Optimization of the Alarm-Management of a Heart Failure Home-Monitoring System

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Abstract

In the present study we show how an algorithm for generating heart failure alerts can be improved by retrospectively evaluating the available data. We built on a previous study on home based monitoring of heart failure patients after an episode of acute decompensations using mobile phones.

Data from patients monitored in the years 2003 to 2008 were analyzed. For the analysis of historic treatment and measurement tables, GNU-R statistical software was used. A data processing algorithm was implemented to optimize the alarm-management of the heart failure home-monitoring system. The improvement was achieved by reducing the number of generated false alarms and by introducing a risk parameter, which could be used to indicate the patient's status.

The algorithm provided adequate sensitivity and specificity and showed a significant improvement to the previous model, reducing the number of false alarms.

1. Introduction

Current studies increasingly use telemonitoring technologies to enhance patient physician interaction. A recent review of 65 empirical studies confirms that patients typically well accept telemonitoring technologies [2]. The reviewed studies conducted between 1990 and 2006 applied telemonitoring to four chronic illnesses: pulmonary conditions, diabetes, hypertension and cardiovascular diseases. Although the review found no conclusive evidence regarding magnitude and significance of telemonitoring effects on patients' health conditions, pulmonary and cardiac studies exhibited more consistent impacts on clinical outcomes (e.g. decrease in emergency visits, hospital admissions, average length of hospital stay) than telemonitoring studies of diabetes and hypertension.

Apart from the aforementioned chronic illnesses, telemonitoring was also successfully used in long term psoriasis therapy [3]. The preliminary results showed that using images recorded by mobile phones was feasible and useful for optimizing the therapy of patients with psoriasis.

Similarly, statistically significant improvement in metabolic control of patients on intensive insulin treatment was found in a study using mobile phone based service for assisting patients with type one diabetes mellitus [4].

An example of such technology is a recently developed toolkit Keep In Touch (KIT) using Near Field Communication and Radio Frequency Identification [1]. KIT is capable of processing relevant patient health information and establishing communication between the patients and caregivers. As such, KIT can be used by the health care service providers and the existing applications show good acceptance by the patients.

Although previous studies showed potential benefits to patients' health, economic viability and cost effectiveness of telemonitoring were analyzed in only a few cases – indicating the need for a more comprehensive evaluation [1,4]. Such an evaluation was provided by a study comparing a home-based telemanagement system with the usual care follow-up program in patients with chronic heart failure (CHF) [5]. The results showed statistically significant financial and health related benefits of the home-based telemonitoring system. While the mean costs for hospital readmission were reduced by 35%, the readmission rates were reduced by 36%, and the number of episodes of hemodynamic instability reduced by 31%.

The present paper builds on the existing studies using telemonitoring of patients with CHF, aiming to further increase reliability and provide opportunities for cost reduction. Previous attempts to improve telemonitoring of patients with CHF examined the use of subjective measures in comparison to physiological indicators to predict the need for medical intervention [6]. The identified key predictors in [6] were the number of system alerts, self-rated mobility, self-rated health and self-rated anxiety. Despite of the promising results in predicting the patient health status, most of the generated telemonitoring system alarms did not require patient physician interaction resulting in only 6.4% of alarms being classified as key medical events.

Similar occurrence of the large number of false alarms was observed during our previous study on effectiveness of home based mobile telemonitoring (MOBITEL) of

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patients with CHF [7]. Although the study showed benefits in using weight, heart rate and blood pressure measurements to reduce frequency and duration of heart failure patients' hospitalizations, the need for more sophisticated alarm management was identified as one of the key requirements for future utilization of telemonitoring systems in CHF treatment.

Therefore, it was the aim of the present paper to develop a new algorithm for alarm management during home monitoring of congestive heart failure patients, decreasing the number of false positive events.

2. Materials and methods

We used the data collected in the MOBITEL study during the years 2003 through 2008. The dataset contained 9128 measurement records from 65 patients. The data included measured patients' physiological parameters, maximum and minimum thresholds used to automatically alarm physicians when exceeded by the measured parameters, as well as records of physician responses to such alarms. The system allowed physicians to record five types of responses, coded as the following: (1) No action, (2) Threshold adjustment, (3) Patient contact, (4) Medication adjustment, and (5) Other actions. Out of such responses, "No action" and "Threshold adjustment" were not related to therapeutic actions, i.e. they were considered to be caused by false alarms. Additionally, false alarms included cases with an alarm occurrence and no responses from physicians. On the other hand, "Patient contact", "Medication adjustment" and "Other actions" were assumed to be the result of true alarms. All alarm occurrences were classified as positive events, while "no alarm" occurrences were classified as negative events. True negative events meant that neither alarms nor physician responses occurred, while false negative classification included cases when no alarms occurred but physicians recorded responses.

Analyses of the original data from [7] revealed that 20% of measurement days indicated alarm condition and coincided with physician responses, while no alarm and no responses occurred in 74% of cases, as presented in Figure 1. In 1% of cases physicians recorded responses during days when no alarms were exhibited, while in 5% of cases physicians had no responses although the alarms were shown.

Initially, all data were cleaned by removing the outliers defined as follows:

(1) diastolic blood pressure greater or equal to systolic, (36 events; 0,4%),
(2) systolic blood pressure outside of range 50-300 mmHg, (254 events; 2,8%),
(3) diastolic blood pressure outside of range 40-150 mmHg, (318 events; 3,5%),
(4) heart rate outside of range 20-200 bpm, (264 events; 2,9%),
(5) weight outside of range 30-500 kg, (216 events; 2,4%).

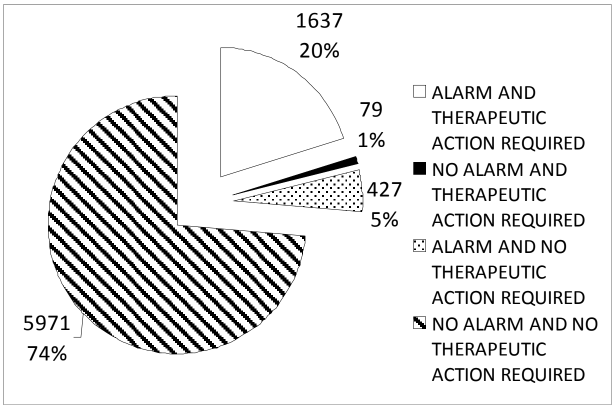

Figure 1. Alarms and therapeutic actions required

Furthermore, the cleaning removed cases when patients recorded measurements isolated in time. The remaining data included inconsistent number of measurements per day, as patients mostly recorded measurements only once but sometimes several times a day. In such cases new single measurement records were created to replace multiple daily measurements. The number of exceeded thresholds was summed for each day, while only the physician response with a maximum code was considered. After the cleaning the number of measured records was reduced to 8114 from 54 patients.

The cleaned data were used to develop several multi threshold alarm flags supplementing single threshold exceeded alarms. Such flags were based upon counts of exceeded thresholds during consecutive measurement days. Specifically, two or more exceeded thresholds and three or more exceeded thresholds were considered during 2 and 3 consecutive days. Considering the increasing number of true positive and true negative events the alarm flags were introduced as follows:

Alarm Level 1 – 1 Day / ≥1 exceeded thresholds,
Alarm Level 2 – 3 Days / ≥2 exceeded thresholds,
Alarm Level 3 – 2 Days / ≥2 exceeded thresholds,
Alarm Level 4 – 3 Days / ≥3 exceeded thresholds,
Alarm Level 5 – 2 Days / ≥3 exceeded thresholds.

Number of various physician actions was counted for each introduced alarm flag level. Reduction of alarm conditions was calculated as a percent difference between the original data and the number of alarms with a particular alarm flag level. Additionally, for each alarm flag, difference and ratio between the false positive and true positive alarm reductions were calculated.

3. Results

Table 1 presents the results after data cleaning, together with the outcomes of multiple exceeded threshold analyses, which serve as basis for the alarm flag level introduction.

Out of the responses physicians recorded, a 78% majority were “No actions”, as presented in the original cleaned data column of Table 1. Additional 6% of physician responses were related to the telemonitoring algorithm and represented by “Threshold adjustment”. Summing up these two classes, 84% of physician responses were not related to therapeutic actions, i.e. they were caused by false alarms.

Table 1. Results of the original data analyses and alarm occurrence due to multiple exceeded thresholds over 2 and 3 consecutive days

Physician responses / Type of alarms / Statistics	1 Day / ≥1 exceeded thresholds	3 Days / ≥2 exceeded thresholds	2 Days / ≥2 exceeded thresholds	3 Days / ≥3 exceeded thresholds	2 Days / ≥3 exceeded thresholds
(1) No actions	1269 (78%)	866 (75%)	720 (74%)	519 (72%)	273 (75%)
(2) Threshold adjustment	108 (6%)	83 (7%)	76 (8%)	49 (7%)	26 (7%)
(3) Patient contact	135 (8%)	106 (9%)	96 (10%)	79 (11%)	54 (9%)
(4) Medication adjustment	89 (5%)	77 (7%)	67 (7%)	59 (8%)	38 (6%)
(5) Other actions	36 (2%)	27 (2%)	20 (2%)	13 (2%)	1 (2%)
True positive TP	260	210	183	151	93
False positive FP	1804	1705	1214	915	401
True negative TN	5971	6070	6561	6860	7374
False negative FN	79	129	156	188	246
Specificity TN/(TN+FP)	0,768	0,781	0,844	0,882	0,948
Sensitivity TP/(TP+FN)	0,767	0,619	0,540	0,445	0,274
Alarm flag	Level 1	Level 2	Level 3	Level 4	Level 5

The overall results in Table 1 showed between 5% and 78% reduction of false positive (FP) alarms depending upon the alarm flag level. However, such results were also followed by a reduction between 19% and 64% in true positive (TP) alarms, respectively. Thus, the FP-TP reduction difference varied between -14% and +14% and the FP/TP reduction ratio between 0,29 and 1,21.

4. Discussion

The results showed the greatest specificity obtained for an alarm indication based on three or more exceeded thresholds over two consecutive days. Also, the specificity was directly proportional to the sum of true positive and true negative events and the alarm flag levels, but inversely proportional to sensitivity. The idea behind the alarm flags was to send additional information to physicians as an indication how important the alarm may be. Consequently, high levels of alarm flags would require immediate attention as it would be more likely that medication adjustment, patient contact or other physician action was necessary.

The increase in alarm flag levels would imply increase in specificity, but also decrease in sensitivity. Specificity vs. sensitivity cost benefit analysis was based upon the obtained difference and ratio between reductions in false and true positive alarms. The reduction difference could be understood as an absolute benefit reflected in the reduced number of FP alarms paid by the cost of TP alarm reductions. The reduction ratio described a relative benefit in the form of FP reduction percentage paid by each percent of TP reductions. The largest absolute benefit, i.e. the greatest difference of 14% between the FP and TP alarm reduction percentages was achieved for the alarm flag level 5 based on three or more exceeded thresholds over two consecutive days. The same maximum alarm flag level also corresponded to the greatest relative benefit, i.e. 1,21% decrease in FP alarms was the maximum achieved for each percent decrease in TP alarms.

The fact that each reduction of false positive alarms followed the reduction of true positive alarms meant that reducing physician efforts in responding to alarms could lead to disregard of some potentially significant patient alarm conditions. The researchers agreed that such negligence was unacceptable and consequently decided not to replace the way alarms were generated, but rather to supplement it with the introduction of the described alarm flag levels.

However, the described analyses might have been negatively impacted by the aforementioned cleaning procedure due to the implemented changes in the database of recorded measurements. Nevertheless, such impact would have been minimal as the cleaning and preprocessing procedure resulted in reduction of available measurement records by 11%, from 9128 to 8114, while the number of considered patients was reduced by 17%, from 65 to 54.

An additional limitation is related to the available alarm records. Namely, the original data collection algorithm allowed physicians to manually adjust threshold values during the course of the measurements. Consequently, the same values of measured parameters may cause an alarm before the threshold is adjusted and indicate normal condition after such adjustment. Thus, in some cases alarm generations may have been adversely impacted by physician interaction with the monitoring algorithm resulting in inconsistent occurrence of alarms among the patients. As an illustration, Figure 2 presents blood pressure threshold adjustments for one of the monitored patients.

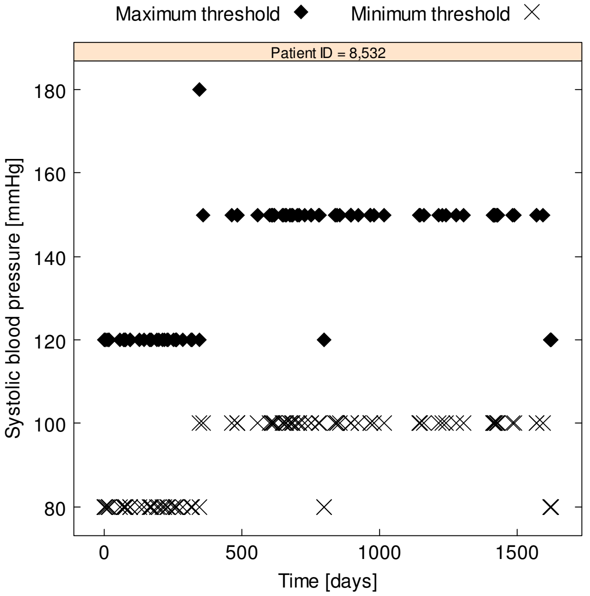

Figure 2. Systolic blood pressure threshold adjustments during a patient telemonitoring

Another limiting factor is related to a certain number of physician responses which may have been a consequence of alarm events occurring during the days of previous measurements, rather than the day of response. This could be one of the reasons Figure 1 shows that 1% of physician responses occur during the day when no alarms were recorded, while 5% of the total number of measurements indicate alarms without accompanying physician actions. However, records of a possibly delayed physician actions exist in only a small number of such events. Consequently, such cases are considered only when calculating the number of false events for the original data.

Future versions of the automated telemonitoring will validate the presented enhanced physician support. Extensive tests are to confirm impacts of such enhancements on system acceptance, number of hospitalizations, and health care costs. Future works will also focus on characterization and modeling of patient physician interaction as part of the control loop towards mathematical modeling of strategies for patient therapy optimization.

5. Conclusions

The current study analyzes occurrence of alarms in the developed MOBITEL algorithm for telemonitoring of heart failure patients after an episode of acute decompensation. The study offers ways to improve the alarm generation towards increasing specificity and reduction of false positive alarms. For the analysis of historic treatment and measurement tables, GNU-R statistical software was used. New 5-level alarm flag is proposed to supplement the original algorithm towards more efficient and precise telemonitoring system.

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