REVIEW ARTICLE

Technological Challenges set up by Continuous Wireless Monitoring designed to Improve Management of Critically Ill Patients in an Internal Medicine Unit (LIMS study): Study Design and Preliminary Results

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ABSTRACT

Background: Wireless vital parameter continuous monitoring (WVPCM) is compared to regular nurse monitoring in order to provide data on the clinical and economic impact of critically ill patients (CIPs) in Internal Medicine Units (IMU). **Study Design:** Pilot prospective randomized controlled open-label multi-center study with WIN@Hospital wearable wireless system creating alerts on portable devices (ipad). **Experimental Arm:** CIPs with MEWS (Modified Early Warning Score) ≥ 3 and/or NEWS (National Early Warning Score) ≥ 5 at admission underwent WCPCM over the first 72 h. **Active Comparator:** CIPs with MEWS ≥ 3 and/or NEWS ≥ 5 at admission undergoing regular nurse monitoring. **Primary outcomes:** Reduction of major complications (MC) from 15% to 5%. **Secondary outcomes:** One day reduction in length of stay (LOS); reduced nurse monitoring time; accurate patient stratification and definition of end stage disease. **Statistical methods:** According to the preliminary study (Manerbio, 2016), 27% of hospitalized patients, of which 15% have MC, are critical (MEWS ≥3), and require monitoring. Clinical significance is set at 5% relative reduction in MCs in the experimental arm. 148 patients shall be recruited per arm (total 296; calculated by setting the alpha error at 5%, beta error at 20%, 80% test power, 5% loss). **Preliminary results:** Enrolled 95 and evaluable 89 patients (35 M/54 F), mean age 80.5 years, Comorbidity: Cumulative Illness Rating Scale CIRS-CI: 4, CIRS SI: 1.8. About 38% scored a BRASS (Blaylock Risk Assessment Screening Score) ≥20 indicating need for discharge planning requiring step-down care. More than 50% of patients present IIA index >3 indicating high dependency from nursing assistance. Nurses saved a minimum of 49,6 minutes to a maximum of 58,1 minutes on time spent monitoring each patient per day. **Conclusions:** WVPCM, detecting early deterioration in CIPs, may facilitate timely response in at-risk patients, increasing safety and reducing costs.

Key words: Acute medicine, internal medicine core competencies, poly-pathological patients, wireless monitoring system

BACKGROUND

In recent years, the Internal Medicine (IM) Ward has been receiving an increasingly heterogeneous group of patients, many affected by acute or chronic diseases of varying severity, who are often elderly, frail, with co-morbidities, requiring intensive care[1] (Figure 1), due to epidemiological transition. Hospitalization of medical patients in large wards without prior stratification of severity, complexity, level of dependence, co-morbidities and without a proper assessment of the risk of rapid clinical deterioration, can lead to suboptimal treatment, resulting in prolonged hospital stay and increased care costs.

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Continuous monitoring of ASST-Garda's activity data has shown an increasing trend, regardless of the season, in Emergency Room (ER) presentation and subsequent hospitalization of patients over 65 years with exacerbation of chronic diseases. Access data to ER in the first quarter of 2017 compared with the same period of 2016, showed that a 1% increase in ER presentations resulted in a 10% increase in Internal Medicine admissions, causing overcrowding both of the ER and IM ward. A recent retrospective study in the IM Department of the Manerbio Hospital demonstrated that 27% of patients admitted to the IM ward are critical (needing continuous monitoring and advanced medical technology), 10% of which fulfilled criteria for intensive care transfer: MEWS≥ 5) presenting 5-6 active pathologies. Furthermore, 25% of hospitalized patients had social difficulties requiring activation of integrated hospital-territory pathways.[2]

To ensure appropriate care, it is therefore essential to stratify patients based on clinical intensity and care complexity and to define end-stage disease in order to provide adequate nursing settings, staff standards and the necessary technological equipment.

In order to provide data on the clinical impact of acute and critically ill patients in an Internal Medicine Unit, as well as economic data regarding the relative cost of acute patient management during ordinary hospitalization, and to asses whether continuous monitoring of vital parameters improves quality of care, an interventional study was proposed by the Internal Medicine Unit of Manerbio Hospital (ASST-Garda) in collaboration with the University of Modena and Reggio Emilia (Medical Statistics Unit). The study aims at assessing the efficacy of a wireless continuous monitoring system in reducing major complications and improving outcome and the quality of care in acute selected patients, while reducing costs, as compared to traditional monitoring performed at regular intervals by the nursing staff. Continuous monitoring of vital signs may permit detection of deterioration of acute patients in a non-intensive care setting (such as those hospitalized in the Internal Medicine Unit), allowing staff to promptly respond urgently to variations in the patient's condition and initiate appropriate care. In order to respond to an apparent lack of specific studies comparing the use of wireless monitoring systems and traditional vital sign monitoring in critical acute patients, the study was designed to highlight the benefits of continuous monitoring of vital signs in the first 72 hours of hospitalization. The study also indirectly aims to assess the reduction in hospitalization costs by using the decrease in average length of stay as a proxy parameter.

Study design [Figure 2]

The LIght Monitor Study (LIMS) is a pilot prospective randomized controlled open-label multi-center study aimed at evaluating the management of critically ill hospitalized patients using wireless monitoring of vital signs as compared to conventional monitoring in the first 72 h of hospitalization,

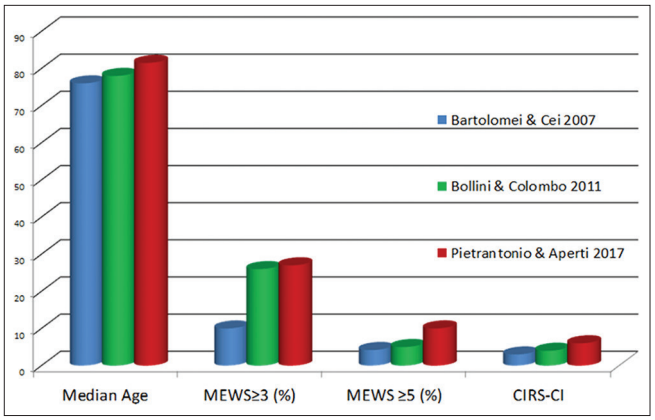

Figure 1: Trend of complexity indicators in Internal Medicine hospitalized patients[3-5]

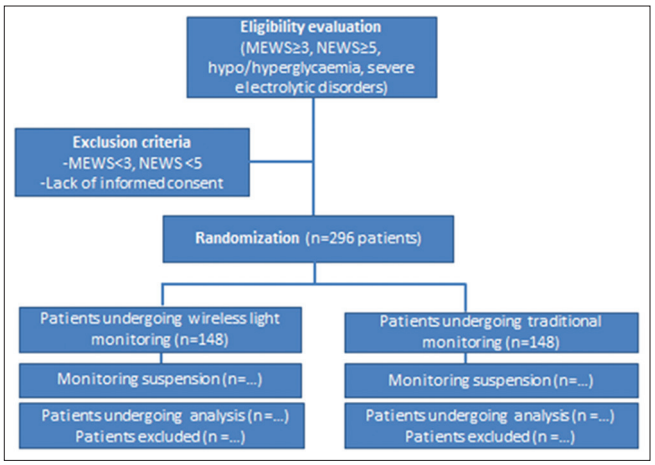

Figure 2: Study design. Moher *et al*. mod[6]

with the option to extend monitoring to 5 days if the MEWS after 72 h is greater than or equal to 3 and/or the NEWS is greater than or equal to 5.

PRESENTATION OF DESIGN

Wireless monitoring versus conventional monitoring in the first 72 h of hospitalization, for unstable CIPs with MEWS ≥3 and/or NEWS ≥5.

Experimental group

All patients with MEWS greater than or equal to 3 and/or NEWS greater than or equal to 5 at admission, regardless of the reason for hospitalization together with all patients with poor glycemic control and/or severe fluid and electrolyte imbalance, regardless of MEWS/NEWS, are deemed eligible for continuous wireless monitoring using the WIN@Hospital system.

Control group

All patients with MEWS greater than or equal to 3 and/or NEWS greater than or equal to 5, at admission, regardless of

the reason for admission and all patients with poor glycemic control and/or severe fluid and electrolyte imbalance, regardless of MEWS/NEWS will continue to undergo traditional monitoring performed at regular intervals (at least 4 times a day) by the nursing staff.

Study population

All critical patients (with the need for continuous monitoring and high technology) without a pacemaker, with MEWS ≥3 and/or NEWS ≥5 at admission and all patients with glycemic decompensation and/or severe fluid and electrolyte imbalance, regardless of MEWS/NEWS.

Identification of the monitoring tool used SYSTEM WIN®Hospital

The WIN@Hospital system is a portable wireless system (Medical Class IIA) that allows continuous, real-time vital sign monitoring, automatic calculation of the NEWS score and creation of a personalized alert system for each patient via a portable device (ipad), reducing the need for nursing staff to be constantly present.

SAFETY ASSESSMENT

The wireless monitoring system WIN@Hospital is a Medical Class II light monitoring system trade registered with the code A CE0434 in accordance with Directive 93/42/EEC. WIN@Medical monitoring systems allow real-time data display, but do not require the continuous presence of nursing staff monitoring data, because, as a class IIA device, it is not designated as an intensive monitoring tool nor life-saving (class II B), but a simple support tool aimed at tracking clinical parameters (to improve diagnosis, for the automation of detection procedures and for the reduction of clinical risk).

Time frame

The time frame is 24 months.

Primary outcomes

Reduction in occurrence of major complications from 15% to 5% in critically ill patients undergoing continuous monitoring using the wireless system.

Secondary outcomes

Reduction in hospitalization costs: reduction by one day in patient's average length of hospital stay; reduction in time dedicated to monitoring vital parameters by nursing staff per 24 hours, stratification of hospitalized patients in Internal Medicine according to level of care intensity (using MEWS and NEWS score) and identification of end stage patients.

Statistical methodology

The detection and treatment of early signs of deterioration in the patient's clinical condition reduce the incidence of major complications and improve patient outcomes. The preliminary study carried out at the Medical Unit of Manerbio Hospital demonstrated that 25% of hospitalized patients can be defined as critical (MEWS≥3) and as such require monitoring. At least 15% of these patients have major complications. Assuming a rate of major complications in the control arm of 15%, we consider a relative reduction by two thirds of this percentage as clinically significant, which translates to decrease in risk from 15% to 5% in the experimental arm. By setting the error α and β equal to 5% and 20%, or 80% power, recruitment of 141 patients per arm would be necessary to detect a statistically significant difference of at least 10%, that is 15% - 5%. In anticipation of a 5% drop-out rate, 148 patients per arm (296 patients in total) should be recruited. As regards to data analysis, descriptive statistics (mean, median and related distribution parameters) will be reported for continuous variables while the absolute frequencies, relative and percentage (n,%) will be calculated for the different categorical variables. The comparison between groups regarding binary outcomes will be assessed using measures of association such as the difference between risk and the relative risk, while for continuous variables the difference between averages and medians. Each point estimate will be reported with the corresponding 95% confidence interval. Using the 2016 figures from the Internal Medicine Unit of Manerbio Hospital (Source: DRG Office Manerbio, January 2017) which reported an average hospital stay of 9.21 days (standard deviation: 6.7 days) in traditionally monitored critically ill patients, we estimate that continuous monitoring of the patient will decrease the length of stay to 8.21 days, a total reduction of one day.

Statistical analysis

This trial was designed as a randomized multi-center study [7].

Univariate comparisons of data were performed using the student t test for continuous variables and the Yates Chi-Square for categorical variables. Adjusted means were calculated as well as mean differences, with corresponding confidence intervals, between the two arms. The covariates included in the model were age, gender, body mass index, MEWS, NEWS, CIRS, BRASS, IIA indexes, end stage disease, and patients' origin. All analyses were conducted using SAS v.9.2 (SAS Institute Inc., Cary, NC).

PRELIMINARY RESULTS

During the first 12 months, out of a total of 95 patients enrolled, 89 were evaluable (35M/54F), with a mean age 80.5 years. Mean CIRS-CI was 4, and CIRS SI was 1.8. Main DRGs (Diagnosis Related Groups): 127 (heart failure), 87 (respiratory failure), 576 (sepsis). End-stage disease so far represents more than 30% of the sample. Of the 89 patients, 38% had a BRASS score of ≥20 indicating cases where discharge may present difficulties and planning of step-down care is required. More than 50% of patients presented with an IIA index > 3 indicating

high dependence on nursing assistance. Nurses saved a minimum of 49,6 minutes to a maximum of 58,1 minutes on time spent monitoring each patient per day, which may translate to increased time spent on other activities which contribute to patient wellbeing. Of a total 1998 patients admitted in one year (2017 activity data of Manerbio Internal Medicine, source: ASST-Garda Statistics Office), only 5% were recruited out of the 27% deemed eligible, due to conditions such as dementia, coma or end stage disease which rendered signing of the informed consent impossible.

As regards to the primary end-point, the preliminary results are encouraging in that a trend towards reduction of major complications in the experimental group appears to be seen (31% in experimental arm versus 45% in the control arm).

Moreover, on analysis of the secondary end-points, a decrease in re-admissions (7% versus 11%) and, impressively, mortality (7.3% versus 23.9%) has been observed.

More than 30% of the patients meet the criteria defining end stage disease (positive answer to "surprise question": "Would I be surprised if this patient died in the next 12 months?"); 42.5% in the experimental arm and 33.3% in the control arm.

Preliminary results have failed to confirm the hypothesis regarding reduction in hospital stay, showing, on the contrary, increased LOS in the experimental arm (11.5 days versus 10.6 days).

This result is probably due to the evidence that in the experimental arm the BRASS>20 (need for discharge planning) is higher (33.3% versus 22.2%).

Preliminary findings of the LIMS Study are summarized in Table 1 and 2.

DISCUSSION

Contrary to current beliefs, upheld nonetheless by scientific studies,[8] the hospital internist regularly faces complex, unstable patients with difficult diagnoses and multiple comorbidities, who pass into their care once relatively stabilized. Management of this phase requires the specific competencies of the internist in diagnosis and management of the unstable, acutely unwell patient. However, the burden of management of clinical complexity, comorbidities, frailty, disability and social problems is appropriately shared with other disciplines (e.g. geriatricians, physiatrists) and may occur in the setting of assisted-care residential facilities, long-term care, home healthcare, or in collaboration with General Practitioners etc.[9]

The increasing role of Internal Medicine units in the management of urgent admissions can be partially explained by the fact that an IM ward is generally present in all hospitals and usually boasts a higher number of beds compared to specialized wards (Geriatrics, Neurology, Pediatrics, etc.), which are less well represented and have a lower number of beds. According to the Literature [10], Internal Medicine units admit mainly complex DRGs with neurological or cardiac issues as well as many patients fitting criteria for Geriatric Unit admission. Older age, together with polypharmacy, absence of formal and/or informal home-help services, history of falls, temporal disorientation, type of residence and use of psychoactive drugs significantly increase likelihood of hospital admission through the ER.

Considering that 55% of hospital admissions in Italy are urgent, and that the IM unit receives 27% of the total emergency admissions, not to mention that 83% of the IM admissions come from the ER, the prevalent activity in IM units is characterized by management of the acute complex patient[11].

ACUTE COMPLEX CARE MODEL (ACCM)[12]

According to these data, the ACCM seems to be an interesting proposal for the appropriate management of the acute patients presenting at ER and admitted in the IM Wards. ACCM represents the hospital counterpart of the chronic care model and is similarly aimed to ensure the efficacious and effective care of complex and poly-pathological patients when they are hospitalized for acute diseases. The target population are acutely ill complex and poly-pathological patients (CIPs), admitted to hospital and requiring high technological resources. The mission is to improve the management of medical admissions through pre-defined intra-hospital tracks and a global, multidisciplinary, patient-centered approach. The ACCM strengths are represented by (a) in-hospital care pathways, based on patients' needs and tailored for CIPs, (b) ability to balance risk and benefits of specialist treatments in any single patient, and (c) managerial competencies applied to CIPs and multi-professional integration.

The acute poly-pathological patient should be identified immediately on arrival at the hospital, and the need for hospitalization should be carefully evaluated while looking for alternative outpatients pathways. The selection of patients for admission to the hospital is essential to avoid overcrowding of emergency and medical wards, to reduce clinical risk, and to allow appropriate and timely care. A patient with a single-organ acute disease, but with multiple chronic comorbidities in labile compensation, should be taken in charge immediately by an internist who, thanks to his training and knowledge, can ensure a global care, coordinate organ specialists in a functional way, and administer poly-pharmacy, synergistically to the patient's health status. The clinical summary and the list of priorities should be written

Table 1: LIMS preliminary results: Patients' characteristics

Variable		Experimental arm (*n*=43)		Control arm (*n*=46)	
Age					
Years	Mean, SD	77.4	12.4	79.2	11.6
>80	*n*, %	24	55.8%	27	58.7%
Gender					
Female	*n*, %	28	65.1%	26	56.5%
Male	*n*, %	15	34.9%	20	43.5%
MEWS score					
0–14	Mean, SD	3.1	1.2	2.9	1.2
>3	*n*, %	15	34.9%	12	26.1%
NEWS score					
0–20	Mean, SD	7.2	2.2	6.8	2.2
>5	*n*, %	34	79.1%	30	65.2%
Weight					
kg	Mean, SD	74.6	18.7	71.4	13.3
Height					
cm	Mean, SD	163.5	8.1	164.8	8.3
BMI					
kg/m^2	Mean, SD	28	7.5	26.4	5
Coming from					
ER	*n*, %	24	55.8%	21	45.7%
Without admission request	*n*, %	15	34.9%	17	37.0%
Other	*n*, %	4	9.3%	8	17.4%
End stage disease					
No	*n*, %	23	57.5%	30	66.7%
Yes	*n*, %	17	42.5%	15	33.3%
CIRS score					
1–5	Mean, SD	1.7	0.3	1.8	0.3
0–13	Mean, SD	3.3	1.5	3.7	1.6
≥4	*n*, %	19	45.2%	25	55.6%
BRASS score					
0–36	Mean, SD	14.8	8.7	14.0	8.2
>20	*n*, %	14	33.3%	10	22.2%
IIA score					
1–4	Mean, SD	2.5	1.1	2.4	0.9
≥3	*n*, %	22	53.7%	23	50.0%

SD: Standard deviation. ER: Emergency room, BMI: Body mass index

down immediately after admission, and the composition of the multidisciplinary team, required by patient's health conditions, should be clearly reported in the medical records.

According to validated criteria, for example the MEWS[13] and the NEWS scores, vital parameters should be monitored continuously[14] or at regular intervals, and wireless systems may permit creation of an adequate care setting[15] for the patient without having to move them to a different department.

Continuous monitoring of vital parameters may allow early detection of deterioration in acute patients not admitted in intensive care such as those hospitalized in IMU, allowing the staff to immediately address the patient's needs achieving promptly the most appropriate care. As there are no studies

Table 2: LIMS preliminary outcomes

Outcome		Experimental arm (*n*=43)		Control arm (*n*=46)	
Complications					
No	*n*, %	29	69.00%	26	56.5%
Yes	*n*, %	13	31.0%	20	43.5%
Re-admissions					
No	*n*, %	38	92.7%	40	88.9%
Yes	*n*, %	3	7.3%	5	11.1%
Length of stay					
No of days	Mean, SD	11.5	4.9	10.6	7.1
Discharge					
Ordinary/voluntary	*n*, %	19	46.3%	26	56.5%
Transferred to acute care facility	*n*, %	1	2.4%	1	2.2%
Transferred to the step-down facility	*n*, %	18	43.9%	8	17.4%
Death	*n*, %	3	7.3%	11	23.9%

comparing the use of wireless monitoring systems and traditional vital signs monitoring in critical acute patients, the study was designed to highlight the benefits of continuous monitoring of vital signs in the first 72 h hospitalization to reduce the MC and improving outcome.

The preliminary results are encouraging as they appear to highlight a trend favouring continuous monitoring over traditional monitoring in terms of reduction in major complications.

Of note, of the secondary end-points studied a promising trend towards decrease in re-admissions reduction in mortality has been observed.

Moreover, between 33.3% and 42.5% of the patients are in the end stage of their disease according to the answer of the "surprise question": this may explain the difficulty often found in stabilizing the clinical condition of more than a quarter of the patients admitted to the Internal Medicine Unit.

More data are needed to confirm the hypothesis of LOS reduction.

Limitation of the study

The aim of this article is to present the study design and the preliminary results. The number of patients recruited at this stage represent less than a third of the total required sample, and as such only apparent trends extrapolated from initial analysis of the data have been reported herein.

CONCLUSIONS

Continuous wireless monitoring of vital parameters may permit early detection of deterioration in critically ill patients allowing prompt intervention, increasing safety and reducing costs. Extending the wireless monitoring system to low intensity facilities and indeed to the home setting may guarantee expert assistance following hospital discharge, reducing overcrowding in the ER and IM units.

Doing the right thing to the right patient at the right time represents the core mantra guiding quality diagnostic-therapeutic pathways that, accompanied by appropriate and efficient clinical reasoning, is the only way to reduce costs and length of hospital stay while at the same time delivering care at a level of excellence.

An important role of the Internal Medicine Unit is improving clinical conditions of patients otherwise in the terminal phase of their illness, such that life expectancy is indeed prolonged. Therefore the IMU also contributes to the active management of end-stage patients, as need for palliative care is effectively deferred as a this newfound clinical stability actually allows discharge after the acute phase.

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