Feasibility of Remote Digital Monitoring using Wireless Bluetooth Monitors, the Smart AngelTM Apps and an Original Web Platform for Patients Following Outpatient Surgery: A Prospective Observational Pilot Study.

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Abstract

Background

Remote monitoring of mean arterial blood pressure (MAP), heart rate (HR) or oxygen saturation (SpO_2) remains a challenge in outpatient surgery. This study evaluates a new digital technology (SmartAngel^{TM}) for remotely monitoring hemodynamic data in real time.

Methods

Adults scheduled for elective outpatient surgery were prospectively enrolled. In the first 5 postoperative days, patients used a tablet three times a day to complete a self-report questionnaire (pain, comfort, nausea, vomiting) and two wireless Bluetooth monitors (oximetry for SpO_2 and HR; MAP) connected to a 4G tablet that transmits data to a website, in real time, using SmartAngel^{TM} software. Before transmission to the website, these data were also self-reported by the patient on a paper basis. The primary endpoint was the number of data recorded in the website using the app compared to paper basis. A system usability scale survey (SUS; score 1-100) was performed at day 5.

Results

From May 2018 to September 2018, data were available for 29 out of 30 enrolled (1 patient failed to discharge at home after surgery). The paper-basis recorded 2656 (82%) data versus 2038 (62%) for the remote monitoring technology (p=0.001). The most common errors with the remote technology were software malfunctioning when starting the MAP monitor and malfunctioning between the tablet and Bluetooth monitor. No serious adverse events were noted. SUS score was 85 (68-93) for 26 patients.

Conclusion

This work evaluates the ability of a pilot system to monitor remote physiological data using digital technology after ambulatory surgery and highlights the digital limitations of this technology. Technological improvement is needed in order to reduce malfunction (4G access, transmission between apps).

Trial registration: ClinicalTrials.gov (NCT03464721)(March 8, 2018)

Background

Ambulatory procedures have become a standard of care for all types of surgery, including more and more invasive or complex surgery (abdominal, gynaecological coelioscopic or robotic approaches, hip or knee arthroplasties etc.)[1–2]. However, safety and adverse events with these procedures remain debated in the literature with regard to potential medical or surgical complications at home [3–7] Recently, digital technologies have been proposed to remotely monitor outpatients at home and in hospital in order to detect patients with early signs of severity or deterioration [8–10].

In ambulatory surgery, patients would normally inform institutions about their perceived condition at home through a text message survey (mobile phone application) or e-mail [11]. Previous studies have described the effect of patients reporting their postoperative recovery after day surgery [11]. Web-based systems collecting alerts, managing and analysing patient-reported outcomes have been added to provide more valuable feedback [12]. The main limitation of these systems is the absence of remote data on physical parameters: heart or respiratory rate, oxygen saturation and arterial blood pressure. This appears to be a major limitation as several studies have demonstrated that remote physiological parameters can significantly reduce postoperative morbidity or mortality over the perioperative period [13, 14].

Using a wireless Bluetooth monitor, heart and respiratory rate (HR, RR), mean arterial blood pressure (MAP) or oxygen saturation (SpO_2) can be recorded via a tablet or smartphone that transmits data from remote monitoring to a web service (central server). Using algorithms and a dashboard, the centre can automatically filter data so that nurses or physicians can focus on patients with early warning signs. Smart-Angel (Evolucare™, France) is a new digital technology for remotely monitoring patients at home using both text messages (self-report questionnaires) and wireless Bluetooth monitors (SpO_2, HR and MAP). Self-report questionnaires include pain relief (numerical rating scale, NRS), comfort and adverse events (nausea, vomiting…). The Smart Angel system is initialized at the ambulatory centre before discharge (login) and continued at home by patients using a specific application on a dedicated tablet used to record the self-assessment and start the wireless Bluetooth monitor. Remote data are collected three times a day (Fig. 1). Before applying and testing this technology in current care, this study represents the first stage in testing the device on patients in real-life situations to evaluate its technological capacities and usability by the patient.

The objective of this study was to evaluate the number of data (seven measurements: pain, quality of recovery, nausea, vomiting, HR, MAP, SpO_2) recorded in the wed-site using the app over the first 5 days following ambulatory surgery. Before transmission to the website, these data were also reported by the patient on a paper basis. The primary endpoint of this pilot study was the number of data recorded in the website using the app compared to the paper basis.

Methods

Institutional Human Committee, consent and setting

In accordance with the current French law and Declaration of Helsinki, this study was approved by the institutional human investigation committee (Comité de Protection des Personnes, Sud Est V, Grenoble, France: 2017, A02790-53) and registered before starting on ClinicalTrials.gov (NCT03464721; March 8, 2018) [15]. This was a single-cohort, non-randomised, open, prospective trial conducted in a French University Hospital (Hôpital Carémeau, CHU Nîmes, France).

Written informed consent was obtained from all participants before inclusion.

Patients

Inclusion criteria:

All patients > 18 yrs (ASA 1–3), with the ability to understand French both orally and in writing, scheduled for intermediate or major ambulatory surgery were eligible and approached by the surgeon or the investigators. Surgeries were as follows: orthopaedic (shoulder repair, knee ligamentoplasty, hallux), abdominal (cholecystectomy, hernia) or gynaecological (hysterectomy, mastectomy).

Non-inclusion criteria were:

Age > 80 yrs, refusal to participate, ASA physical status > 3, emergency and inpatient surgery, psychiatric disorder.

Exclusion criteria:

If previously included, patients were excluded if they failed to use the remote technology.

The tablet and wireless Bluetooth monitor were presented by a nurse with the investigators and tested by patient before surgery. Their ability to perform remote monitoring involved switching the tablet on, using the login, completing the self-report questionnaire, adapting the monitor (for MAP, HR and SpO^2) and starting the monitor using the app (see above). Connection to a 4G network at home was also required.

Intervention

- Classical ambulatory follow-up

After surgery and before discharge from the ambulatory centre, patients received standard information regarding postoperative recovery and all the necessary information concerning postoperative care at home (analgesia, changes of dressing …). They were instructed to contact a 24-h telephone helpline if they had any questions or concerns outside office hours. Participants were advised to contact the local hospital's emergency department should any emergency care be required.

- Smart Angel™ monitoring:

The Smart Angel™ device was handed over to the patient who took the first measurements in the presence of the team to ensure that the system was properly working and understood. Functionalities of the Smart Angel™ system were carefully explained, and clear instructions for use were given by the research nurse and investigators, including how to move from question to question, how to enter an answer, and how to use the monitors. The Smart Angel™ system is a digital application using remote technology solutions and includes:

- 1: a Web administration centre which collects, in real time, all the data transmitted by the remote technology for each patient. These remote data are exported via the web (4G collection) to a secure

server (Adista™, France). All data are filtered and presented on a dashboard which summarizes all data so that the nurses and/or physicians can focus on any warning signs in the patient. Each patient is depicted on the dashboard in the form of a coloured square (green: in the normal range = no problem; yellow: in the limit of ranges = no sign of severity, red: warning signs = emergency action required). Using the dashboard, all investigators can (1) see all patients enrolled in the study, their assessment and their flags (2) see all the measurements for each patient on a specific new window (see Fig. 2).

- 2: Remote physical parameters (HR, SpO_2, MAP) with ranges (min, max) of normal values were defined before starting the study and included in the algorithm (Fig. 2). In the event of a specific pathology or treatment (e.g. patient on beta blocker treatment), ranges can be adapted to specific patient characteristics and/or treatment.
- 3: The tablet and app. technology uses a tablet (Samsung™, Korea) integrating the software (Evolucarelabs™, France) that generates health questionnaires (scores of pain, quality of recovery, nausea, vomiting) which the patient answers (see above) and communicates with a connected monitor positioned by the patients themselves (discontinuous measurement for the patient: app assessing self-report questionnaires and wireless Bluetooth monitors to record physiological discontinuous measurement (heart rate, mean arterial blood pressure, blood oxygen saturation): wireless pulse oximeter (iHeathlabs™, USA) clipped to the finger and blood pressure monitor (iHeathlabs™, USA) at the wrist. When the patient is ready with the monitor, the software triggers the monitors and records the values. The patient can instantly see the tablet screen. Measurement data for each item is depicted with normal and abnormal value ranges. All these data are then exported via the web (4G collection) to a secure server (Adista™, France).
- Follow-up:

From the day of surgery to postoperative day 5, three times a day (morning, noon and evening), the application asks the patient to complete the health questionnaire and follow-up with the monitors. Seven measurements are performed for each assessment:

1. Blood oxygen level (SpO2, %)
   Heart rate (HR, min^{-1})
   Mean arterial blood pressure (MAP, mmHg)
   Vomiting (yes/no)
   Nausea (yes/no)
   Pain score (scored on an 11-point numerical pain scale; 0: no pain-10: worst pain)
   Quality recovery score (scored on an 11-point numerical pain rating scale; 0: bad condition, 10: excellent quality of postoperative recovery)

- End of the study period: After the 5th day, monitoring was stopped and the material was sent back to the hospital by express delivery.

Outcomes and data collection

Surgical, anaesthetic and patient characteristics data were collected by the research nurse and investigators. Seven measurements (pain, quality of recovery, nausea, vomiting, HR, MAP, SpO2) were recorded by the app for all patients before their discharge from the centre and then three times a day from Day 1 to Day 5.

In addition, all the data measured by patient and monitor were noted on a conventional paper-basis and returned to the centre, along with the device, at end of the study.

On Day 5, the patient had to answer a 10-item questionnaire with five response options ranging from “Strongly agree” to “Strongly disagree” (total: 1-100 points) and the result was converted into a System Usability Scale (SUS) based on a Lickert scale.

Endpoints

The primary endpoint of this pilot study was the number of data recorded in the website using the app compared to the paper basis. The secondary objectives were to assess patient safety (medical rescue, readmission, and surgical complications) and patient use with this medical device.

Sample Size Calculation

As it is a pilot study, we predefined to test the system in 30 patients without sample size justification. Some published data showed that you need at least 12 patients for pilot studies [16]. The theoretical number of data collected by the app for 30 patients was 3360 = 30 patients x [7 measurements before discharge + 7 measurements 3 times per day for 5 days)]. The same number was required for the conventional paper basis.

Statistical analysis

Statistical analysis was conducted using SAS (9.4; SAS Inc., Cary NC).

Statistical results were expressed with mean (SD) or median with interquartiles [IQ] according to distribution. The numbers (with percentages, %) were given for categorical variables. The main judgment criterion was analysed in relation to a referential volume of theoretical information based on the following calculation: number of patients (n = 30) x number of data collection periods (i.e. one on D0 and 3 per day from D1 to D5, i.e. 16 in total) x number of parameters measured i.e. physiological parameters (heart rate, blood pressure, oxygen saturation and self-evaluation parameters (pain score, nausea, vomiting, comfort), i.e. 7 in total. Thus, the maximum reference volume of theoretical information is 30 × 16 × 7 = 3360. In addition, a referential volume of theoretical information was calculated per day and by parameters

Comparisons of continuous variables between the app and paper questionnaire were performed using a Student’s t-test or Wilcoxon-Mann-Whitney test according to distribution. Categorical variables were

compared between groups by X^2 or Fisher's exact test. All statistical tests were conducted as 0.05 two-sided tests and the analysis of secondary outcomes was descriptive.

Results

Population of the study, surgery and ambulatory setting

From May 2018 to September 2018, 30 patients were included and 29 analysed (1 patient was excluded in the ambulatory centre because not discharged at home (delayed surgery)). Patients (15 males, 14 women) were 47±13 years with a body mass index at 25±3 $kg.m^{-2}$ and ASA physical status 1/2 (n = 14/15). Surgeries were orthopaedic (n = 24, shoulder: 3, Foot: 12, Knee: 9) and abdominal (n = 5) ones. Duration of surgery was 42±21 min.

Primary outcome

Over the 5 days, 3248 (29 × 16 × 7) data were collected by paper or remote monitoring technology, respectively in 29 patients. The conventional paper basis recorded 2656 (82%) data versus 2038 (62%) for the remote monitoring technology (p = 0.001) meaning that the remote technology recorded about 75% of the paper assessment (Table 1). Figure 2A and 2B showed the percentage of data recorded by patients on paper or via the web-solution per day at each time.

For paper, the highest score was noted for the morning of Day 2 (93%).

Concerning remote technology : 3 patients reported malfunctioning of the MAP monitor for all assessments from Day 0 to Day 5 (absence of measurement which was secondarily attributed to an internal software malfunction). On the evening of the day of surgery, 12 (41%) patients reported difficulty to use the technology at home (password or login forgotten for starting or using the tablet = 4, absence of 4G connection = 1, difficulty to transmit data from monitor to tablet = 7). On Days 1 and 2, 11 (39%) patients reported difficulty (4G connection = 1, difficulty to transmit data from monitor to tablet = 10). From Day 3 to Day 5, 9 (35%) patients reported similar difficulties.

Secondary endpoint

Three patients did not perform the SUS survey. In the 26 patients, the SUS score was 85 (68–93).

The most frequent adverse events recorded were nausea in 7 patients and vomiting in one. On D5, no patients were admitted for adverse events. On Day 30, 3 (10%) patients were readmitted for minor adverse outcomes (surgical complications), but none were due to the device.

Discussion

In this first study reporting the use of a real-time remote monitoring device (SmartAngel™) for outpatient surgery, this technology enabled > 60% of information to be recorded by the patient. However, many

technological failures were reported. These findings imply that real-time remote monitoring technology could be feasible in outpatient surgery but still requires improvement, especially regarding connection to the central computer.

To our knowledge, the use of MAP, HR and SpO2 remote monitors has never been evaluated in ambulatory surgery. Similar systems have been extensively tested and evaluated in cardiology, oncology and diabetes [17–20]. In these cases, they have contributed to optimising remote medical monitoring and adapting treatments [20]. In this sense, after ambulatory surgery, these monitors may be effective in detecting early postoperative adverse events in patients at home.

Out of 29 patients evaluated, 80% were able to visualize the values for MAP, HR and SpO_2 on their monitors and could copy these values onto paper (Table 1). The originality of our study was to show that digital technology facilitates transmission of these data to a centre without any action from the patient (no recopying of data by the patient onto a smartphone or a web server). In this digital setting, the data transmission rate by the SmartAngel™ device was disappointing as it was 62%. Apart from the fact that patients forgot to carry out their measurements, several technological reasons explain this lack of data feedback and our study has allowed us to better understand them:

1) An ineffective 4G environment at the patient's home. The 4G defect altered data transmission between the tablet and the central web service in 3% of patients corresponding to the rates reported in teletransmission studies [16].

2) Malfunctioning of the SmartAngel™ program installed on the tablet. Computer program patches were required to stabilize the program for 3 patients as it had failed to activate the remote MAP monitors (confidential data provided upon request).

3) Insufficient battery charge for discontinuous but frequent use of the monitors. This is crucial for patients as they need to be informed of the need to charge the batteries regularly.

For the 62% of patients for whom all the data were correctly transmitted (Fig. 2B), the SmartAngel™ tool provides a real original monitoring dashboard which has never been proposed before providing questionnaire data combined with physiological data. The number of patients included was insufficient to demonstrate the interest of the system as an aid to follow-up, but the data presented are a step forward in ambulatory follow-up and would be useful for a multicentric study.

Our study shows a decrease in the data collected at D4 and D5 on paper (Fig. 2A): this may suggest that optimal monitoring should be done from the evening of D0 to the evening of D3 (with systematic measurements morning, noon and evening) and at least one measurement per day from D3 onwards to optimize patient adherence. Interestingly, the postoperative complications peak classically occurs between D1 and D3 [7]. However, an extension of monitoring to D5 or D7 could be proposed for patients or surgeries at risk.

In this study, the patient was monitored over the 5-day postoperative period without any manipulation from the expert centre. The high SUS score suggests good acceptance and usability for the patients [21]. The small-sized connected objects were easily accepted by our patients. The fact that there was a bag to transport all the objects home probably facilitated acceptance of the device.

Limitations of the study.

The main limitations of the study are the monocentric design and the small number of patients included. However, the main objective of this first pilot study was to validate the concept and identify technological errors before carrying out a multicentric study. To this aim, the present study provided the opportunity to report all potential issue with this technology, essentially, connection to the central computer, whatever the cause. Moreover, this technology would not be able to replace human surveillance (nurse) but could possibly assist the nurse for a better patient monitoring during postoperative follow-up.

Conclusion

Future research is required to determine the exact role of remote non-invasive digital technology for delivering patient healthcare benefits and to evaluate the feasibility of large-scale implementation.

Abbreviations

HR
heart rate
MAP
mean arterial blood pressure
RR
Respiratory rate
PONV
Postoperative nausea vomiting
SpO_2
oxygen saturation

Declarations

Ethics approval and consent to participate: In accordance with the current French law and Declaration of Helsinki, this study was approved by the institutional human investigation committee (Comité de Protection des Personnes, Sud Est V, Grenoble, France: 2017, A02790-53) and registered before starting on ClinicalTrials.gov (NCT03464721; March 8, 2018) [15]. This was a single-cohort, non-randomised, open, prospective trial conducted in a French University Hospital (Hôpital Carémeau, CHU Nîmes, France). Written informed consent was obtained from all participants before inclusion.

Consent for publication: not applicable

Availability of data and materials: The data that support the findings of this study are available from "Department of Biostatistics, Epidemiology, Public Health and and Methodological innovation (BESPIM), Nîmes University Hospital, University Montpellier 1,

France" but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of [Chevallier T.].

Competing interests: "The authors declare that they have no competing interests"

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Authors' contributions: all authors have read and approved the manuscript. TC: study design and statistical analyzis; GB: data acquisition and inclusion; BO : study design and methodology; PR : study design and statistical analyzis; CB : inclusion and funding acquisition; NS : data management and collection; CM data acquisition and inclusion ; Noemie Chaniaud: Software design; NV: data acquisition and inclusion , JYL : writing and and review of the manuscript, PC: principal investigator, study design and writing the manuscript.

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- Theresa Sawyers: rewriting the manuscript and English spelling

Authors' information (optional): none

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Tables

Table 1 : data recorded

	Theoretical	Paper	SmartAngel
Pain	464	390 (84)	297 (64)*
Comfort	464	394 (85)	297 (64) *
Nausea	464	394 (85)	297 (64) *
Vomiting	464	390 (85)	297 (64) *
Heart	464	370 (80)	297 (64) *
MAP	464	333 (72)	256 (55) *
SpO_2	464	385 (83)	297 (64) *
Total	3248 (100)	2656 (81)	2038 (62)*
Results are number and percentage			
*p<0.05 compared to paper			

Figures

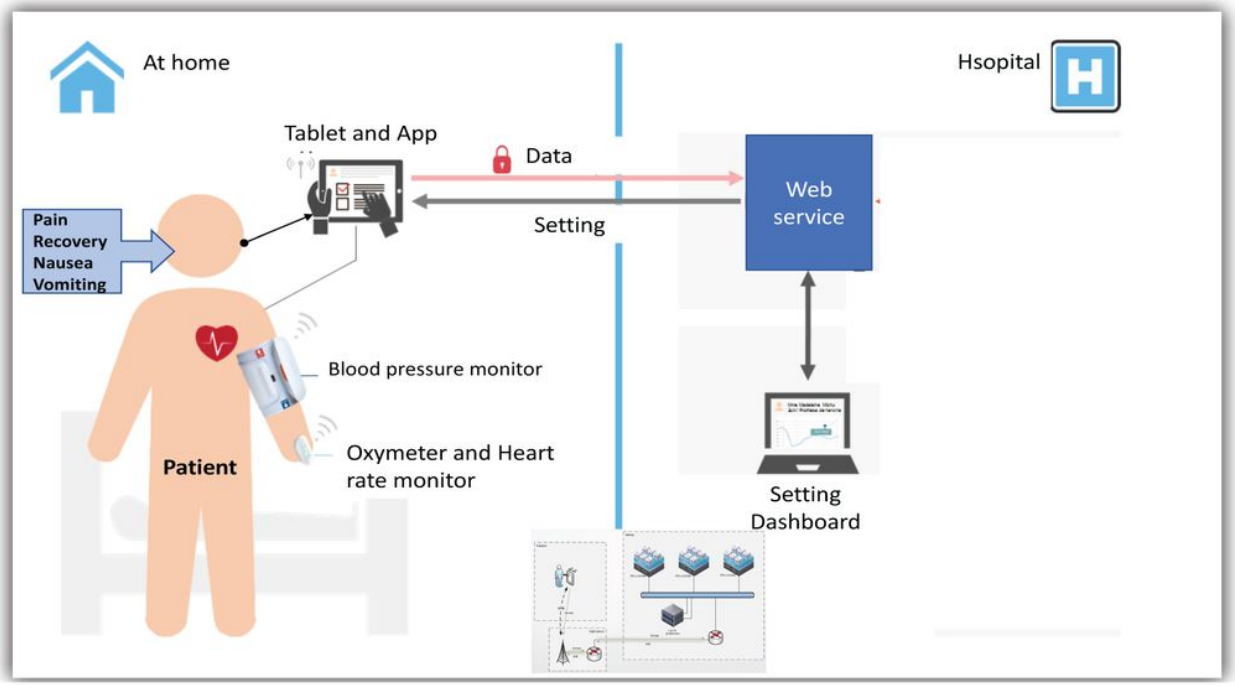

Figure 1

overview of the remote monitoring (Figure from author never published elsewhere)

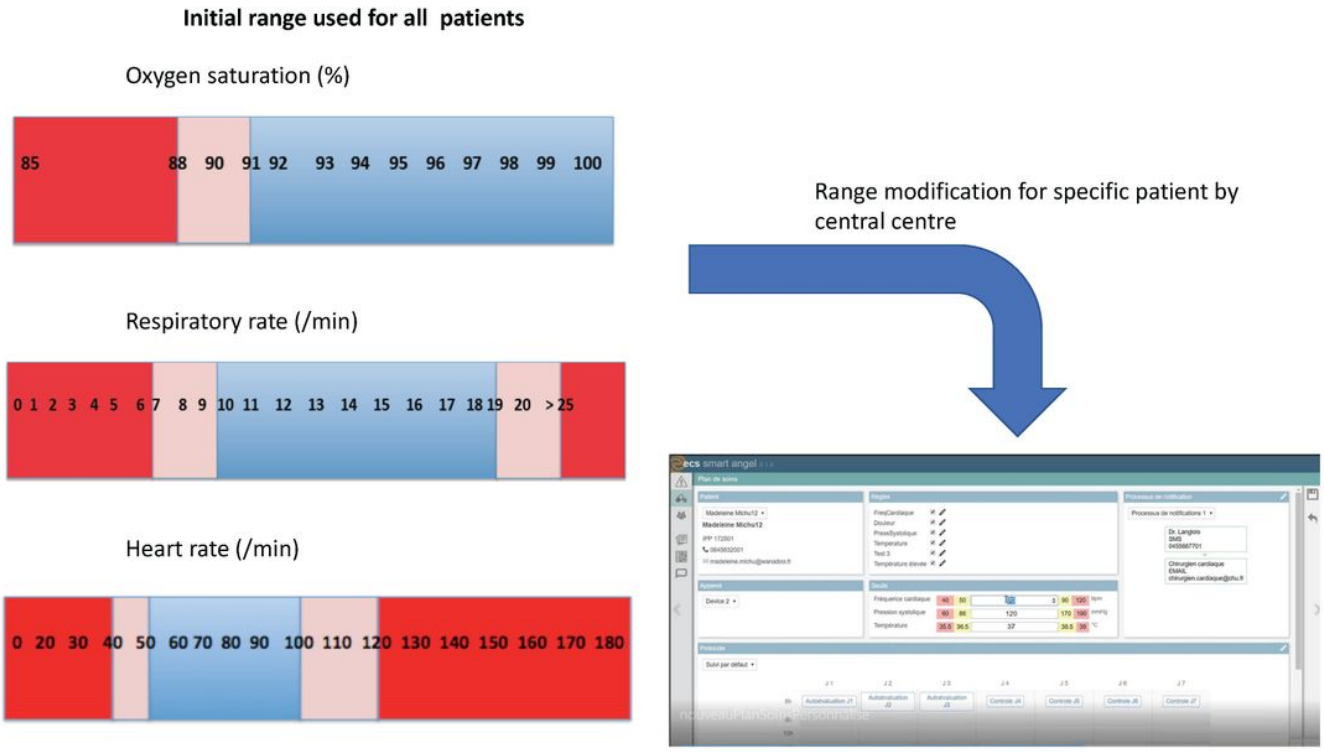

Figure 2

range of MAP, SpO2, HR for the remote monitoring

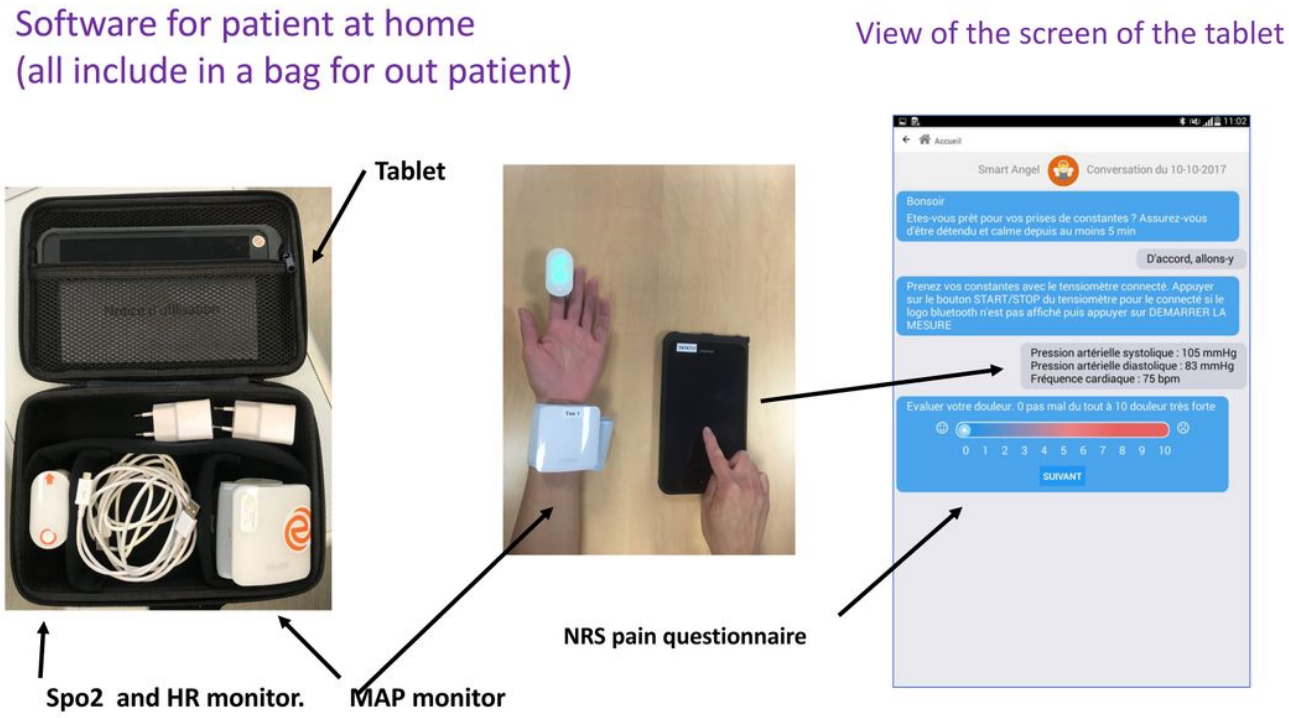

Figure 3

remote wireless monitoring, view of the patient with the monitors and screen of the tablet (Figure from author never published elsewhere)

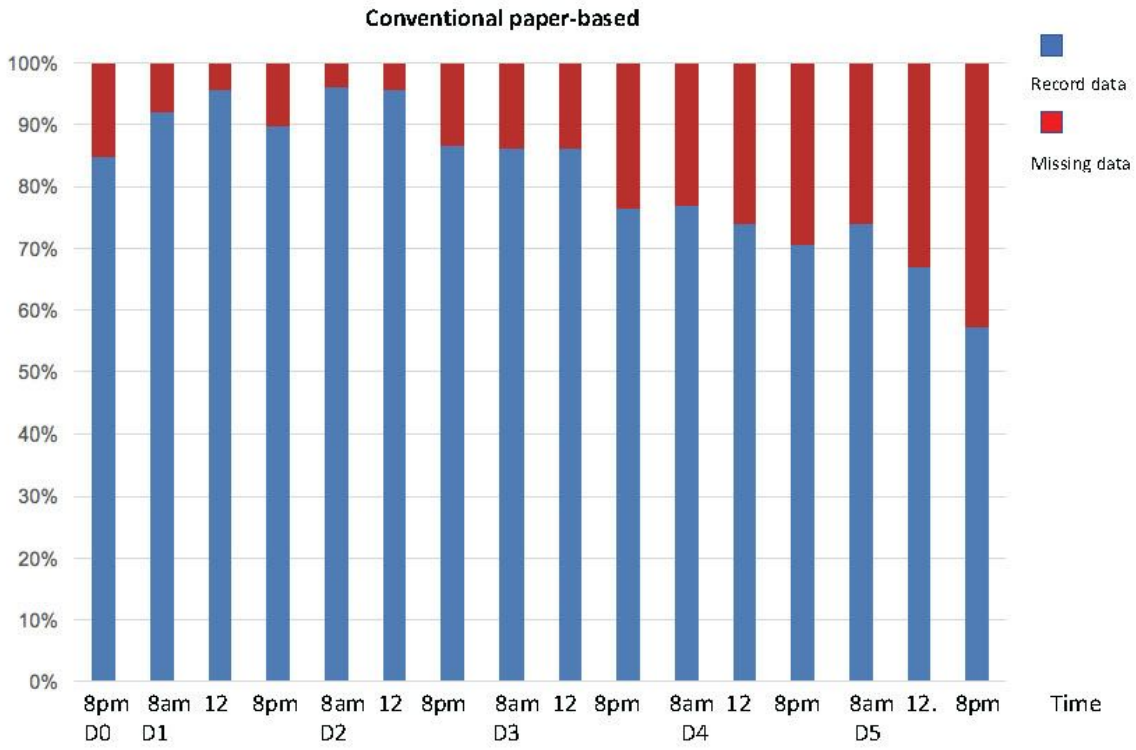

Figure 4

data from paper

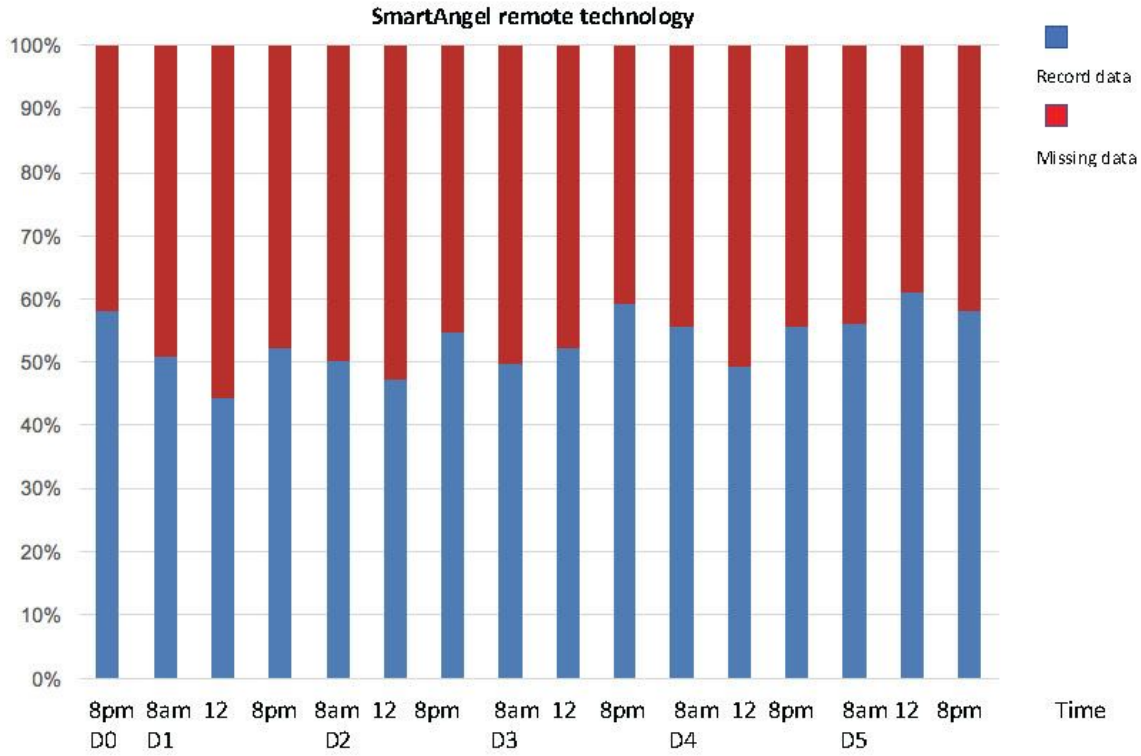

Figure 5

data from SmartAngel device