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Improving time-sensitive processes in the intensive care unit: the example of 'door-to-needle time' in acute myocardial infarction

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Abstract

Objective. To assess and reduce delays in coronary thrombolysis in patients with acute myocardial infarction.

Design. Prospective, descriptive study using statistical process control.

Setting. Interdisciplinary intensive care unit of a 300-bed community hospital.

Subjects. Thirty-seven consecutive patients with acute myocardial infarction who were receiving thrombolytic therapy.

Interventions. To perform an interdisciplinary formal process analysis aimed at detecting delay-causing factors, review of existing house rules, generation and implementation of new practice guidelines.

Main outcome measures. Comparison of 'door-to-needle times' of patients admitted before, during and after formal process analysis and implementation of new guidelines.

Results. Mean 'door-to-needle time' fell significantly from 57 minutes ($\pm$25.4) in 16 patients studied before, to 32 minutes ($\pm$9.0) in 16 patients studied after the formal process analysis and the implementation of new guidelines ($P< 0.002$). An even more pronounced but transient decrease to 24 minutes ($\pm$3.8) was observed in five patients studied during the phase of formal process analysis ($P< 0.004$). Delay-causing factors were identified in the areas 'communication', 'people' and 'methods/rules/guidelines'. Equipment failure was never responsible for delays.

Conclusions. Formal process analysis, followed by implementation of revised guidelines resulted in a significant reduction of 'door-to-needle time'. An initial dramatic but transient reduction of 'door-to-needle time' was considered observational and must not be mistaken as the definite new level of performance. We conclude that formal process analysis techniques are suited to improve processes in the intensive care unit.

Keywords: door-to-needle time, formal process analysis, myocardial infarction, quality assessment in health care, thrombolytic therapy

The main driving forces of today's medicine are the continuing scientific progress and the increasingly rigid cost constraints. Quality of care has emerged as a third key element. In the quality debate, attention is shifting increasingly towards process quality. Many processes in the hospital, such as the care of patients with acute myocardial infarction (AMI) receiving thrombolytic therapy, are highly time-sensitive. Prognosis of patients with AMI is significantly improved by early thrombolysis [1,2]. Benefit is reported up to 12 hours after onset of symptoms [3,4], the major effect being observed within the first few hours [5]. Apart from precious time losses in the pre-hospital phase [6–10], delays also occur after hospital admission [8,11–13]. The reduction of the time span between hospital admission and the initiation of thrombolytic therapy – commonly known as the 'door-to-needle time' (DTNT) – is thus a worthwhile target for improvement. A DTNT of 30 minutes is a generally accepted standard [14–16]. When viewed as a marker of efficiency of the team involved, DTNT can serve as an indicator of process quality.

Despite the many time-sensitive tasks in the hospital

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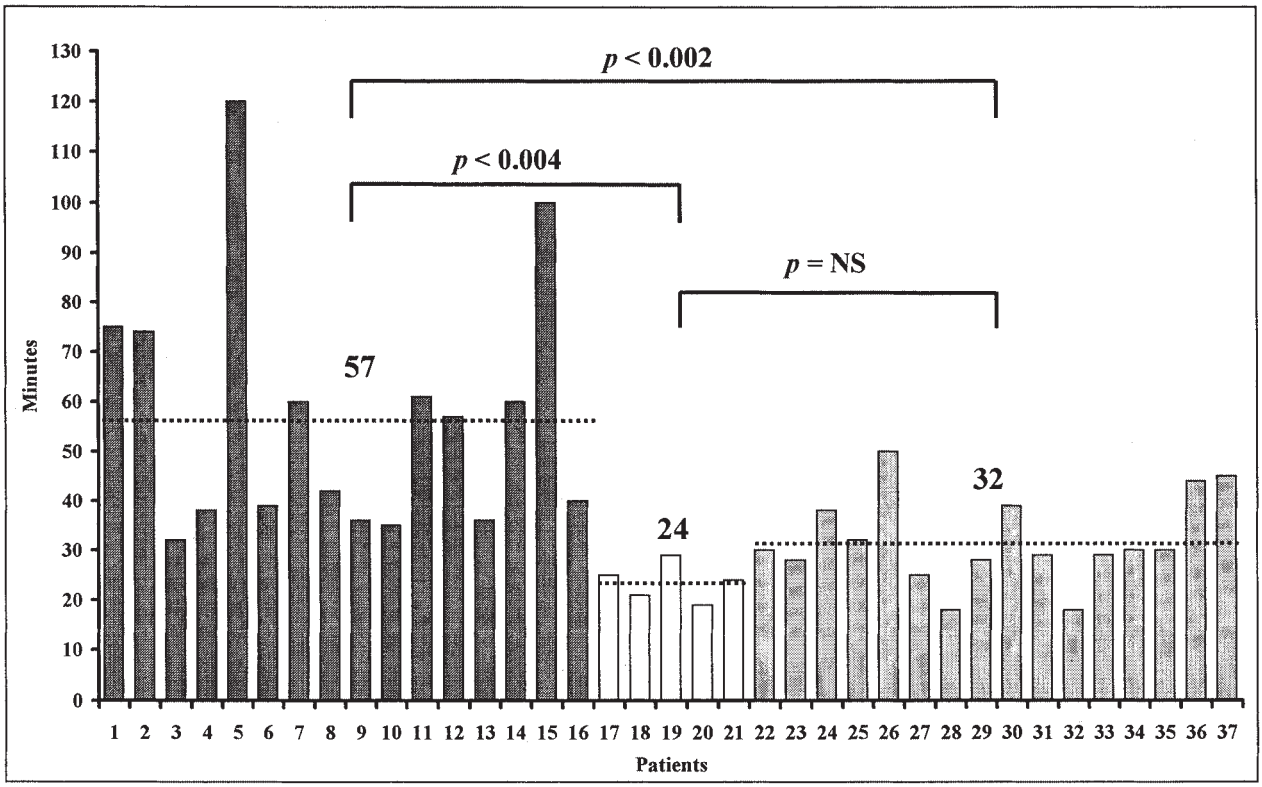

Figure 1 'Door-to-needle times' of 37 consecutive patients divided into three groups. First group (patients 1–16): control period; second group (patients 17–21): period of formal process analysis; third group (patients 22–37): period after implementation of new practice guidelines. Horizontal dotted lines denote mean 'door-to-needle time' of each group.

and the manifold opportunities for improvement connected herewith, clinicians are mostly unfamiliar with the practical use of quality management tools. We conducted a clinical study to assess and improve the process of thrombolytic therapy by using formal process analysis techniques. Our work tries to exemplify the successful use of formal quality control measures in the hospital.

Methods

We undertook a prospective, descriptive quality control study over 16 months from January 1996 to April 1997; we recorded DTNT (defined as the interval between hospital arrival and application of the thrombolytic bolus) of all consecutive patients with AMI receiving i.v.-thrombolysis at our 10-bed intensive care unit (ICU). Our institution, a 300-bed community hospital, serves a mountain area with 160 000 inhabitants.

All patients fulfilling the following lysis criteria were included in the study:

- ST-segment elevations > 1 mm in two or more standard limb leads of the electrocardiogram (ECG);
- or > 2 mm in two or more contiguous precordial leads;
- or a newly appeared left bundle branch block on ECG;
- and onset of typical, persisting chest pain less than 6 hours before admission.

Recombinant tissue plasminogen activator and streptokinase were the thrombolytic agents used. The drugs were administered exclusively in the ICU. All patients admitted to the hospital with proven or suspected AMI were transferred directly to the ICU. Patients with non-specific chest pain were initially evaluated in the emergency department (ED). Those, who were found to have AMI and fulfilled the above criteria were consecutively transferred to the ICU for thrombolysis. The unit is adjacent to the ED; therefore transfer related delays were minimal.

We studied three phases. First, we only documented the DTNT of 16 consecutive patients and compared them with the set standard of 30 minutes. In a second phase we conducted a formal process analysis to detect factors causing delays in the in-hospital management. In an interdisciplinary session among involved physicians and nurses of all functional levels the patient's way from hospital arrival to the application of the thrombolytic bolus was analysed step by step. Every participant named causes for delays he had personally experienced. All identified factors were depicted in a 'fishbone diagram' [17]. This was followed by rewriting our previous guidelines, adding an additional section with explicit instructions about optimal timing of these cases. In a third phase implementation of the new guidelines occurred by

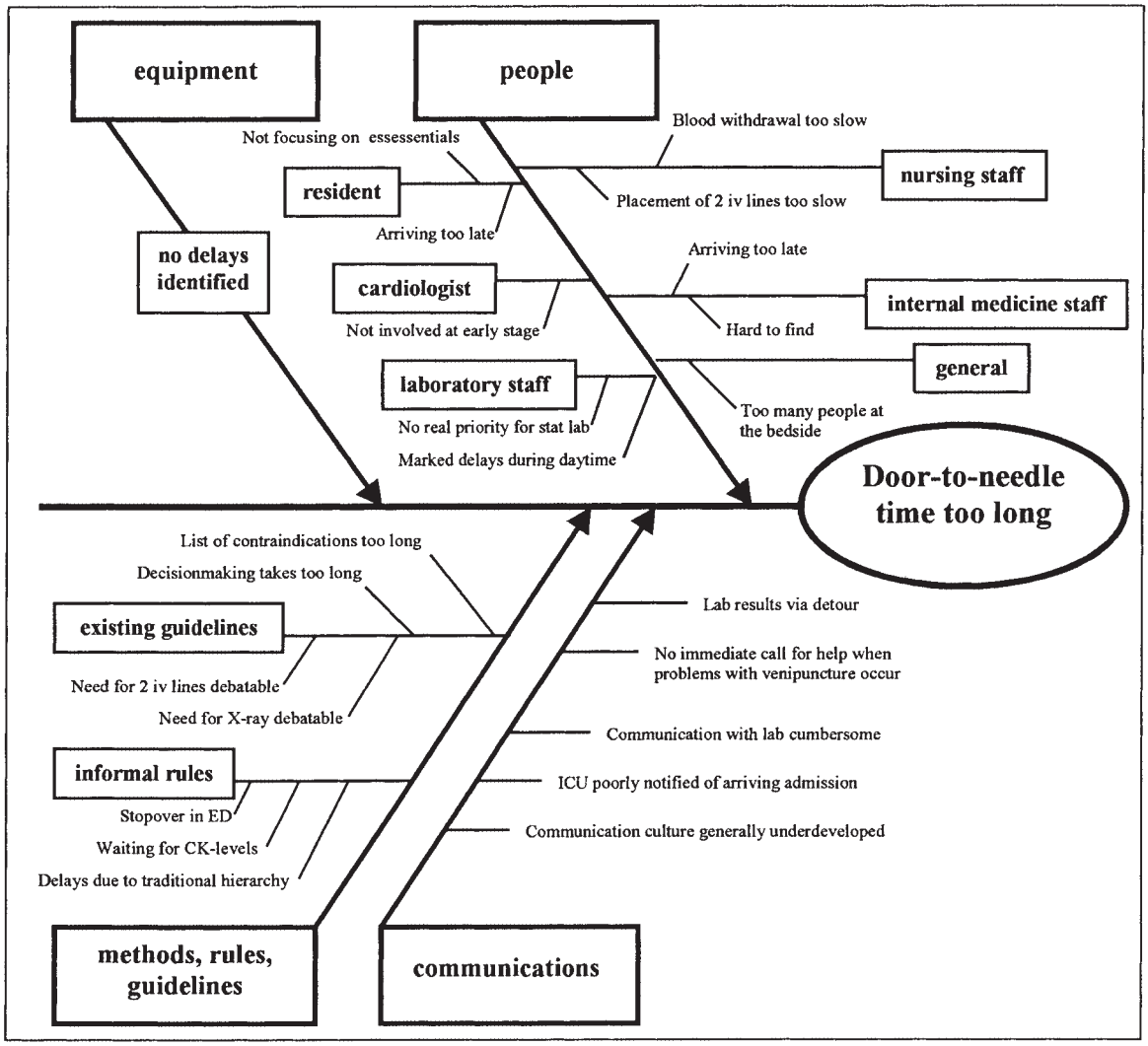

Figure 2 'Fishbone diagram' depicting the factors identified as causing delays in the in-hospital treatment of patients with AMI receiving thrombolytic therapy.

formally teaching unit staff about the modified written rules, which were from now on readily available. Target DTNT was explicitly set at 30 minutes or less. By comparing the new DTNTs with those recorded during the preceding phases we assessed the impact of the new guidelines and their implementation.

Data were analysed with non-parametric ANOVA and adequate *post hoc* methods. In addition, methods of statistical process control [18] were used for longitudinal chronological analysis. Analysis was performed by using the software Statistica 5.1 (StatSoft Inc, Tulsa, OK, USA) and Memory Jogger Version 3.21 Fa (Goal/QPC, Methuen, MA, USA).

The hospital ethics committee waived informed consent for this type of quality control study.

Results

During the study period a total of 116 patients with AMI were admitted. Thirty-seven (32%) qualified for and received thrombolytic therapy. Each diagnosis of AMI was confirmed by elevated CK levels later in the hospital course. The mean DTNT for the first 16 patients (before process analysis) was 57 minutes ($\pm$25.4) (Figure 1).

The 'fishbone-diagram' compiles the findings of our process analysis (Figure 2). Factors causing delays were identified in the fields 'communications', 'people' and 'methods/rules/guidelines'. One of the most striking factors involved was an apparent lack of communication. Aside from late or even absent notification about patients to be admitted to the ICU and interaction deficits between different in-hospital services (e.g. ICU laboratory) we perceived a generally underdeveloped communication culture (e.g. nurses not calling for immediate support when venipuncture failed). Often, too many people were present at the bedside, thereby slowing down the coordination of ongoing procedures. Internal medicine staff were notoriously not arriving in time. Often residents in charge were wasting time by not focusing on essentials. Delays also occurred when the involvement of a cardiologist was necessary. Delays in processing urgent laboratory analyses

were seen, especially during the daytime. An unwritten law that had demanded a chest X-ray before the administration of thrombolysis was discussed and abandoned. Similarly the practice of awaiting certain lab results was given up, specifically the creative kinase (CK) levels. Furthermore the list of contraindications for thrombolysis was considered too long and too restrictive.

Areas not found to cause delays were equipment, technology and availability of nursing staff.

Our new guidelines including the list of indications and contraindications for thrombolysis – the result of our final interdisciplinary discussion – are shown in Tables 1 and 2.

Mean DTNT for five patients studied during the ongoing analysis but before implementation of new guidelines was significantly shorter: 24 ± 3.8 minutes ($P < 0.004$). Having finished the process analysis we implemented the new written guidelines. Mean DTNT for the next 16 patients remained significantly lower than in the pre-analysis period (32 ± 9.0 minutes; $P < 0.002$). Ten (62.5%) patients of the final group were treated within the new set DTNT standard of 30 minutes. In contrast none of the first-phase patients but all five patients of the second-phase group had received treatment within the targeted 30 minutes.

Analysis by statistical quality control charts (Figure 3) showed that the process of in-hospital patient management in the first 16 patients, apart from being too slow, had also drifted outside of statistical control limits; this is reflected by an unnatural variability of DTNT in this group. After initiating the formal process analysis variability of DTNT was clearly reduced, indicating the presence of a statistically controlled process.

During the study period no major complications of thrombolysis (e.g. intracranial haemorrhage) occurred.

Discussion

Smooth processes will become key issues in the quality of health care debate. Among other factors, good timing will be a main target for improvement. To analyse specific processes it is necessary to quantify them. Overall process quality cannot be measured directly; we must resort to the use of quality indicators as easy to assess surrogate markers reflecting overall quality. DTNT, in our example, is a prototype of such an indicator, because it represents the result of a very complex set of processes but nevertheless is simple to measure.

In our ICU, as in other institutions [7,11,13], DTNT was usually too long. In order to improve, we applied a quality control tool, well known to the industrial world but not to clinicians. This step-by-step analysis of the in-hospital course of patients with AMI receiving thrombolysis was based on the experience of different staff members (physicians and nurses). The results therefore represent the collective expert knowledge about the investigated process. The 'fishbone-diagram', a classical quality management tool [17] allowed for a clearly arranged presentation of the entire complex process. The main delay-causing factors could be detected easily in the fields communication, co-ordination and existing guidelines.

Table 1 Indications and contraindications for thrombolysis in AMI. Adapted from [23]

Indications
Typical thoracic pain
• Time from onset of pain to thrombolysis < 6 hours
• Pain resistant to treatment with nitroglycerine
• Pain lasting more than 30 minutes
• ECG alterations
• ST-segment elevations > 1 mm in two or more standard limb leads or
• ST-segment elevations > 2 mm in two or more contiguous precordail leads or
• New left bundle branch block
Contraindications
Absolute contraindications
• Known bleeding diathesis, current use of anticoagulants in therapeutic doses (INR > 2–3)
• Active peptic ulcer
• Recent internal bleeding (within 2–4 weeks)
• Recent major trauma or surgery within 6 weeks
• Recent cerebrovascular stroke within 12 months or intracranial/intraspinal surgery within 6 months
• Previous haemorrhagic stroke at any time
• Known intracranial neoplasm
• Suspected aortic dissection, bacterial endocarditis, pericarditis
Relative contraindications
• Severe uncontrolled hypertension on presentation (blood pressure > 180/110 mm Hg)
• Recent traumatic or prolonged (> 10 minutes) cardiopulmonary resuscitation
• Proliferative haemorrhagic retinopathy (e.g. diabetic)
• Previous intramuscular injection
• Pregnancy

INR, International normalized ratio; CPR, cardiopulmonary resuscitation.

Availability of technology and staffing was not a delay-causing factor in our setting. We did not, however, attempt to measure the identified items separately. The very complexity of the process with its major and minor contributing elements did not permit any pinpointing.

Table 2 Guidelines for management of patients with typical chest pain and suspected AMI

Timing	Physicians' tasks	Nurses' tasks
10 minutes	Patient's history	Record admission-time
	Short examination	Obtain 12-lead ECG
	Interpretation of ECG	Aspirin p.o. or i.v.
		Placement of first i.v. line
		Draw blood for serum cardiac markers, haematology, chemistry and lipid profile
10 minutes	Rule out contraindications	Placement of second i.v. line
10 minutes	Staff physician decides about thrombolysis	Prepare and administer thrombolytics
		Record 'door-to-needle time'

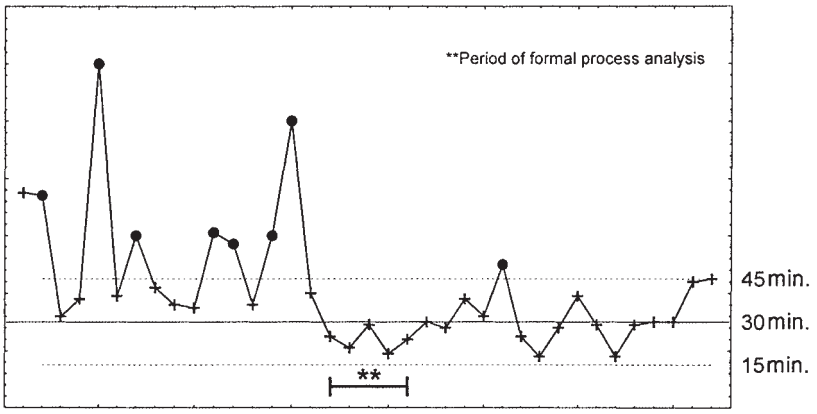

Figure 3 Process control chart of 'door-to-needle times' of 37 consecutive patients. Centre line denotes target 'door-to-needle time' of 30 minutes with a desired 3 SD of 5 minutes (dotted lines). ●, 'Door-to-needle time' out of statistical control; +, 'door-to-needle time' within statistical control.

The exercise was impressively cost-effective. Except for some extra time and effort spent by the ICU team our study consumed no additional resources. We can thus prove that meaningful and significant improvements in ICU care can indeed be achieved with minimal or no additional investment.

Potential for improvement was found mainly on the operational side. This knowledge was turned into management decisions and resulted in the generation and implementation of new guidelines (Tables 1 and 2). Clinical practice guidelines are a helpful tool in a physician's daily practice. Checklists with indications and contraindications for thrombolysis may shorten the decision making in patients with acute chest pain and suspected AMI. To be of value, guidelines must be clearly formulated and readily available. They have to be reviewed and adapted regularly as shown in our example.

In view of the self-evident results the use of statistics could be debated. We used statistical process control tools, expecting to learn more about monitoring an ongoing process. *Post hoc* analysis by ANOVA showed that mean DTNT after, and even during, our effort was significantly lower than before the analysis. Any intervention will change a defined process and even merely measuring DTNTs in our unit represents an intervention. Thus, our process was already influenced at the beginning. Because methods of classical statistics require independence of variables, the evaluation of our data with a *post hoc* analysis was considered insufficient. Furthermore it is appropriate to analyse continuous processes by using methods of statistical process control. So-called control charts [19] allow insight in to the investigated process and permit monitoring of consecutive events. In contrast, classical statistical methods control charts provide additional longitudinal information [18].

Evaluation of our data by using control charts showed that in the beginning there was considerable variability of DTNT signifying that the process of in-hospital management of patients with AMI was out of statistical control. Shortly after the initiation of formal process analysis DTNTs were reduced significantly and remained within a narrow range, now showing a stable and statistically controlled pattern. Thus, process quality was significantly improved by our efforts.

The control charts revealed another interesting phenomenon, namely the changes observed in the beginning of

formal process analysis. We consider this initial improvement of performance to be an observational bias, a consequence of the increased general awareness of all people involved in the analysis. It is important to note that this observational effect was only temporary and did not represent the definite new level of performance. Such transient improvements must not be mistaken for the real result.

One might also argue that most of the delay in treatment of patients with AMI happens before hospital admission, especially by patient-related variables [9,10] and that assessing insignificant in-hospital delays has little meaning. However, attempts to reduce pre-hospital delays by community education programmes seem to be disappointingly ineffective [20,21]. Even if programmes intending to defer diagnostic procedures and therapy to the pre-hospital period showed benefit in certain studies [11,22], they are not feasible everywhere. As long as hospitals lack influence on the pre-hospital phase, they should at least keep the in-hospital course of these patients as short as possible.

In our study, a simple and straightforward process analysis technique significantly and persistently improved the quality of a time-sensitive process: the in-hospital treatment of patients with AMI receiving thrombolysis. Measuring lower and less variable DTNTs substantiated this result. We conclude that methods of formal process analysis, together with proper implementation of the findings, are well suited to improve complex procedures in the hospital. Not only the result of the analysis but also the analytic process by itself will influence the process in question and therefore observational effects do occur. Observational effects are transient and must not be mistaken for the definite result. We recommend the use of process management techniques as quality control tools for time-sensitive tasks in the ICU.

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