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Clinical impact of multi-parameter continuous non-invasive monitoring in hospital wards: a systematic review and meta-analysis

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Abstract

Objective: Delayed response to clinical deterioration as a result of intermittent vital sign monitoring is a cause of preventable morbidity and mortality. This review focuses on the clinical impact of multi-parameter continuous non-invasive monitoring of vital signs (CoNiM) in non-intensive care unit patients.

Design: Systematic review and meta-analysis of primary studies. Embase, MEDLINE, HMIC, PsycINFO and Cochrane were searched from April 1964 to 18 June 2019 with no language restriction.

Setting: The search was limited to hospitalised, non-intensive care unit adult patients who had two or more vital signs continuously monitored.

Participants: All primary studies that evaluated the clinical impact of using multi-parameter CoNiM in adult hospital wards outside of the intensive care unit.

Main outcome measures: Clinical impact of multi-parameter CoNiM.

Results: This systematic review identified 14 relevant studies from 3846 search results. Five studies were classified as Group A – associations found between measured vital signs and clinical parameters. Nine studies were classified as Group B – comparison between clinical outcomes of patients with and without multi-parameter CoNiM. Vital signs data from CoNiM were found to associate with type of presenting complaint, level of renal function and incidence of major clinical events. CoNiM also assisted in diagnosis by differentiating between patients with acute heart failure, stroke and sepsis (with sub-clustering of septic patients). In the meta-analysis, patients on multi-parameter CoNiM had a 39% decrease in risk of mortality (risk ratio [RR] 0.61; 95% confidence interval [95% CI] 0.39, 0.95) when compared to patients with regular intermittent monitoring. There was a trend of reduced intensive care unit transfer (RR 0.86; 95% CI 0.67, 1.11) and reduced rapid response team activation (RR 0.61; 95% CI 0.26–1.43). A trend towards reduced hospital length of stay was also found using weighted mean difference (WMD –3.32 days; 95% CI -8.82–2.19 days).

Conclusion: There is evidence of clinical benefit in implementing CoNiM in non-intensive care unit patients. This review supports the use of multi-parameter CoNiM outside of intensive care unit with further large-scale RCTs required to further affirm clinical impact.

Keywords

Vital signs, continuous monitoring, clinical decision making, clinical outcome

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Introduction

Failure to detect clinical deterioration is an important cause of preventable morbidity and mortality in hospitals as vital sign changes can occur up to several hours before the incidence of adverse events.[1–6] Underlying causes such as sepsis, acute coronary syndrome and pulmonary embolism may be treated promptly with early detection.[7–12] Such delays have been highlighted in the 2018 National Confidential Enquiry into Patient Outcome and Death Common Themes and Recommendations report.[13] In response to the need for early detection, the National Early Warning Score was introduced by the Royal College of Physicians in 2012 with further updates in 2017.[14,15] The vital signs monitored by the National Early Warning Score include heart rate, respiratory rate, blood pressure, temperature and peripheral capillary oxygen saturation (SpO_2). The National Early Warning Score is used for all non-obstetric adult in patients (aged $\geq$ 16 years).[15] Similar early warning scoring systems have been adopted in the United States, Denmark and Australia, among other countries.[16–18]

Is graded response strategy adequate?

However, in the current guidelines from the National Institute for Health and Care Excellence, patients with low to average National Early Warning Scores are only intermittently monitored (i.e. graded

response strategy) and the question remains whether these patients will also benefit from continuous monitoring.[15] A recent systematic review has flagged the intermittent nature of monitoring in non-intensive care unit hospital wards as a limitation of current track and trigger systems worldwide.[19] Vital sign changes that occur between the intermittent observation checks may be missed and early warning signs may go undetected due to technical errors that might have been avoided with repeated readings. Furthermore, user-dependent errors such as incomplete documentation of respiratory rate and SpO_2 were found to be prevalent due to the intermittent observations being conducted manually.[20] Manual observations were also found to be disruptive and resulted in inaccurate measurements.[21,22]

Increasing availability of continuous non-invasive monitoring (CoNiM) technology

Currently, CoNiM is only standard practice in intensive care unit but with the advent of wireless, light-weight and low-cost wearable sensors, there is a possibility of bringing CoNiM to all hospital inpatients. Developments by technology companies such as Apple and Google have brought about advancements in sensor technologies such as miniaturisation, improved battery life and reduction in production cost.[23] These improvements have made bringing CoNiM into general hospital wards feasible. Moreover, the National Institute for Health and Care Excellence has implemented electronic tracking system for National Early Warning Scores to release nursing resources.[24,25] Likewise, CoNiM may also achieve a similar effect on staff resources as the implementation of wearable sensors will reduce the need for manual observations by nurses. A recent survey has also shown CoNiM to be positively received by nurses and doctors as a tool for reassuring patients and supporting inter-disciplinary communication.[26]

Study aim

The present review aims to investigate the clinical impact of implementing CoNiM. The clinical benefits of CoNiM will be categorised as associations between vital sign data from CoNiM and clinical parameters (Group A) and differences in clinical outcomes between patients with and without CoNiM (Group B) . We postulate that better understanding of clinical needs through finding associations between vital signs data from CoNiM and clinical parameter may enhance early detection.[27,28] This may then impact clinical outcomes such as mortality, hospital length of stay and transfer to intensive care unit, which are measures of success of the intervention in the context of current resource availability.[29,30]

The hypothesis of this systematic review and meta-analysis is: CoNiM in adult hospital wards will aid the diagnostic process through earlier detection of clinical deterioration with the potential to improve patient outcomes. Continuous monitoring of single vital sign parameter such as heart rate telemetry and SpO_2 through oximetry have already been well described.[31–33] The focus of this review will therefore be on the clinical impact of multi-parameter CoNiM on patient outcomes which is still largely unknown.[34,35]

Methods

The protocol of this review was guided by the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement.[36]

Search strategy

The search was performed on 18 June 2019. Embase, MEDLINE, HMIC, PsycINFO and trials in the Cochrane Library were searched with no restriction on language and publication date. The search strategy included keywords and Medical Subject Headings of the following concepts: continuous monitoring; vital signs; adult; hospital; and patient outcomes. The keywords and Medical Subject Headings terms can be found in Appendix A. To ensure inclusion of all relevant primary literature, references of reviews in this subject area were also surveyed.

Inclusion criteria

Studies to be included in this systematic review had to include continuous non-invasive monitoring of two or more vital signs in an adult hospital ward outside of the intensive care unit with clinically relevant endpoints. Vital signs had to be monitored at a minimum frequency of once every 30 min. Vital signs could include any of the following: heart rate; respiratory rate; temperature; SpO_2; and blood pressure. Derived indices such as cardiac indices and mean arterial pressure could also be included; however, indices derived from the same vital sign were only considered as a single parameter. Specific technology used in continuous monitoring was not limited. Outcome measures were association to clinical parameters and clinical outcomes.

Exclusion criteria

Studies with only single vital sign, intermittent monitoring, paediatric, neonatal or obstetric patients were

excluded. Studies set in primary care, outpatient clinics, nursing homes and intensive care unit were excluded. Studies that included high-risk acute patients whose clinical status highly resembled those of intensive care unit patients were also excluded. Studies without clinically relevant end-points were excluded. Reviews, case reports, editorials and commentaries were excluded.

Outcome measures

Relevant studies were categorised into those which analysed association with clinical parameters (Group A) and those which analysed clinical outcomes (Group B). Clinical parameters included any clinically relevant information that could be used in the process of investigating, diagnosing or managing patients. Clinical outcomes were measurements of the result of care received in the hospital.

Data extraction and review of results

Two reviewers (LS and MJ) screened the search results for relevant studies independently. The full text of these studies were then examined in detail and if subsequently excluded, the reasons were noted. Any disagreement between the first and second reviewers was resolved by a third reviewer (HA). A PRISMA flow diagram was used to chart studies and reasons for inclusion and exclusion. Reviews relevant to the subject area were also flagged to survey their reference list for any empirical studies not found in our database search.

Data synthesis and statistical methods

Qualitative assessment was performed on studies that examined associations between CoNiM and clinical parameters (Group A). Meta-analysis was performed on controlled studies with clinical outcomes as end-points (Group B). For continuous variables, weighted mean difference was used for meta-analysis. Median was assumed to equal to mean if the sample size was greater than 25.[37] Standard deviation was calculated from confidence interval if required.[38] Risk ratio (RR) with 95% confidence interval (95% CI) was calculated for categorical variables. The statistical analysis was carried out using Stata 13.1 (StataCorp., College Station, TX, USA). Meta-analysis was performed with random effects model using the method of DerSimonian and Laird and inverse-variance method was used to estimate the degree of heterogeneity (I^2 statistics).

Risk of bias assessment

All relevant studies were scored from 0 to 9 on the Newcastle-Ottawa Scale to determine the study quality.[39] A score of 7 or higher was regarded as high.

Results

The literature search identified 3846 references (Supplemental Figure 1) and two studies were identified through the reference list of a related narrative review.[40] After screening the titles and abstracts of all identified references, 96 articles were reviewed in full. Fourteen articles met the inclusion criteria and were relevant to the research question. Five of the 14 articles were in Group A (association with clinical parameters) while 9 of the 14 articles were in Group B (impact on clinical outcomes). Eight out of the nine articles in Group B had quantitative data suitable for meta-analysis. Clinical outcomes included in the meta-analysis were mortality, hospital length of stay, intensive care unit transfers and rapid response team alerts. A summary of studies including sensors used, vital signs monitored and outcome measurements can be found in Supplemental Tables 1 and 2.

Characteristics of studies

Group A had prospective data collection and retrospective data analysis. Explicit mention of blinding of healthcare workers to CoNiM data was present in two of the five studies (Nowak et al.[27,28]) and all five studies did not generate any alerts from the monitored vital signs in order to not alter clinical pathways.[27,28,41–43] The most commonly monitored vital sign was heart rate, being present in all five studies, followed by blood pressure in four studies, respiratory rate in two studies and SpO_2 in one study. Temperature was not included in any. Recording frequencies for all studies were greater than once per 15 min, except heart rate and blood pressure in Kanaoka et al.[42] and blood pressure in Hubner et al.[41] were measured only once per 30 min. Hubner et al.[41] enrolled patients from the waiting area of the Emergency Department while Nowak et al.[27,28] enrolled patients in the Emergency Department who were able to give informed consent. Zimlichman et al.[43] and Kanaoka et al.[42] recruited patients from medical wards.

Group B had controlled prospective studies with the exception of Kisner et al.[50] In all studies, vital signs were monitored continuously in the intervention group. When a study included multiple control groups, only control data from the same ward prior to intervention were used to reduce complications arising from heterogenous populations. Randomisation was present in five of the studies.[44–48] Monitoring

devices used were specified except in Cavallini et al.[46] Vital signs monitored were specified in all except Pearl et al.[49] All studies in this group only included non-acute and non-high-risk patients from general medical or surgical wards.[29,44–51]

Association with clinical parameters

All five studies in Group A demonstrated clinically relevant information can be derived from data obtained through multi-parameter CoNiM. There were three main themes: patient information; predictive information; and diagnostic information.

Patient information such as presenting complaint (chest pain, dyspnoea, collapse, palpitations and hypertension) and kidney function (urine albumin excretion rate and estimated glomerular filtration rate) were found to correlate with continuously monitored vital signs; in particular, the course of four parameters (heart rate, blood pressure, respiratory rate and SpO_2) were found to be dependent on the patient's presenting complaint such as dyspnoea, chest pain and collapse.[41,42] Data from changes in continuously monitored blood pressure and heart rate were also found to be predictive of potential cardiac arrest, transfer to intensive care unit and need for mechanical ventilation.[43] Diagnostic data from continuously monitored blood pressure and heart rate also helped to identify patients with acute heart failure, sepsis or stroke and were used in sub-clustering septic patients into groups with different prognosis.[27,28]

Impact on clinical outcome

Eight of the nine studies in Group B were included in this meta-analysis. Clinical outcomes meta-analysed were mortality, hospital length of stay, intensive care unit transfers and rapid response team activations.

Mortality. There was reduced mortality in patients with CoNiM in five studies[29,45,46,49,51] except Langhorne et al.[47] Langhorne et al.[47] included 'early mobilisation' as a separate intervention; therefore, half of the control population and half of the CoNiM population were also enrolled in 'early mobilisation'. The heterogenous population compounded by a small sample size (n = 32) may have skewed the results. Nonetheless, the overall effect of 1748 patients with CoNiM and 1644 patients in control group demonstrated statistically significant reduction of 39% (RR 0.61; 95% CI 0.39–0.95) in risk of mortality (Supplemental Figure 2.1).

Hospital length of stay. Three studies were included in the meta-analysis for hospital length of stay using weighted mean difference with 1236 patients in intervention group and 1002 patients in control group.[29,44,45] There was a trend towards shorter hospital length of stay with a weighted mean reduction of 3.32 days (weighted mean difference −3.32; 95% CI -8.82–2.19 days) (Supplemental Figure 2.2).

Transfer to intensive care unit. Three studies were included in the meta-analysis for transfer to intensive care unit with a total of 3852 patients in intervention group and 2851 patients in control group.[29,48,51] A trend towards 14% (RR 0.86; 95% CI 0.67–1.11) reduction in risk was found (Supplemental Figure 2.3).

Rapid response team activations. Three studies were included in the meta-analysis for rapid response team activations and there were a total of 3852 patients in intervention group and 2851 patients in control group.[29,48,51] A trend towards 39% (RR 0.61; 95% CI 0.26–1.43) reduction in risk was found (Supplemental Figure 2.4).

Other clinical outcomes. Kisner et al.[50] focused on the effect of continuous monitoring of SpO_2 and heart rate on the incidence of atrial fibrillation in post-cardiac surgery patients. The study showed significant reduction in occurrence of atrial fibrillation in the CoNiM patient group (p value = 0.016) after coronary artery bypass graft.[50] However, when a subset of patients who underwent only valvular surgery were included in the comparison, the reduction in atrial fibrillation only approached statistical significance (p value = 0.056).[50]

Risk of bias assessment

As Group B studies were cohort studies with control groups, Newcastle-Ottawa Scale analysis was performed (Supplemental Table 3). All nine studies had a score of 7 and higher; all studies had adequate follow-up period and there was no loss to follow-up as all outcomes were in-hospital events. Kisner et al.[50] and Langhorne et al.[47] received the lowest score as their patient population were found to be least representative of general non-acute in-hospital patients. Brown et al.[48] and Weller et al.[29] received top scores for including multiple control groups to

account for both the effect of intervention and temporal changes.

Discussion

This is the first systematic review and meta-analysis on the association of vital signs data from multi-parameter CoNiM with clinical parameters and eventual clinical outcomes. Two previous systematic reviews (only one included meta-analysis) have been published in this area. This study has the advantage of including recently published studies and focusing on multi-parameter monitoring. Multi-parameter CoNiM best represents the function of light-weight portable monitoring devices that are becoming increasingly available.[23,40,52]

In general, Group A studies presented the utilities of multi-parameter CoNiM, while Group B studies presented the net clinical benefit of implementing multi-parameter CoNiM. Studies in Group B were of higher quality than studies in Group A as all Group B studies had strictly continuous monitoring and only medical or surgical ward patients. Moreover, Kisner et al.,[50] which had a relatively low Newcastle-Ottawa Scale score, was not included in the meta-analysis. This is notable as evidence from Group B is of greater significance to the research question; the strong relevance, good quality and relative homogeneity of study characteristics in Group B studies are key strengths of this study.

Group A studies showed that one of the many advantages of multi-parameter CoNiM technology in a non-intensive care unit hospital setting is the possibility of more timely identification of clinical deterioration. An example would be early prediction of cardiac arrest or transfer to intensive care unit.[43] However, multi-parameter CoNiM was found to aid in ways other than being a rapid alarm. Multi-parameter CoNiM was also found to be a good reflection of patients' presenting complaints and therefore could improve the efficiency of triage nurses.[41] It also helped to classify patients into groups that differ in their medical needs.[27,28] Continuous monitoring of blood pressure and heart rate were also found to reflect renal function.[42] Instead of replacing essential renal markers such as urine albumin excretion rate and estimated glomerular filtration rate, this technology could serve as an indicator for more invasive or laborious tests.

Group B studies found strong evidence of clinical outcome improvements. The risk of mortality was significantly reduced (RR 0.61; 95% CI 0.39–0.95) in patients with CoNiM. As statistical significance was achieved while Langhorne et al.[47] was included in the meta-analysis, despite its opposing trend and relatively low Newcastle-Ottawa Scale score, the true reduction in mortality may even be greater. This is contrary to a meta-analysis conducted in 2016 where no improvement in mortality rate was found.[52] However, the previous meta-analysis included only four studies and two of which were with high-risk patients; interestingly the two studies were also duplicates of the same trial.[53,54] Moreover, several new primary studies on multi-parameter CoNiM have been published in recent years and they have been included in this review.

There was also evidence of reduced mean hospital length of stay (weighted mean difference −3.32 days; 95% CI -8.82–2.19 days) when patients were continuously monitored. In addition, despite increased monitoring, there was a trend towards reduced risk of intensive care unit transfers (RR 0.86; 95% CI 0.67–1.11) and rapid response team activation (RR 0.61; 95% CI 0.26–1.43). One possible explanation may be earlier detection of deterioration that has allowed prompt response to prevent further care escalations. This is supported by a previous study that showed increased morbidity in delayed treatments for patients with physiological deterioration.[55] These results were found in the context of current staffing levels and resource settings despite worries about increased alarms and resultant alarm fatigue from the proposed change.[56,57]

Rate of false-positive alarms is an important issue due to its impact on staff attention and alarm burden. While some false positives can be corrected with better technical accuracy, the less tractable false positives are a measure of the true utility of early physiological changes in predicting future clinical events. Increased alarm types and frequency are already a risk for healthcare workers to becoming more desensitised to alerts.[58,59] It would be detrimental if the alarms were also of little clinical value.

Of the 14 studies, only Zimlichman et al.[43] addressed this question with their focus on the sensitivity, specificity and positive predictive value of multi-parameter CoNiM alarms. However, the study used the maximum sensitivity and specificity to retrospectively decide the alarm thresholds; thus, it is not a reflection of the true predictive values in actual implementation. Also, the prospective randomised trials on clinical outcomes would not have been able to investigate this as interventions were necessary as part of the study design. Therefore, it remains an opportunity for future studies to investigate the predictive power of CoNiM.

The concern with false-positive alarms also stems in part from the staffing levels that current healthcare systems have. Studies of CoNiM in high-risk patients

found insufficient nurses on the ward to be the factor limiting its full potential.[53] Nonetheless, our study was able to demonstrate clinical benefits in spite of the limitations in current resource settings; it also suggests that CoNiM might have an even greater impact with appropriate staffing level. Cost-effectiveness is another concern of implementing CoNiM. A previous systematic review has already addressed this issue satisfactorily as they found three relevant studies and all of which have found significant cost-savings.[40]

Limitations

A possible confounding factor could be that the healthcare workers were being more meticulous in their care when they noticed the presence of a monitoring device. However, it would be impractical to implement blinding since the benefit of the intervention was reliant on a more timely response from the healthcare team. Moreover, Group B had an average intervention period of 9.89 months, ranging from 3 to 28 months. This intervention period would have allowed healthcare workers time to be accustomed to the change and be less affected by the presence of monitoring equipment. Further studies with long-running intervention periods will strengthen the evidence.

Group A was also susceptible to publication bias. Studies that did not find significant association between a clinical parameter of interest and CoNiM would less likely be published. However, this analysis is not reliant on the complete reporting of all investigations. The presence of improvement to clinical outcomes in Group B studies would be testament to the actual usefulness of those associations found.

There were also a variety of methods among the 14 studies. At least 10 different monitoring devices were used and numerous combinations of different vital signs were monitored among the studies. A clinical trial of any new monitoring device will still be needed to validate its diagnostic accuracy before large scale implementation. Finally, the number of studies included in our meta-analysis is limited and therefore we were not able to perform cross-validation and meta-regression.

Conclusion

This systematic review and meta-analysis found evidence of reduced mortality in non-acute hospitalised patients with CoNiM. There was also a trend of reduced mean hospital length of stay, intensive care unit transfers and rapid response team activations. The presumed underlying reason for these clinical benefits is the improved understanding of patients' clinical status through the information gathered by CoNiM.

Declarations

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Guarantor: AD.

Contributorship: MJ and SK had the idea for the article; LS, MJ and HA did the literature review. LS wrote the first drafts of the article; HA and LS performed the meta-analysis. MJ, SK, HA and AD contributed to the analysis and redrafting of the article.

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Supplemental Material

Supplemental material for this article is available online.

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