo, Norway) (10). The software was installed on a laptop, and it was connected to the unit's virtual local area network for patient monitors through a Siemens Gateway Server (11). The software was used for logging, viewing, and exporting vital signs data.

To collect wireless blood pressure measurements, dedicated LabView software developed by MemsCap was used for logging and viewing. The graphical user interface of the software prototype is similar to a traditional patient monitor displaying continuous waveforms and numerical data. To set up the system, the WisMos Bluetooth unit was switched on, with a blue light indicating wireless operation. When the Bluetooth unit on the laptop was activated, any wireless devices within range were identified and respective Bluetooth serial ports allocated. To establish a connection to the appropriate sensor device, a four digit number and the serial port number was entered manually. The connection to the actual device could be verified with a "Check-button" in the software that initiated a flashing red light in the WisMos device. The software enabled logging of time-stamped sample data by pushing a button on the screen. The files could be imported in appropriate applications for statistical analysis and processing. The distance from the wireless biomedical sensor to the laptop was 6.5 m.

The blood pressure data from wired and wireless biomedical sensors were logged during the entire procedure. Before logging, the clocks in the wireless blood pressure sensor and the Siemens monitor were synchronized manually. Thus, a simultaneous logging of wired and wireless invasive arterial blood pressure could be performed.

A low-pass filter with a cut-off frequency at 1000 Hz was used to band-limit the signal. Amplitudes were quantized by a 4-byte uniform quantizer, ensuring antialiasing.

Digital samples from the wireless blood pressure biomedical sensor had an amplitude resolution of 4 bytes and a sampling frequency of 135 Hz. The samples had timestamps, reducing the problem of reorganizing the packets, which according to the Bluetooth

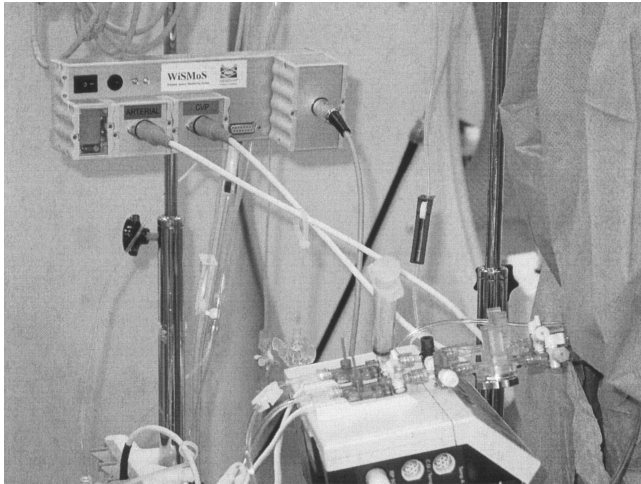


Figure 1. Setup in the operating room with arterial blood pressure serial connection of wired and wireless biomedical sensors connected to the same arterial line.

standard arrived with short time intervals in a random manner.

Because both systems were operating in two different sampling frequencies, the samples from the wireless blood pressure biomedical sensor were resampled from 135 to 100 Hz using multistage decimator-interpolator technique (12) before the sample-by-sample comparison. The comparison was performed in a manner in which a time window of 10 s was used to limit the number of samples whenever a biomedical device was in use. The implementation and analysis were performed in MATLAB (13).

A number of biomedical devices that theoretically could cause electromagnetic disturbance to the wireless system were in use in the OR during the experiment. The devices in permanent use were two Ivac P7000 syringe pumps, a Dräger Cato anesthesia machine, a video rack from Olympus (VHI-3, OTV-ST, and CLV-S40), a Sony monitor, a Warm Touch patient heater, a Sony DV-CAM recorder, and a Siemens SC 9000 XL patient monitor. Devices in intermittent use were Autosonix ultrasound scalpel and Valleylab diathermia. During each operation, a manual logbook was maintained, describing in detail the surgical procedure and the use of biomedical devices. Each time a device was used, it was registered in the logbook. This log was used in the data analysis phase to identify time sequences of the biomedical sensor data and identify potential incidents of electromagnetic disturbance. Properties of the coagulating biomedical devices (Valleylab Force FX 8; Valleylab, a division of Tyco Healthcare Group, Boulder, CO; AutoSonix, United States Surgical Corporation, Norwalk, CT), are generation of strong electromagnetic energy fields and use of strong electric power. These devices were used to transect, ablate, and coagulate soft tissue, and for

selective tissue disintegration and surgical aspiration by use of ultrasonic sound waves.

A statistical approach based on graphical techniques and simple calculation of deviation, along with the assessment of repeatability, was presented by Bland and Altman (14). This method was used for assessing agreement between two different methods of clinical measurements of the same physiological parameter. We defined wired arterial blood pressure signal as

$$\tilde{Y} = [y_1, y_2, \dots, y_N],$$

and wireless blood pressure signal as

$$\tilde{X} = [x_1, x_2, \dots, x_N],$$

where N was the number of samples. The difference, \tilde{D} , was defined as

$$\tilde{D} = \tilde{X} - \tilde{Y},$$

mean difference, d , was

$$d = \frac{\sum_{i=1}^N D_i}{N},$$

and standard deviation, s , was

$$s = \sqrt{\sum_{i=1}^N (D_i - d)^2}$$

Assuming the differences are normally distributed (Gaussian), 95% confidence interval (CI) is given as $(d - 1.96 \times s$ and $d + 1.96 \times s)$. Bland and Altman argued that such differences, vector \tilde{D} , were likely to follow a normal distribution because local variations were removed. Reproducibility of the measurements was estimated by plotting the standard deviation against their mean and then using one-way analysis of variance (15). Mean arterial blood pressure (MAP) was defined as one third of maximum and two thirds of minimum (MIN).

Results

The average values were calculated from all samples belonging to a procedure. Average pressures of MIN, maximum, and MAP for wired and wireless blood pressure measurements were calculated. A full agreement between variables was found in measurements from Patients 1 (251 257 samples) and 4 (537 584 samples). In Patients 2 (953 169 samples) and 3 (675 717 samples), 1% differences in MIN values and consequently MAP values were found (Table 2).

Corresponding waveforms are shown in Figure 2. We observed that the curves were synchronized in both time and amplitude, indicating that both methods were correlated.

Table 2. Average Minimum (MIN), Maximum (MAX), and Mean Arterial Blood Pressure (MAP) Values in mm Hg for WisMos and Siemens Data

Pressure	Patient 1	Patient 2	Patient 3	Patient 4
MIN (mm Hg)	58	71	53	58
	58	70	52	58
MAX (mm Hg)	93	116	85	112
	93	116	85	112
MAP (mm Hg)	70	86	64	76
	70	85	63	76

The first row in each set contains the wireless values; digits in bold represent deviations.

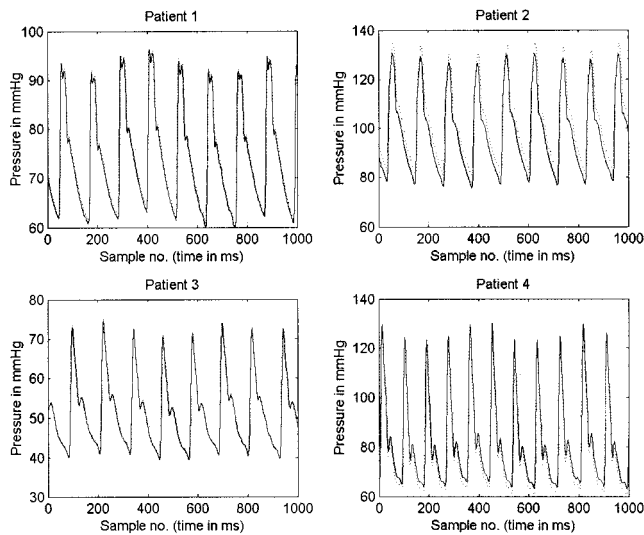


Figure 2. Corresponding waveforms from WisMos (solid line) and from the Siemens monitor (dashed line).

Sample-by-sample statistical analysis was performed on data from Patient 1. From 251,257 samples mean, d , and standard deviation, s , was calculated. A window of 1000 samples corresponding to 10 s was chosen assuming that a minimum window size of 10 s was sufficient to detect interferences both statistically and visually.

Difference, \bar{D} , was plotted for the device groups AutoSonix, Valleylab, and devices in permanent use. Ideally, d and s should be zero. However, s was 0.14 and d was 0.71. The calculated 95% confidence interval (CI) was (-1.28 and 1.56). The upper and lower CI limits are shown as solid lines in Figure 3. The periodical fluctuations in the plot are measurement artifacts caused by limitations in the computer clock's resolution in seconds. This shows that, although the actual discrepancies described between wired and wireless measurements, the limits of agreement were well within the CI limits to conclude that the WisMos prototype equals Siemens SC 9000 XL patient monitor for clinical pressure measurements.

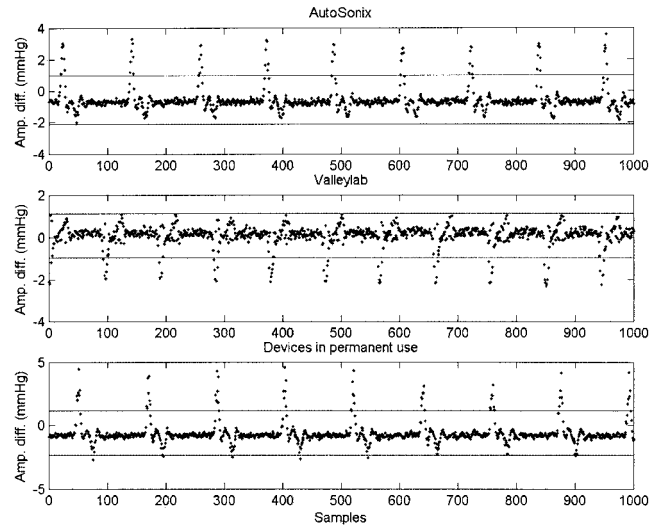


Figure 3. Amplitude difference between Siemens and WisMos for Patient 1. The upper and lower confidence intervals are shown by solid lines.

For all patients, the CI and upper and lower limits were calculated (Fig. 4). The figure shows the box-and-whisker plots for all patients. Each column in a subplot describes AutoSonix, Valleylab, and devices in permanent use. For Patient 1 the upper and lower CI limits were less than 1 mm Hg, for Patient 2 they were <2 mm Hg, for Patient 3 <1 mm Hg, and for Patient 4 <2 mm Hg. Absolute values showed that 95% of the samples values had <1.25% deviation. The small deviations among columns in Figure 4 showed that none of the devices, AutoSonix, Valleylab, or devices in permanent use caused any interference. Outliers shown in the figure represents the precision problem with time sequencing because of clock resolution mentioned above. This implies that the outliers in the figure are less clinically interesting. Notches (analysis of variance), the horizontal lines under each box in the plot in Figure 4, represented an estimate of the uncertainty about medians. They were within the limits of the 95% CI, indicating reproducibility as described in the Methods section.

Visual inspections of other biomedical devices in use during the procedure did not indicate any disturbances as a result of wireless transmission or *vice versa* (Figs. 2, 3, and 4). This means that from statistical and visual analyses, there were neither electromagnetic interferences caused by biomedical devices nor radio transmission interferences caused by Bluetooth transmission.

Discussion

The statistical analysis performed on arterial blood pressure data from both systems indicated a high degree of agreement of the measurements by the two

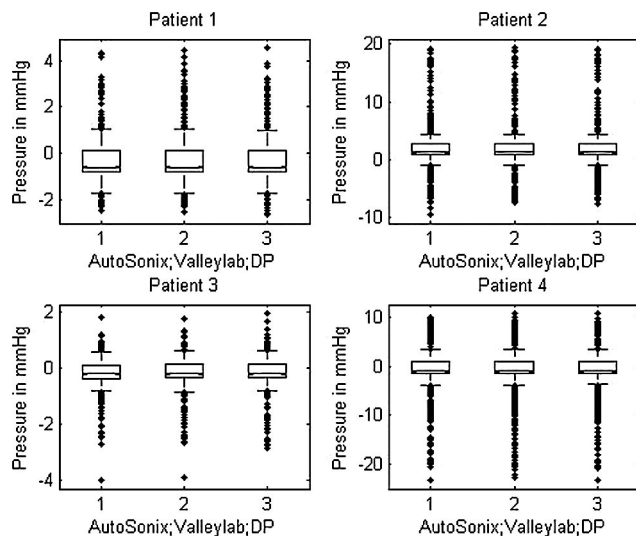


Figure 4. Boxplots of AutoSonix, Valleylab and Devices in permanent use. In each plot, column 1 = AutoSonix, column 2 = Valleylab, and column 3 = devices in permanent use. The horizontal lines over and under each box in the plot represented an estimate of the uncertainty about medians.

systems. Despite the high resolution of the data, only small fluctuations in the averaged MIN and MAP values were shown. The small deviations found, from 1 to 2 mm Hg, can be regarded as insignificant in clinical practice. Figure 4 shows some blood pressure values outside the notches. The outliers do not contribute to the phenomenon of interference but represent measurement artifacts. They were observed as scattered individual samples and not as a continuous array of samples. In practice too, we do not consider the outliers to have a significant impact on the continuous blood pressure curves presented on the patient monitor. Monitoring systems perform advanced signal postprocessing of data before displaying them on monitors, thus effectively filtering outliers and obtaining smooth waveform curves. The high sampling rate used in the study may also have practical implications. The system tends to produce a vast amount of samples that may require large storage facilities.

Wallin and Wajntraub (16) studied generic Bluetooth radio signals in the OR but did not consider how the individual blood pressure samples were influenced, as investigated in our study. They were uncertain whether their test method was able to detect potential interference. We have demonstrated a method for detection of alterations in individual arterial blood pressure samples potentially caused by electromagnetic interference.

The wireless biomedical sensor was stable during use on an immobilized patient's arm. The sensor performance during movement of the arm, patient ambulation, or patient transportation were not investigated in this study.

The Bluetooth standard has options to manually lock devices to each other during setup to prevent incorrect connections in environments where multiple Bluetooth devices are in simultaneous use. Connection between the Bluetooth sender and receiver in the WisMos prototype was based on entering of a four-digit code in the receiver, verified by a blue light on WisMos during connection and wireless operation. Finally an optional visual verification check of proper device connection allowed a test procedure with a flashing red light on the WisMos device in response. Guidelines for infrastructure and proper use of wireless biomedical sensors in clinical practice require further development. The Bluetooth standard has built-in 128-bit encryption options that can be used to secure appropriate device connection, patient identity, and confidentiality. On the other hand, the biomedical sensor samples do not have any tags with specific patient information compromising the integrity of the patient.

Research efforts have been reported in studies on wireless solutions (17). Most of the studies, however, do not include wireless invasive arterial blood pressure measurement. More than one third of critically ill and unstable patients need to be transported within hospitals for diagnostic or therapeutic interventions (2–4, 18–21). During patient transport, maintenance of standard patient monitoring is one of the important aspects to avoiding mishaps and adverse events. Future mobile monitoring systems based on the wireless Bluetooth standard may contribute to reducing this problem.

Bluetooth has sufficient bandwidth to cover relevant information from standard vital signs variables captured from invasive and noninvasive biomedical sensors. Battery capacity on wireless biomedical sensors is an important issue. The WisMos prototype had a battery capacity of 20 h. Another interesting issue is the cost of using Bluetooth technology, which is an open standard with potentially inexpensive hardware cost compared with commercial patient monitoring systems.

The pilot study had four patients. This may be interpreted as a limitation. However, for interference and sample-by-sample studies, we had adequate numbers of samples (several hundred thousand) for each patient. Another potential shortcoming could be the lack of physiological extremes, such as hypotensive or hypertensive episodes, in the material. Rasid and Woodward (22) describe blood pressure biomedical signal characteristics to have a frequency range from dc-60Hz. According to the Nyquist's sampling theorem (12), an analog signal sampled at a sampling rate twice the highest frequency of the signal can be exactly recovered. This means that the digital signals

will adequately represent potential physiological extremes including hypotensive or hypertensive episodes. Other catheters, manufacturers, or electrical equipment could produce discrepant results.

In the pilot study, wireless arterial blood pressure was investigated. However, Bluetooth has a bandwidth up to 720 kbit/s. The WisMos prototype had the possibility to display three invasive blood pressures, and two-channel, five-lead ECGs (Fig. 1). A future version with pulse oximetry and two temperatures in addition to the mentioned variables is feasible within the Bluetooth bandwidth.

Conclusion

In conclusion, arterial blood pressure can be monitored by the wireless WisMos sensor with the same accuracy and safety as with a wired sensor. The effective wireless signal range was 5-7 m, which was adequate in the OR. The use of standard OR equipment did not interfere with the wireless measurements. Wireless biomedical sensors can replace wired biomedical sensors for arterial blood pressure measurements in the OR, thereby facilitating transport of critically ill patients.

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