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Title: Communication in critical care : measuring and monitoring quality of care to improve patient safety

Issue Date: 2016-10-13

Chapter 4

“Unexpected” versus all-cause mortality as the endpoint for investigating the effects of a Rapid Response System in hospitalized patients

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Accepted for publication Critical Care

Abstract

Objective: To assess the effect of replacing all-cause mortality by death without limitation of medical treatments (LOMT) as endpoint in a study on Rapid Response Teams in hospitalized patients. Furthermore, to describe the time-course of LOMT orders in patients dying on a general ward and the influence of RRTs on such orders.

Design: This study is a secondary analysis of the COMET-trial, a pragmatic prospective Dutch multicenter before-after study.

Setting: We repeated the original analysis of the influence of RRTs on death before hospital discharge by replacing all-cause mortality by death without LOMT-order. In a subgroup of all patients dying before hospital discharge, we documented patient demographics, admission characteristics and LOMT orders of each patient.

Patients: All patients 18 years or above admitted to the study wards were included.

Measurements and Main Results: In total, 166,569 patients were included in the study. The unadjusted ORs were 0.865 (95% CI 0.77-0.98) in the original analysis using all-cause mortality and 0.557 (95% CI, 0.40-0.78) when choosing death without LOMT as endpoint. In total, 3,408 patients died before discharge. At time of death, 2910 (85%) had an LOMT order. Median time from last change in LOMT status and death was 2 days (inter quartile range (IQR) 1-5) in the before phase and median 1 (IQR 1-4) after introduction of the RRT (p=NS).

Conclusions: The improvement of survival in hospitalized patients after introduction of an RRT in the COMET-study was more pronounced when choosing death without LOMT, rather than all deaths as endpoint. Most patients who died during hospitalization had LOMT orders instituted, often shortly before death.

Introduction

Patients who are admitted to general wards in hospitals may deteriorate which may result in unplanned ICU admission, cardiac arrest or even death. ¹ Rapid Response Systems have been developed for timely identification and treatment of patients on general wards at risk for clinical deterioration. ² In the literature, these systems have different names, including Rapid Response Team, Outreach Team or Medical Emergency Team. In this paper we will use the term Rapid Response Team (RRT) for both the actual outreach team and the rapid response system as a whole.

Three large controlled studies investigated the effects of the introduction of an RRT on clinical outcomes. ³⁻⁵ Endpoints of these studies were mortality, unplanned ICU admission and cardiac arrest rates. While studies in the United Kingdom and the Netherlands reported improved survival ^{4,5} and decreased cardiac arrest rates ⁴, an Australian study could not demonstrate improvement of a composite endpoint including mortality, unplanned ICU admission and cardiac arrests. ³

Crude mortality may not be the optimal endpoint to study effects of an RRT on survival. Patients with untreatable diseases may be admitted to a hospital for palliative end-of-life care. Clearly, RRTs are not set up to prevent death in those patients. For this reason, unexpected death has been proposed as a more suitable endpoint for studying the effects of RRTs on survival. ³ Death was considered 'expected' if a patient had limitations of medical treatment (LOMT) orders present at time of death. This, however, may not be a correct definition for expected death. First, some patients may prefer not to undergo life-sustaining treatments in case of cardiac arrest, but this does not mean that death is imminent or that these patients don't want optimal treatment. Furthermore, treatment limitation orders are sometimes instituted shortly before death when the clinical condition has deteriorated progressively to a point that survival is no longer considered possible. Clearly, RRTs could have been beneficial in these patients if called in an earlier phase when the clinical condition was not yet hopeless.

Aim of our study was to explore the association between treatment-limitation orders and hospital death in a multicenter study on RRTs in the Netherlands. First, what is the effect of an RRT on mortality if 'all cause hospital mortality' was replaced by 'death without LOMT-order'? Second, what proportion of patients dying on a general hospital ward is given a LOMT-order, how do these LOMT-orders change over time during hospitalization and are LOMT-policies influenced by the introduction of an RRT.

Methods

Design, setting, participants

This study is a part of the Cost and Outcomes analysis of Medical Emergency Teams (COMET) multi-center study. The COMET study was designed as a prospective pragmatic before-after trial enabling the analysis of clinical outcomes after sequential introduction of the Rapid Response System components. Twelve Dutch hospitals participated in this study. Four study wards, two surgical and two medical wards were included in each hospital, the so called COMET-wards. Included patients were 18 years or above. The full design of this study has been described previously^{4,6} and is shown in Figure 1.

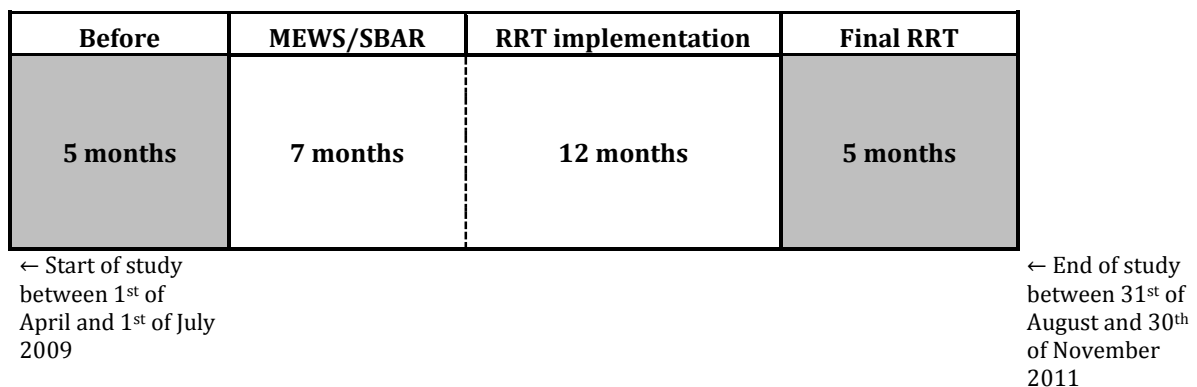


Figure 1. Design of the COMET study.

Following the baseline period of 5 months, the Modified Early Warning Score (MEWS)/Situation-Background-Assessment-Recommendation (SBAR) was implemented for 7 months and subsequently followed up by 17 months in which the rapid response team (RRT) was available. Effects of the RRT on outcomes were measured during the last 5 months and compared with the 5-month baseline period. During the entire length of the study, data were collected on all the endpoints. For further clarification, hospitals were able to start with the study in a 3-month time period. The total study took 30 months, in which each hospital participated for 27 months.

The study consisted of a before period followed by two study phases. The before period comprised of five months in which baseline characteristics were collected. After that a two-steps implementation of the RRT was performed. The first phase lasted seven months in which the Modified Early Warning Score (MEWS) and the Situation-Background-Assessment-Recommendation (SBAR) communication tool were implemented. In the second phase, which consisted of 17 months, the Rapid Response Team (RRT) was introduced. This phase was divided into the RRT implementation phase and the final RRT phase. The before period and the final RRT phase were used to compare the effects on outcome of patients. To exclude seasonal effects on the outcome, the before period and the final RRT phase in each hospital covered the same calendar months.

Definitions

Unexpected death was defined as all deaths without a pre-existing limitation of medical treatment (LOMT) order.^{3,7} Definitions of the limitations of medical treatment (LOMT) in this study were: *Code A* for 'full active care', *Code C* "do not perform cardiopulmonary resuscitation" and/or "do not admit to ICU"; *Code D* "only palliative care". Code B was used in the past, but was no longer used in any of the participating hospitals. In this study, if no LOMT was recorded in the charts, this was considered equivalent to code A "for full active care".

Ethical consideration

The medical ethics committee of the Academic Medical Center in Amsterdam waived the need for formal evaluation of the study due to the observational nature of the study. Consequently, the need for informed consent was not applicable.

Intervention

Incidences of all death were collected during the study period using a clinical report form. All deaths included the patients who were admitted on the COMET ward and transferred at a certain point to a non-COMET ward and died. Clinical information systems in the hospitals were used to identify death during this study. We collected the following data: basic patient demographics (age, gender), admission characteristics (date of admission, transfer date to COMET ward, COMET ward specialty, length of hospital stay, date and time of death), and limitation of medical treatment (date of recorded LOMT). After implementation of the RRT, members of the RRT collected the following data during consultation: who activated the RRT?, the indication for RRT call, direct outcome after RRT and treatment code before and after consultation.

Statistical analysis

Data analysis was performed using SPSS version 20.0 (Armonk, New York, USA). Generalized linear mixed modeling (GLMM) was applied to assess differences in outcomes per 1,000 admissions between the before and final RRT periods while correcting for potential confounding following the before-after study design. In the GLMM, a binominal distribution was assumed for death. Potential confounders were included as fixed or random variables. Hospitals were modeled as a random variable. Age of patients was modeled as a random component, whereas patients' sex and admission type (planned vs unplanned/emergency) were modeled as fixed variables. The uncorrected odds ratios (ORs) and ORs after correction for confounding are reported along with their CIs and corresponding *p* values. Descriptive analyses are presented as raw numbers and percentages. Continuous data were presented as

medians with inter quartile range (IQR) due to non-normally distributed data. To compare groups the non-parametric Mann-Whitney *U*-test was used for non-normally distributed continuous variables. Categorical variables were compared between groups by χ^2 tests. The level of significance was set at $p < 0.05$.

Results

In total 166,569 patients were included in the COMET-study, of whom 2,345 patients died on a medical ward and 1,063 patients on a surgical ward. Of the patients who died, surgical patients were older, median 81.4 years [IQR 73.6 to 87.0] in comparison to medical patients, median 78.4 years [68.3 to 85.6]. The median hospital length of stay (LOS) was 7 days (IQR 3 to 16 days) for surgical patients compared to 6 days (3 to 13 days) for medical patients. In 13% of patients who died and for whom an RRT was called, a LOMT was instituted or changed after consultation of the RRT. Baseline characteristics of patients are presented in Table 1.

Table 1. Demographics

| | | Medical | Surgical |
|--|--------------------|------------------|------------------|
| Deaths | | 2345 | 1063 |
| <i>Implementation phases of the Rapid Response System, n (%)</i> | Before | 387 (17) | 189 (18) |
| | MEWS | 643 (27) | 267 (25) |
| | RRT implementation | 940 (40) | 460 (43) |
| | Final RRT | 375 (16) | 147 (14) |
| Gender, male, n (%) | | 1261 (54) | 1084 (54) |
| Age (median, IQR) | | 78.4 (68.3-85.6) | 81.4 (73.6-87.0) |
| Death on Intensive Care Unit, n (%) | | 48 (2) | 43 (4) |
| Time of death, n (%) | 00:00 - 05:59 | 701 (30) | 302 (28) |
| | 06:00 - 11:59 | 555 (24) | 255 (24) |
| | 12:00 - 17:59 | 530 (23) | 245 (23) |
| | 18:00 - 23:59 | 508 (22) | 241 (23) |
| | Unknown | 51 (2) | 20 (2) |
| Hospital Length Of Stay (median, IQR) | | 6 (3-13) | 7 (3-16) |
| Number of RRT consultation before death | | 56 (45) | 68 (55) |
| | 0-24 hours | 45 (80) | 62 (92) |
| | 24-48 hours | 3 (5) | 5 (7) |
| | > 48 hours | 8 (14) | 1 (1) |
| Initiation of LOMT order by RRT | | 7 (13) | 9 (13) |

The odds-ratio's for death before hospital discharge for patients admitted during the last 5 months of the RRT phase (n=27820) were compared with the baseline period before implementing the RRT (n=26659). The originally reported unadjusted OR for all-

Table 2. Comparison of effect of RRT on all-cause in-hospital mortality vs. death without LOMT in hospitalized patients

| | Uncorrected OR | 95% CI of uncorrected OR | Corrected OR | 95% CI of corrected OR | p value corrected OR |
|--|-------------------|-----------------------------|-----------------|---------------------------|-------------------------|
| Death, n/1,000 (95%CI) | 0.865 | 0.768-0.975 | 0.802 | 0.644-1.0 | 0.05 |
| Death without LOMT, n/1,000 (95%CI) | 0.557 | 0.397-0.782 | 0.549 | 0.385-0.784 | 0.001 |

Odds ratio (OR) represent differences between final RRT phase versus the before phase. Corrected ORs are adjusted for sex, age, hospital and emergency of admission. Number of admissions in before period = 26,659; number of admissions in rapid response team period = 27,820.

cause mortality in the final RRT period compared to the before period was 0.865 (95% CI, 0.77–0.97).⁴ In the same cohort of patients, the unadjusted OR for death without LOMT ('unexpected death') was 0.557 (95% CI, 0.40-0.78). Likewise, the ORs after adjustment for age, gender, individual hospital and urgent vs. planned admission were 0.802 (95% CI, 0.64-1.0) in the original analysis using all-cause mortality and 0.549 (95% CI, 0.38-0.78) when choosing death without LOMT as endpoint (Table 2).

Table 3. Treatment limitations (LOMT status) at different time points in patients who all died during hospital admission

| <u>All deaths</u> | | Medical | | Surgical | |
|--|--------------|-----------|------------|----------|------------|
| | | n (%) | Days* | n (%) | Days* |
| | All | 2345 | 2 (1 - 5) | 1063 | 1 (1-5) |
| LOMT at time of admission | A | 736 (31) | | 459 (43) | |
| | C | 1278 (55) | | 464 (44) | |
| | D | 331 (14) | | 140 (13) | |
| LOMT at time of death | A | 280 (12) | 5 (1 - 10) | 218 (21) | 4 (1 - 11) |
| | C | 790 (34) | 3 (1 - 8) | 352 (33) | 3 (1 - 8) |
| | D | 1275 (54) | 1 (0 - 2) | 493 (46) | 1 (0 - 2) |
| Change in DNR status between admission and death | A-A | 279 (12) | | 217 (20) | |
| | A-C | 137 (6) | 3 (1 - 8) | 79 (7) | 3 (0 - 7) |
| | A-D | 320 (14) | 1 (0 - 2) | 163 (15) | 1 (0 - 2) |
| | C-C | 649 (28) | | 273 (26) | |
| | C-D | 629 (27) | 1 (0 - 2) | 190 (18) | 1 (0 - 2) |
| | C-A | 0 (0) | NA | 1 (0) | n=1 |
| | D-D | 326 (14) | | 140 (13) | |
| | D-C | 4 (0) | 5 (2 - 30) | 0 (0) | NA |
| | D-A | 1 (0) | n=1 | 0 (0) | NA |
| Length of Hospital stay | 0 - 3 days | 762 (32) | 1 (0 - 2) | 324 (30) | 1 (0 - 2) |
| | 4 - 7 days | 541 (23) | 2 (1 - 5) | 228 (21) | 3 (1 - 5) |
| | 8 - 14 days | 517 (22) | 3 (1 - 9) | 217 (20) | 2 (1 - 9) |
| | 15 - 21 days | 219 (9) | 3 (1 - 12) | 101 (10) | 2 (1 - 15) |
| | >21 days | 306 (13) | 3 (1 - 20) | 193 (18) | 3 (1 - 26) |

*Days: delta time between last code change and time of death. Data presented in median and IQR.

Table 3 shows the treatment limitations at different time points in patients who died during hospital admission. In both medical and surgical patients, most of patients who subsequently died already had a LOMT at hospital admission. The median time between last LOMT order and death was three days in patients who had a Code C and one day in patients with code D. A short time between LOMT order and death was also found in patients who had a prolonged hospital-length of stay. Unexpected death was defined as death without a pre-existing LOMT order. In 12% of medical and in 20% of surgical patients no LOMT was present at time of death.

Table 4. Effects of implementation of Rapid Response System on LOMT status

| | | Before N=576 | Final RRT N=522 | <i>p-value*</i> |
|---|------------|------------------------|---------------------------|-----------------|
| LOMT at time of admission, n (%) | A | 221 (38) | 187 (36) | 0.31 |
| | C | 271 (47) | 269 (52) | |
| | D | 84 (15) | 66 (13) | |
| LOMT at time of death, n (%) | A | 99 (17) | 64 (12) | 0.06 |
| | C | 170 (30) | 174 (33) | |
| | D | 307 (53) | 284 (54) | |
| Delta time (days) between last change in LOMT status and death, median, IQR [n] | | 2 (1-5) | 1 (1-4) | 0.09 |
| Stratified by hospital-length of stay, median, IQR [n] | 0-3 days | 1 (0-2) [195] | 1 (0-2) [178] | 0.74 |
| | 4-7 days | 3 (1-5) [130] | 2 (1-5) [110] | 0.27 |
| | 8-14 days | 3 (1-9) [100] | 2 (1-7) [125] | 0.09 |
| | 15-21 days | 2 (1-10) [54] | 3 (1-15) [38] | 0.55 |
| | > 21 days | 5 (1-25) [97] | 2 (1-12) [71] | 0.12 |

Medical and surgical patients are combined. * Chi-square or Mann Whitney U test if appropriate.

In Table 4 the effect of RRT implementation on treatment limitations in patients who died during hospital stay is presented. No differences were found in institution of LOMT after introduction of the Rapid Response System. The delta time between last code change and death was 2 days (median 1-5) in the before phase and 1 day (median 1-4) in the Final RRT phase, this was not significant.

Discussion

In this study we demonstrate that the effects of introducing an RRT on in hospital death is more pronounced if death without LOMT is used compared to the original COMET analysis using all-cause mortality as endpoint. ⁴

The underlying hypothesis why 'death without LOMT' might be a better endpoint than all deaths, is that patients with LOMT are expected to die and for these patients an RRT call will not be initiated. Thus, it has been argued that the true effects of an RRT are underestimated if all patients are analyzed as was done in the original analyses of the COMET-study. ⁶ In one earlier controlled trial on the effects of an RRT in Australian hospitals, 'unexpected death', i.e. death while having no LOMT, was included in the composite endpoint consisting of unplanned ICU admission, or cardiac arrest, or unexpected death. However, the negative findings in this study may be related to factors such as insufficient statistical power and contamination of the control group. ^{3,8,9}

In this cohort of patients all dying before hospital discharge, 85% had some LOMT at the end of life. At hospital admission LOMT was present in 65% of patients dying in the hospital. We are not the first to show that most hospitalized patients who eventually die have limitations of medical treatment. In a study from Canada and the USA, in a cohort of patients with community-acquired pneumonia who required admission to a hospital, 51 from 65 patients (78%) who died had do-not-resuscitate orders instituted before death. ¹⁰ In 1995 in the United States, among a representative sample of Medicare patients hospitalized with congestive heart failure, acute myocardial infarction, pneumonia, cerebrovascular accident, or hip fracture, 49% of patients who died had LOMT orders. ¹¹ In a study in Saudi Arabia, after implementing an RRT, of 3191 patients dying in the hospital, 2793 (88%) died on the general ward with LOMT orders instituted. ¹²

Patients with a LOMT are believed not to benefit from an RRT because death is 'expected'. This, however, is not necessarily true. First, there may be many reasons for limiting medical treatments. Patients may prefer not to undergo some invasive procedures, such as mechanical ventilation, or physicians may consider treatments inappropriate due to a patient's poor prognosis. In both circumstances, patients may still be successfully treated and discharged from the hospital. Moreover, in our study, we found that 84% of patients who died had some limitation of medical treatments at the time of death. However, in most of these patients that LOMT-order was instituted in the last days before death, sometimes even less than one day earlier. Thus, having treatment limitations at the time of death cannot be interpreted as death being expected during the entire hospital stay. It appears that LOMT instituted shortly before death is more a reflection of deteriorating condition of the patient during hospital stay, eventually leading to the clinical conclusion that death is inevitable and that some treatments be

better withheld. It does not imply that RRT could not have improved outcome in the earlier period in these patients.

RRTs have been installed in hospitals with the aim for timely identification and treatment of patients deteriorating on general wards preventing morbid outcomes. An additional role for the rapid response team is to be involved in decisions and discussions with the physicians on the ward about palliative care, and LOMT if patients have no real prospects of surviving with reasonable quality of life.¹³ In an earlier study, an RRT was associated with improved documentation of comfort care orders, pain scores, patient distress, and chaplain visits.¹⁴ In a recent review, Jones and coworkers mentioned several reasons why RRTs may need to be involved in end of life decisions. Firstly, the usual care team may not have recognized or may not accept that 'the patient is dying'. Secondly, the usual team may not be comfortable or skilled in having end of life care discussions with patients or families. Lastly, the usual team may have difficulty in accepting a LOMT despite the presence of advanced comorbidities and an irreversible new illness due to personal or religious reasons.¹⁵ Also, RRTs may confront situations in which LOMT orders are postponed awaiting discussion with team or family members.¹⁶

In our study 13 % of RRT-calls were followed by the institution of LOMT orders. This is less than found by others. Smith and coworkers reported that 28% of RRT activations were associated with new LOMT orders.¹⁷ Casamento and coworkers observed a LOMT order in 32% of RRT calls.¹⁸ In a study by Jones et al 31% of RRT activations were associated with LOMT.¹⁹ A possible explanation for the low rate of LOMT orders after RRT calls in our study is the already high prevalence of LOMT orders at hospital admission. It appears that most patients at the end of life already had a LOMT before the RRT was called. Accordingly, in our study, we found no differences in the institution of LOMT before and after implementation of an RRT, although the relatively low number of patients cannot exclude a small effect in favor of the RRT period.

In this study there are some limitations. First, during the review of the medical charts of the patients who died, we assumed that if there was no LOMT recorded in the patient charts medical treatments were not limited. However, it is possible that implicit limitations of medical treatment were present in some of these cases. Therefore, we cannot exclude some underestimation of the LOMT during this study and consequently an overestimation of the number of patients dying unexpectedly. Second, to estimate the effect of replacing "all cause hospital mortality" by "death without LOMT" when studying the effects of an RRT, patients dying with an LOMT were considered as not having reached the endpoint just as patients surviving up to hospital discharge. Preferentially, patients with LOMT orders should be excluded from the study population. However, as information about LOMT was only present for patients who died, this was not possible. When excluding only patients who died with a LOMT, we found ORs that were almost

identical to those presented here. As relatively few patients surviving up to hospital discharge have LOMT orders, we believe that it is unlikely that these patients have major influence on our findings. Lastly, we have a relatively low percentage of RRT calls recorded during this study. This may be due to administrative concerns. It was not always clear to the physician of the ward when to call the RRT or to call the ICU for rapid consultation. Thus, the real number of RRT calls may have been higher than documented.

Conclusion

We found higher improvement of survival up to hospital discharge when choosing death without LOMT, rather than all deaths as endpoint in a study on the effect of implementation of RRTs in Dutch hospitals. Implementation of Rapid Response Systems was not associated with significant change in LOMT. Most patients who died during hospitalization had LOMT orders instituted, often shortly before death. The presence of LOMT does not necessarily mean that death is expected and that these patients could not benefit from Rapid Response Teams.

Conflict of interest

The authors declare that they have no conflict of interest.

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