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ORIGINAL PAPER

Relation of lowering door-to-balloon time and mortality in ST segment elevation myocardial infarction patients undergoing percutaneous coronary intervention

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Abstract

Background Current guidelines for the treatment of ST-segment elevation myocardial infarction (STEMI) recommend a door-to-balloon time (DBT) of ≤ 90 min for patients undergoing primary percutaneous coronary intervention (PCI). We aimed to investigate the possible impact of further reduction in DBT intervals beyond the 90 min cutoff on short and long-term outcomes among STEMI patients undergoing primary PCI.

Methods We retrospectively studied 889 STEMI patients (median age 61 years, 83% men) who underwent successful primary PCI and had a DBT of ≤ 90 min. Patients were stratified according to DBT into 2 groups: < 60 min and 60–90 min. Patients records were assessed for the occurrence of in-hospital complications, 30-day and 1-year mortality.

Results Patients having DBT < 60 min ($n = 608$, 68%) were more likely to present earlier, in daytime and weekdays, and had better post-procedural left ventricular ejection fraction and lower 30-day mortality (3% vs. 6%, $p = 0.03$). Mortality over 1-year was significantly lower among patients having DBT < 60 compared to DBT of 60–90 min (4.6% vs. 9.6%, $p = 0.004$). In a binary logistic regression model DBT < 60 min was associated with 51% risk reduction for 1-year mortality (OR 0.49, 95% CI 0.25–0.93, $p = 0.03$).

Conclusions Among STEMI patients undergoing primary PCI within 90 min of admission DBT < 60 min was independently associated with better 1-year mortality.

Keywords ST-segment elevation myocardial infarction · Door-to-balloon time · Primary percutaneous coronary intervention · Cardiac intensive care unit

Introduction

Early reperfusion with primary percutaneous coronary intervention (PCI) is currently the recommended treatment strategy for patients presenting with ST segment elevation myocardial infarction (STEMI) [1]. Door-to-balloon time (DBT) is related as the interval from arrival at the hospital until inflation of the balloon to restore flow in the occluded artery.

Studies showed a direct relationship between the duration of coronary occlusion and ischemic myocardial cell injury [2]. Thus, longer time to treatment results in higher mortality [3–9]. On that account DBT has emerged as key quality indicator for hospital performance [10, 11]. On basis of this time-dependent effect current clinical guidelines recommend that patients should be treated within a DBT of ≤ 90 min (Class I recommendation) [12, 13]. Numerous strategies have been proposed to reach this goal including the admission of patients directly to the cardiac catheterization laboratory or the cardiac intensive care unit bypassing the emergency room (ER) [14–17]. The utilization of these and other strategies enables many STEMI patients nowadays to be treated within recommended time intervals [18–22]. Limited data exists, however, whether further reduction in

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DBT beyond the 90-min benchmark has a beneficial effect on outcomes. We aimed to investigate the possible impact of further reduction in DBT intervals beyond the 90-min cutoff on short and long-term outcomes in STEMI patients undergoing primary PCI.

Methods

A retrospective, single-center observational study was performed at the Tel-Aviv Sourasky Medical Center, a tertiary referral hospital with a 24/7 primary PCI service.

Included were all 1223 consecutive patients admitted between January 2013 and August 2017 with the diagnosis of acute STEMI subsequently treated with primary PCI (as previously described [23, 24]. We excluded patients transferred from other hospitals ($n=4$), patients in whom information regarding survival during the first year after PCI was not available ($n=155$) and patients with no documented DBT in medical records ($n=16$). We further excluded patients with DBT > 90 min ($n=159$). The final study population included 889 STEMI patients. Diagnosis of STEMI was established in accordance to published guidelines including a typical chest pain history, diagnostic electrocardiographic changes, and serial elevation of cardiac biomarkers [13]. Primary PCI was performed in patients with symptoms ≤ 12 h in duration, as well as in patients with symptoms lasting 12–24 h if pain consisted at the time of admission. Symptom duration was defined as the time from symptom onset (usually chest pain or discomfort) to ER/catheterization laboratory admission. Door-to-balloon time was defined as the time in minutes between a patient's arrival at the hospital (taken from the computerized patient file) and the first balloon inflation or device deployment in the culprit artery as documented in the patient's medical record. A culprit artery was defined as one with an identifiable thrombotic lesion on an angiogram corresponding to electrocardiographic changes. For the purpose of evaluating differences in patient characteristics and outcomes associated with DBT, we stratified patients into 2 groups: < 60 and 60–90 min. Baseline demographics, cardiovascular history, clinical risk factors, treatment characteristics and laboratory results were all retrieved from the hospital electronic medical records. Patient records were evaluated for in-hospital mortality and complications occurring during the hospitalization. These included cardiogenic shock or the need for intra-aortic balloon counterpulsation treatment, mechanical ventilation or heart failure episodes treated conservatively, clinically significant tachyarrhythmia's, bradyarrhythmias requiring pacemaker and major bleedings (requiring blood transfusion). Assessment of survival for 1 year following hospital discharge was determined from computerized records of the population registry bureau.

Continuous variables were presented as mean ± standard deviation and compared with the independent sample *t* test when normally distributed. Median and interquartile range was used in cases of non-normally distributed continuous variables. These variables were compared with Mann–Whitney *U* test. Categorical variables are presented as percentages; *p* values were calculated with the Chi-squared test. Independent predictors of 1-year mortality were determined in a multivariate binary logistic regression model adjusted for all baseline variables found to be significant in the univariate analysis. Survival rates were described by the Kaplan–Meier method. A two-tailed *p* value of <0.05 was considered significant for all analyses. All analyses were performed with the SPSS software (SPSS Inc., Chicago, IL).

Results

Study population included 889 STEMI patients (median age 61 years [Interquartile range 52–69], 83% men), 608 of whom (68%) had DBT < 60 min. Table 1 presents the baseline characteristics of patients with DBT under 60 min and patients with DBT between 60 and 90 min. Patients having DBT < 60 min were more likely to present to hospital earlier following symptom onset, at daytime, weekdays, and to bypass the emergency room. Table 2 presents the procedural

Table 1 Baseline patient characteristics according to door-to-balloon time

	DTB < 60 min ($n=608$)	DTB 60–90 min ($n=281$)	*p* value
Age (years), median(IQR 25–75)	61 (52–68)	62 (53–71)	0.07
Gender (male), *n* (%)	509 (84)	229 (82)	0.41
Diabetes mellitus, *n* (%)	154 (25)	81 (29)	0.27
Hyperlipidemia, *n* (%)	292 (48)	148 (53)	0.19
Family history, *n* (%)	162 (27)	65 (23)	0.26
Smoking, *n* (%)	329 (54)	137 (49)	0.14
Past myocardial infarction, *n* (%)	135 (22)	39 (14)	0.004
Hypertension, *n* (%)	268 (44)	129 (46)	0.61
Symptom duration > 2 h, *n* (%)	200 (33)	127 (46)	< 0.001
Time of day (daytime)[a], *n* (%)	472 (78)	132 (47)	< 0.001
Time of Week (weekday)[b], *n* (%)	454 (75)	192 (68)	0.048
Direct PCI, *n* (%)	88 (15)	7 (3)	< 0.001

PCI percutaneous coronary intervention, *DBT* door-to-balloon-time, *IQR* interquartile range

[a]Daytime = 7:00–19:00

[b]Weekday = Sunday 00:00–Thursday 23:59

Table 2 Periprocedural outcomes and in-hospital complications according to door-to-balloon time

Variable	DTB < 60 min ($n = 608$)	DTB 60–90 min ($n = 281$)	p value
Heart failure, n (%)	60 (9.9)	36 (12.8)	0.19
Acute kidney injury, n (%)	56 (9.2)	32 (11.4)	0.31
Ejection fraction (%), mean ± SD	47.3 ± 7.8	45.1 ± 7.7	< 0.001
Ejection fraction ≤ 45%, n (%)	307 (51)	170 (62)	0.002
CPK (IU/L), median (IQR 25–75)	946 (418–1967)	907 (409–1908)	0.61
Coronary artery disease, n (%)			0.74
1	248 (41)	107 (38)	
2	183 (30)	88 (31)	
3	177 (29)	86 (31)	
Bleeding, n (%)	34 (5.6)	13 (4.6)	0.55
VT/VF, n (%)	69 (11.3)	22 (7.8)	0.11
Bradycardia, n (%)	40 (6.6)	15 (5.3)	0.48
Intra-aortic balloon catheter, n (%)	14 (2.3)	14 (5.0)	0.03
Mechanical ventilation, n (%)	30 (4.9)	15 (5.3)	0.79

CPK creatine phosphokinase, *VF* ventricular fibrillation, *VT* ventricular tachycardia, *DBT* door-to-balloon time, *IQR* interquartile range, *SD* standard deviation

outcomes and in-hospital complication of both patients groups. Compared to patients having a DBT of 60–90 min, patients with DBT < 60 min were less likely to have left ventricular (EF) ≤ 45% (51% vs.62%, $p = 0.002$) and had lower 30-day mortality (3% vs. 6%, $p = 0.03$). During 1-year follow–up, 55 (6.1%) of study patients died. Mortality was significantly lower among patients having DBT < 60 min (4.6% vs. 9.6%, log-rank $p = 0.004$, Fig. 1).

As presented in Table 3 in a multivariate binary logistic regression model DBT < 60 min was independently associated with 51% risk reduction for 1-year mortality (OR 0.49,95% CI 0.25–0.93, $p = 0.03$). Other factors independently associated with 1-year mortality risk included age > 60 years, hypertension and left ventricular EF ≤ 45%.

Discussion

The main finding of our study is that among STEMI patients undergoing primary PCI, further reduction in DBT, even among patients treated successfully within 90 min of admission is independently associated with better 1-year survival.

Primary PCI for STEMI patients has been recommended within a DBT of ≤ 90 min for over the last decade [13, 25]. Based on current guideline recommendations assessment of this cut-off became focus of large registries and was utilized as a major objective for quality assessment [10, 11]. Furthermore, the AHA/ACC launched a campaign named "door-to-balloon (D2B): an alliance for quality" aimed to increase the percentage of STEMI patients treated within DBT of ≤ 90 min. Studies showed that all these efforts brought remarkable improvement, enabling a large share of patients to be treated within the "acceptable" time intervals nowadays [19, 22].

Delay in primary PCI from the time of arrival at a medical center correlates with infarction size [26]. It is well established as well that prolonged DBT results in increased mortality [3–5, 27]. The specific shape of association is, however, a matter of debate. It is still unclear whether any postponement in treatment is harmful or outcome worsens only after an initial time delay [2, 28]. Pushing beyond the 90-min DBT benchmark is well possible nowadays raising the question what time interval should be desirable for STEMI patients today [19, 22, 29].

Most studies evaluating DBT restricted categorical modelling to cutoffs of 90 min or 2 h [5, 7, 8]. Others presented a statistical linear relationship between treatment delay and mortality risk describing time as continuous variable without being able to suggest target cutoffs for improved outcome [3, 6]. Limited data is present regarding DBT cutoffs under 90 min. Gibson et al. reported a significant fall in in-hospital mortality associated with a reduction of median DBT from 111 to 79 min over a time period of 20-years in patients enrolled in the National Registry of Myocardial Infarction (NRMI) [29]. This finding, however, was questioned by later observations from large databases failing to show improved short-term outcome despite significant decline in median DBT over the years [19, 22]. Berger et al. demonstrated improvement in 30-day survival when DBT was reduced from 90 to < 60 min. This report published over 20 years ago, included a limited amount of patients who were part of a larger multicenter trial (GUSTO-IIb) comparing thrombolytic therapy to PTCA, thus being limited to past pharmacological treatment protocols and prone to bias due to varying procedural quality between centers [4]. Another

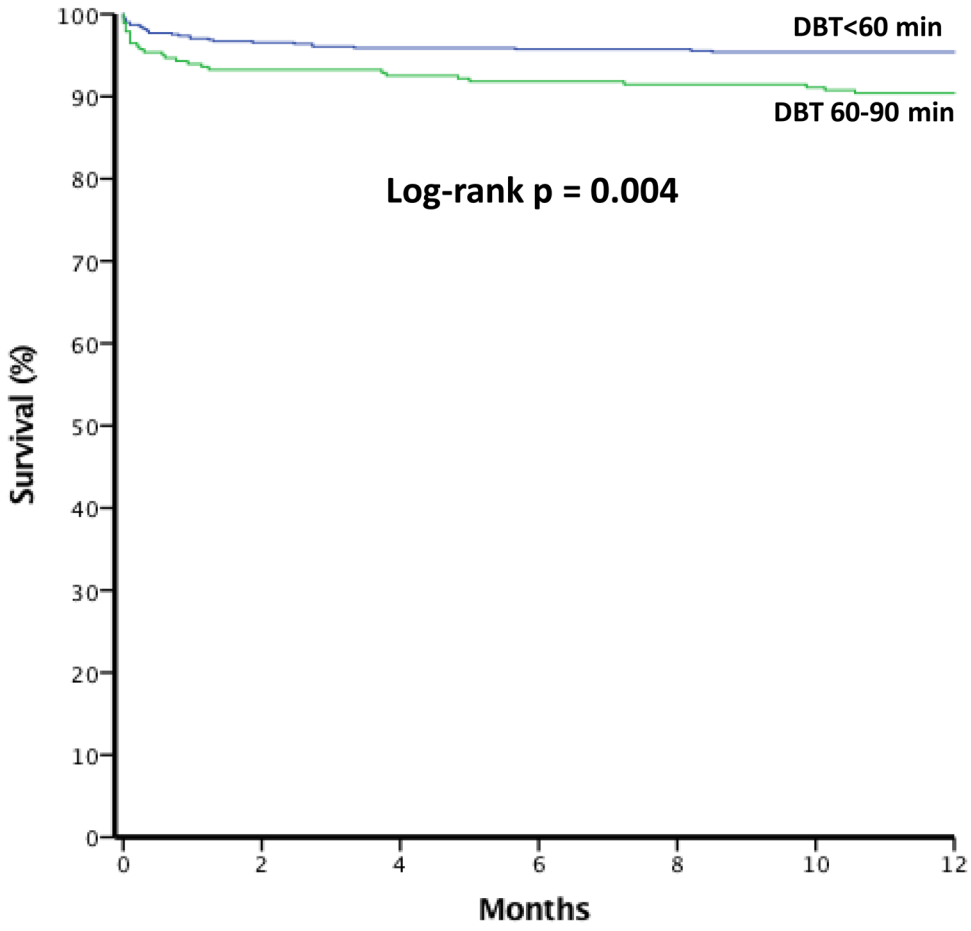

Fig. 1 Kaplan–Meier 1-year survival curves for patients with DBT < 60 min vs. DBT 60–90 min. *DTB* door-to-balloon time

Table 3 univariate and multivariate binary logistic regression analysis for 1 year mortality

	Univariate analysis		Multivariate analysis	
	OR (95% CI)	*p* value	OR (95% CI)	*p* value
DBT < 60 min	0.45 (0.26–0.79)	0.005	0.49 (0.25–0.93)	0.03
Age > 60 years	8.17 (3.46–19.27)	< 0.001	5.68 (1.94–16.6)	0.002
Ejection fraction ≤ 45%	2.79 (1.39–5.56)	0.004	2.38 (1.13–5.01)	0.02
Hypertension	3.93 (2.11–7.32)	< 0.001	2.61 (1.25–5.48)	0.01
Female sex	2.56 (1.42–4.64)	0.002	1.64 (0.79–3.35)	0.18
Family history	0.22 (0.08–0.60)	0.003	0.35 (0.10–1.18)	0.09
Diabetes mellitus	1.79 (1.02–3.15)	0.04	0.89 (0.44–1.79)	0.75
Smoking	0.38 (0.21–0.69)	0.001	0.83 (0.43–1.60)	0.58
Past myocardial infarction	2.11 (1.73–3.81)	0.013	1.69 (0.82–3.51)	0.16
Symptom duration > 2 h	1.49 (0.86–2.60)	0.15	1.08 (0.57–2.05)	0.82

DBT door-to-balloon time, *OR* odds ratio, *CI* confidence interval

report presented an analysis of a large cohort of STEMI patients treated with primary PCI who were enrolled in the American college of cardiology national cardiovascular data registry [9]. Results showed increased in-hospital mortality for treatment delays even within the endorsed 90-min' time interval with lowest mortality rates among patients with DBT below 30 min. Because data were collected from over 600 different catheterization laboratories results may be biased by inconsistent operator quality and different procedural protocols all affecting DBT. In contrast to the current study, both trials mentioned above failed to report outcomes later than 30 days after PCI.

Numerous strategic approaches have been recommended to shorten the time interval from admission to treatment

[17]. Bypassing the ER was first recommended by the European Society of Cardiology in 2012 [14]. Pre-hospital electrocardiogram (ECG) diagnosis is one of the strategies recommended by the D2B campaign. Prehospital ECG and subsequent direct ambulance admission bypassing the ER both showed significant impact on DBT [15, 16, 30]. Indeed, our data showed a higher probability of achieving shorter DBT when bypassing the ER.

Many STEMI networks accept primary PCI within 120 min after first medical contact based on recent guidelines [12, 13]. The organization of an optimal STEMI network needs to be customized and refined by regional health system. Components should include a system for early diagnosis, fast patient transfer, optimal door-to-device organization, and an experienced team of interventionists. Regular control of time delays in existing STEMI networks by running a registry is important to detect potential time delays and respective reasons and to improve the quality of such networks [30].

We acknowledge several important limitations of our study. This was a single-center retrospective and non-randomized observational study; thus findings might be attributed to biases related to unmeasured factors. We attempted to mitigate this effect through robust risk adjustment but cannot preclude the possibility of residual confounding by other non-measured patient or hospital factors associated with DBT time or mortality. In addition, as the study included only patients who were undergoing primary PCI, the results cannot be generalized to all STEMI patients.

Compliance with ethical standards

Conflict of interest On behalf of all authors, the corresponding author states that there is no conflict of interest.

Ethical approval The study protocol was approved by the local institutional ethics committee and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

Informal consent All persons gave their informed consent prior to their inclusion in the study.

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