

Evaluation of an Implementation

Specialized Clinical Care Pathway for Non-ST-Elevation Myocardial Infarction

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Abstract

Background: The mortality reduction associated with immediate coronary reperfusion in patients with ST-elevation myocardial infarction is extensively documented. The gap between available knowledge and care delivery is primarily due to lacking coordination between the patient contact points. We postulate that the same applies to non-ST-elevation myocardial infarction (NSTEMI) and that a more consistent care delivery could improve outcomes.

Methods: We conducted a single-center retrospective observational study in NSTEMI patients who presented to the emergency department (ED) at our institution between October 2017 and September 2019, covering the last twelve months before implementing our new NSTEMI care pathway (pre-intervention) and the first twelve months thereafter (post-intervention). Primary endpoint was the door-to-cardiology time, i.e., time between ED admission and admission to the cardiology department. Co-primary endpoint was the door-to-needle time, i.e., time between ED admission and initiation of coronary angiography. Secondary endpoints included total hospital stay (time between ED admission and discharge), in-hospital mortality (%), and retrospective misdiagnoses with the coronary angiography showing no or non-relevant coronary lesions (%).

Results: 271 consecutive NSTEMI patients were treated during the study period. 112 (41.3%) in the year before and 159 (58.7%) in the year after the NSTEMI care pathway implementation. NSTEMI care pathway led to a significant reduction in median door-to-cardiology time from twelve hours (interquartile range [IQR] 6–24 hours) pre-intervention to six hours (IQR 4–9 hours) post-intervention ($p < 0.0001$); a significant reduction in median length of hospital stay from five days (IQR 3–10 days) pre-intervention to three days (IQR 2–7 days) post-intervention ($p < 0.0001$); and a significant reduction of misdiagnoses from 16.96% pre-intervention to 8.81% post-intervention ($p = 0.0341$). There was no significant change in median door-to-needle time (28 hours pre-intervention to 24 hours post-intervention, $p = 0.0736$) nor in in-hospital mortality (0.89% pre-intervention versus 2.52% post-intervention, $p = 0.6519$).

Conclusions: The NSTEMI care pathway significantly reduced door-to-cardiology time, length of hospital stay and number of misdiagnoses. It proved feasible in routine clinical practice and could be implemented on a larger scale.

Keywords: Acute coronary syndrome; care pathway; clinical pathway; emergency department; non-ST-elevation myocardial infarction; quality improvement

Introduction

The benefit of timely coronary reperfusion in patients with ST-elevation myocardial infarction (STEMI) is extensively supported by research [1]. The persistent gap between available knowledge and delivery of care is primarily due to the lack of coordination between the various patient contact points and the time lag between the onset of symptoms and the first contact with medi-

cal aid (including inter- and intra-hospital patient transfers and the involvement of multiple specialized teams) [2]. We postulate that the same issue applies to non-ST-elevation myocardial infarction (NSTEMI) patients and that a more consistent delivery of evidence-based NSTEMI care would result in an optimized timing of care delivery, as has already been shown in STEMI patients [3, 4].

An early invasive strategy as defined by the European Society of Cardiology is a coronary angiography performed within the first 24 hours of hospital admission [5]. To comply with the guidelines, our center needed to match optimal care with optimal care delivery, the central question being how care is delivered. Vanhaecht et al. demonstrated that care pathways methodically convert guidelines into a coordinated set of key interventions tailored to the improvement priorities and resources of an institution [6]. The implementation process plays a central role. Indeed, studies on clinical care pathways have shown ambiguous effects on professional practice, patient outcomes, length of stay and hospital costs [7], therefore, a move toward clear intervention descriptions and systematic implementation methods may strengthen care pathway research [1].

We used our own guidelines to address this question. We slightly modified the endpoints to comply with the commonly used standard outcome measures. Our primary and co-primary endpoints were the door-to-cardiology time and the door-to-needle time, respectively. Secondary endpoints included the total length of hospital stay, in-hospital mortality, and misdiagnoses.

Materials and Methods

Methods

We conducted a single-center retrospective observational study in NSTEMI patients treated at our institution between October 1, 2017 and September 30, 2019. The study period covers the last twelve months prior to the implementation of our new NSTEMI care pathway (pre-intervention) and the first twelve months after its implementation (post-intervention).

Study Population

Patients were eligible for inclusion if they presented to the emergency department (ED) of our institution, underwent a coronary angiography in our catheterization laboratory, and:

- pre-intervention: had an acute coronary syndrome (ACS) without ST-elevation, a positive troponin level and no contraindication to coronary angiography assessed by the interventional cardiologist.
- post-intervention (included in the NSTEMI clinical care pathway): ACS without ST-elevation (clinical criteria and electrocardiogram), initial (T0) high-sensitive cardiac T troponin level ≥ 52 ng/l or change of ≥ 5 ng/l in the first hour (T1), and intermediate (HEART score 4–6 [8], recurrent symptoms) or high risk stratification (HEART score 7–10).
- Patients were excluded if they presented one of the following conditions: acute cardiac heart failure; secondary ACS or elevated troponin level from another cause; contraindication to coronary angiography, hypertensive emergency/urgency, (hemodynamically unstable) pulmonary embolism, sepsis, severe renal failure, or allergy to contrast media (relative contraindication).

Patients transferred from another hospital and those already hospitalized were excluded from the clinical care pathway, even if they passed through our ED. Obviously, patients included in the STEMI care pathway were excluded as well (this criterion is not part of our institutional guidelines).

During the 24-month study period, 271 consecutive patients meeting the criteria (pre- and post-intervention) were treated at our institution (fig. 1). The patients were divided into two groups: 112 patients were treated before the implementation of the NSTEMI care pathway (control group) and 159 patients were treated via the novel NSTEMI care pathway (post-intervention group).

The post-intervention group was further divided into several subgroups for subsequent analysis. In a first step, we divided the post-intervention group into four quarters (Q1–Q4) to determine the dynamics of the intervention regarding the primary and co-primary endpoints throughout the year. In a second step, we divided the post-intervention group into a ‘week’ group (Monday 08:00 a.m. to Friday 05:59 p.m.) and a ‘weekend/holiday’ group (Friday 6:00 p.m. to Monday 7:59 a.m. + holiday eve 06:00 p.m. to next business day 07:59 a.m.). It should be noted that during the time of the study, coronary angiography for patients presenting with NSTEMI on weekends and during holidays could not be scheduled earlier

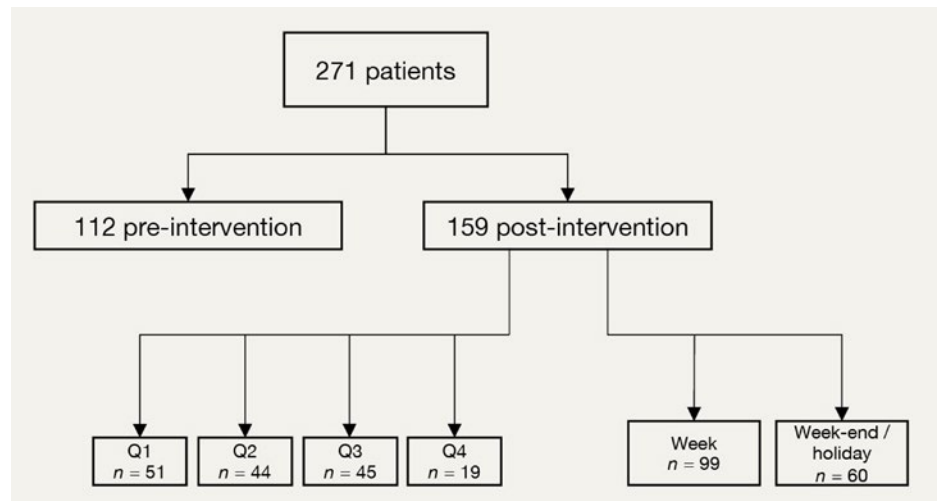


Figure 1: Flowchart with primary endpoint subgroups. Q1–4: quarter of post-intervention year; week: business days from Monday 08:00 a.m. to Friday 05:59 p.m.; weekend/holiday: Friday 6:00 p.m. to Monday 7:59 a.m.; holiday eve 06:00 p.m. to next business day 07:59 a.m.

than the next business day (usually Monday) due to a lack of qualified staff.

Study Protocol

The study took place in a large tertiary (university) hospital in Western Switzerland, which is also a regional referral center for the STEMI care pathway since 2013.

As defined in the official institutional guidelines concerning the new NSTEMI specialized clinical care pathway implemented on October 1, 2018, the diagnostic and therapeutic sequence of NSTEMI involves clinical risk assessment, biomarker assay, continuous monitoring and invasive investigations. This procedure aims to guarantee timely, high-quality care according to international guidelines, facilitate invasive examinations, reduce the length of stay and respond to institutional requirements regarding the patient flow through the ED [9].

The emergency and cardiology departments, the patient flow management desk, and potentially all departments of the hospital follow this procedure. It applies to all patients admitted to the ED with suspected NSTEMI, but not to those who are already hospitalized or are being transferred from another hospital.

The main steps of this procedure are: 1) to identify patients eligible to enter the care pathway for patients with suspected NSTEMI admitted to the ED and to receive protocol-driven evidence-based medical therapy (performed by resident or chief resident physician); 2) to ensure the availability of two beds with telemetric monitoring in the cardiology department; 3) to proceed to invasive diagnostic examinations within 24 hours (weekend: on Monday); 4) to aim for a discharge from the care pathway within 36 hours (weekend: 72 hours).

Unstable patients were taken directly to coronary angiography (as in the classic STEMI care pathway). Patients requiring surgical revascularization were referred to the cardiac surgery team.

Institutional Guidelines on Evidence-based Therapy for NSTEMI

Given as soon as possible: Aspirin 500 mg PO or IV bolus, then 100 mg PO QD.

- Ticagrelor 180 mg PO single dose, then 90 mg PO BID (if contraindicated or not available clopidogrel 600 mg PO single dose, then 75 mg PO QD).
- Fondaparinux 2.5 mg SQ QD (if contraindicated or not available: unfractionated heparin 50–70 IU/kg [maximum 5000 IU] IV bolus, then 12 IU/kg/h as a continuous infusion). Target partial thromboplastin time (PTT): 1.5–2× baseline value or PTT 50–70 sec.
- Glycoprotein IIb/IIIa inhibitors (administration has to be discussed with the interventional cardiologist)

Outcome Measures

Our primary study endpoint was the door-to-cardiology time (time between admission to the ED and admission to the cardiology department). Our co-primary endpoint was the door-to-needle time (time between registered admission to the ED and start of the coronary angiography). Secondary endpoints included total length of hospital stay (time between admission to the ED and final hospital discharge), in-hospital mortality (%) and retrospective misdiagnoses with the coronary angiography showing no or non-relevant coronary lesions (%).

In the classic STEMI care pathway, the hospital patient flow protocol is the following:

ED → catheterization laboratory → cardiology department → transfer to another department or discharge. In this scenario, the door-to-cardiology time is typically longer than the door-to-needle time.

The new NSTEMI care pathway proposed the following hospital patient flow sequence: ED → cardiology department → catheterization laboratory → cardiology department or another department (e.g., internal medicine) → discharge (fig. 2). In this scenario, the door-to-cardiology time is expected to be shorter than the door-to-needle time. This was the case in our study.

Statistical Analysis

Continuous data with an admitted normal distribution are expressed as mean ± standard deviation. Skewed data are expressed as median and interquartile range (IQR). Categorical data are expressed as percentages.

Continuous variables with a normal distribution were compared using the Student's *t* test. Skewed data were compared using the Mann-Whitney *U* test. Categorical variables were compared using the Fisher's exact test. Statistical significance was set at $p < 0.05$. Statistical analyses were performed using Prism for macOS, version 9.2.0. by GraphPad Software, San Diego (CA), USA.

Ethical Issues

Our study protocol complies with the Declaration of Helsinki regarding investigations in humans. It has been approved by Swissethics (CER-VD 2019–01767).

Results

In total, 271 consecutive NSTEMI patients were treated at our institution during the study period, 112 (41.3%) in the year before and 159 (58.7%) in the year after the implementation of the NSTEMI care pathway.

Baseline Demographics and Global Population Outcomes

The mean age of the patients was 68 ± 13 years (pre-intervention: 66 ± 13 years, post-intervention: 70 ± 13 years); 73% of patients were male (pre-intervention: 72%, post-intervention 74%). There were no significant differences in clinical characteristics between the two groups (table 1).

Over the entire two-year study period, the median door-to-cardiology time was seven hours (IQR 4–14 hours), the median door-to-needle time was 26 hours (IQR 16–49 hours), the median length of hospital stay was four days (IQR 2–8 days), the mortality rate was 1.84% and the proportion of misdiagnoses was 12.2%.

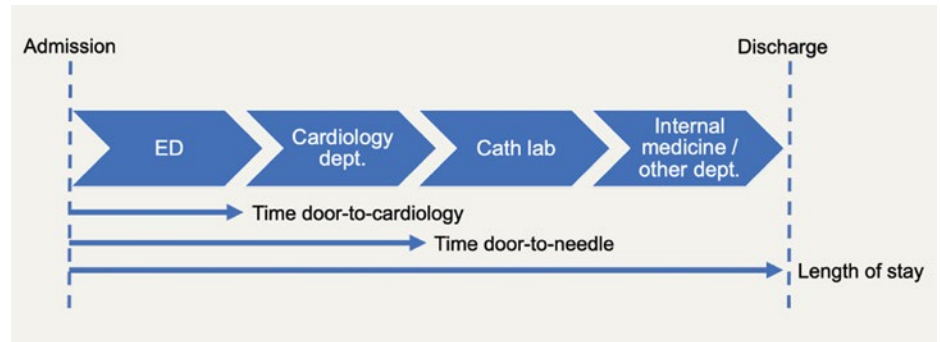


Figure 2: Synoptic view of the NSTEMI clinical care pathway.

Door-to-cardiology Time

The implementation of the NSTEMI care pathway led to a significant reduction in the median time between ED admission and transfer to the cardiology department for patients meeting the institutional NSTEMI criteria. The pre-intervention door-to-cardiology time was twelve hours (IQR 6–24 hours), while post-intervention door-to-cardiology time was reduced to six hours (IQR 4–9 hours) ($p < 0.0001$). Subgroup analysis showed a statistically significant reduction of the median door-to-cardiology time in all four quarters. No difference between the week and the weekend/holiday subgroups could be observed (table 2 & 3).

Door-to-needle Time

The implementation of the NSTEMI care pathway led to no significant difference in the median waiting time between ED admission and coronary angiography (needle introduction) for patients meeting our institutional NSTEMI criteria. The pre-intervention door-to-needle time was 28 hours (IQR 18–57 hours), while the post-intervention door-to-needle time was slightly reduced to 24 hours (IQR 15–44 hours) ($p = 0.0736$) (table 3).

When comparing the pre-intervention period with each quarter of the post-intervention period, only the Q1 subgroup showed a statistically significant reduction in the median door-to-needle time down to 21 hours (IQR 16–35 hours) compared to the 28 hours pre-intervention ($p = 0.0126$). This could be linked to a novelty effect that quickly faded over time.

When comparing the week with the weekend/holiday subgroups in the one-year post-intervention period, we noticed a median difference of 16 hours, with 21 hours (IQR 10–32 hours) during the week and 37 hours (IQR 23–52 hours) during weekends/holidays ($p = 0.0001$) (table 2). This was expected because of the catheterization laboratory's reduced activity outside business days. It is a typical staffing and organizational issue many institutions share that must be addressed by hospital management.

Total Length of Hospital Stay

The implementation of the NSTEMI care pathway led to a significant reduction in the median length of hospital stay for patients meeting our institutional NSTEMI criteria. Pre-intervention length of hospital stay was five days (IQR 3–10 days) which was reduced to three days post-interventional (IQR 2–7 days) ($p < 0.0001$) (table 3).

In-hospital Mortality

In-hospital mortality was 0.89% (1/112) in the pre-intervention group and 2.52% (4/159) in the post-intervention group. The difference not being statistically significant ($p = 0.6519$) (table 3).

Misdiagnoses (non-NSTEMI)

There was a significant reduction in the number of misdiagnoses from 16.96% (19/112) pre-intervention to 8.81% (14/159) post-intervention ($p = 0.0341$) (table 3).

Table 1: Baseline demographics

	Total (n = 271)	Pre-intervention (n = 112)	Post-intervention (n = 159)
Age (years), mean (SD)	68 (13)	66 (13)	70 (13)
Men, n (%)	199 (73)	81 (72)	118 (74)

SD: Standard deviation.

Discussion

The implementation of a specialized clinical care pathway for NSTEMI patients led to a significant decrease in the time between ED admission and transfer to the cardiology department. The median time spent in the ED was divided in half (twelve hours pre- to six hours post-intervention). This novel clinical care pathway has facilitated a rapid and efficient transfer of NSTEMI patients to the highly specialized environment of the cardiology department with telemetric monitoring and undoubtedly relieved congestion in the ED. As stated by Birkhahn et al. [10], “the focused use of a rapid cardiac disposition protocol can dramatically impact resource utilization, expedite

patient flow, and improve short-term outcomes for patients with suspected ACS”. The mid- and long-term outcomes should be further analyzed.

The time between ED admission and start of coronary angiography (door-to-needle time) was not significantly influenced by the clinical care pathway implementation, except during Q1 post-implementation, possibly due to a novelty effect. These results highlight the need for a second deeper consolidation step within the cardiology department itself. The focus should be on optimizing patient flow between the cardiology department and the catheterization laboratory.

A central operational variable in hospital management, the total length of hospital stay in days (median), was decreased by two days (five days pre- to three days post-intervention) leading to a more efficient and cost-effective bed usage.

There was no statistical difference in mortality between the groups. The mortality rate for the whole study population was 1.84%, which is what could be expected in interventional cardiology. A recent study by Castro-Dominguez et al. [11] showed a median hospital risk-standardized mortality rate of 1.9%, ranging from 1.1 to 3.3% (IQR 1.7–2.1) in patients undergoing percutaneous coronary interventions (n=706,263).

The rate of patients with a final non-cardiac diagnosis (non-NSTEMI or misdiagnoses, as defined in the methods section) was approximately 17% pre-intervention and 9% post-intervention. Patients were discharged rapidly and safely following cardiac catheterization. This could be attributed to the more precise patient selection due to the exhaustive inclusion and exclusion criteria of the NSTEMI care pathway compared to the more subjective cardiologist clinical evaluation before implementation of the new clinical care pathway. The results are comparable with other studies. In a study by Gallagher et al., 31 out of 311 pa-

Table 2: Post-intervention time difference between week and weekend/holiday

	Week (n = 99)	Weekend/ holiday (n = 60)	p-value
Door-to-cardiology time (hours), median (IQR)	6 (4–7)	6 (4–9)	0.14
Door-to-needle time (hours), median (IQR)	21 (10–32)	37 (22–52)	0.0001

IQR: Interquartile range.

Table 3: Outcome results by quarter subgroups

	Total (n = 271)	Pre-intervention (n = 112)	Post-intervention (n = 159)	p-value
Door-to-cardiology time (hours), median (IQR)	7 (4–14)	12 (6–24)	6 (4–9)	<0.0001
Q1 (n = 51)			5 (4–8)	<0.0001
Q2 (n = 44)			6 (4–9)	0.0001
Q3 (n = 45)			7 (5–11)	0.0003
Q4 (n = 19)			6 (4–7)	<0.0001
Door-to-needle time (hours), median (IQR)	26 (16–49)	28 (18–57)	24 (15–44)	0.07
Q1 (n = 51)			21 (16–35)	0.0126
Q2 (n = 44)			28 (14–55)	0.85
Q3 (n = 45)			24 (17–37)	0.31
Q4 (n = 19)			25 (6–58)	0.40
Total length of hospital stay (days), median (IQR)	4 (2–8)	5 (3–10)	3 (2–7)	<0.0001
In-hospital mortality, n (%)	5 (1.84)	1 (0.89)	4 (2.52)	0.65
Misdiagnoses (non-STEMI), n (%)	33 (12.2)	19 (16.96)	14 (8.81)	0.0341

IQR: Interquartile range; Q1-4: Quarters of post-intervention year; STEMI: ST-elevation myocardial infarction.

tients (10%) had another cardiac cause for chest pain (including pericarditis or myocarditis), whereas 45 out of 311 (14.5%) had a non-cardiac cause for their symptoms [12].

Some limitations of this study should be mentioned. It was an observational study designed to assess the feasibility of a novel change in practice to optimize care in NSTEMI patients. Detailed and exhaustive clinical outcome data on the entire study population (except for mortality) was not collected and it can therefore only be speculated as to whether the implementation of this clinical care pathway brought additional clinical benefits to NSTEMI patients. Moreover, it is difficult to interpret the safety of an earlier hospital discharge (shorter cardiac monitoring after reperfusion) from the limited data. As summarized by Laut et al. [13], the implementation of a clinical care pathway for patients with NSTEMI appears to be “a complicated matter”. While it may lead to a localized reduction in the length of hospital stay, “healthcare organizations should be alert to adverse effects on patient selection and changes in care processes”. The overall efficiency on the healthcare system should always be kept in mind. Other studies [7, 12–15] have shown that clinical care pathways are associated with reduced in-hospital morbidity and mortality, and improved documentation without negatively impacting the length of stay nor hospital costs. Our study corroborates the results of these studies while adding a real-world practice point of view. The novelty of our approach lies in the inversion of the paradigm that considers door-to-needle time as the gold standard primary endpoint typically used in studies on STEMI care pathways. Using door-to-cardiology time instead of door-to-needle time as the primary endpoint is much more relevant because it corresponds more to the real in-hospital patient flow sequence of NSTEMI patients.

It should also be mentioned that our study is underpowered to detect differences in hard clinical outcomes, such as in-hospital mortality, because of the small size of the groups.

Further studies focusing on mid- and long-term clinical and financial outcomes associated with NSTEMI care pathways are required.

Future Perspectives

The patient flow analysis within the institution should be improved with more precise measures (timing definitions, unique database for ED, catheterization laboratory and cardiology department) and systematic identification of major delays through an incident (delay) reporting system. A multicenter randomized study should be conducted to assess the re-

sults. A future perspective is an extension of the NSTEMI clinical care pathway to in-hospital (already hospitalized) patients, local/regional hospitals and extra-hospital NSTEMI patients, as it is already the case for the STEMI clinical care pathway. A cost analysis should also be conducted to assess the cost-effectiveness of the implantation of such a clinical pathway.

Conclusion

The implementation of a new NSTEMI specialized clinical care pathway was associated with a reduction of six hours in the median door-to-cardiology time, a reduction of two days in the length of hospital stay, as well as a significant reduction in the number of misdiagnoses. Its feasibility in routine clinical practice in a large university hospital has been demonstrated with a door-to-needle time <24 hours as advocated by the European Society of Cardiology (except during weekends/holidays, due to the previously mentioned lack of qualified staff during these critical periods). The updated institutional guidelines (2020) on NSTEMI management should solve the problem by extending the <24-hour objective to weekends/holidays, thereby fostering a deeper institutional organization and a human resource change.

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Ethics Statement

The study protocol complies with the Declaration of Helsinki regarding investigations in humans. It has been approved by Swissethics (CER-VD 2019–01767).

Conflict of Interest Statement

No financial support and no other potential conflict of interest was reported.

Author Contributions

Jérôme Dällenbach wrote the manuscript with the assistance of Pierre Monney and Wongsakorn Luangphiphat, who made very important improvements and corrections. Jérôme Dällenbach collected the data and performed the computations. Eric Eeckhout and Grégoire Girod conceived the initial idea and supervised the project. Pierre Monney helped supervise the project as an internal expert. All authors discussed the results and contributed to the final manuscript.

Data Availability Statement

The data underlying this article can be shared pending reasonable request to the corresponding author.

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