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Eroding the Denominator

The Incomplete Story of Door-to-Balloon Time Reporting

To the Editor: Door-to-balloon time (DTB) is the focus of national guidelines, and intense efforts to reduce it have been a core component of many national quality improvement campaigns. Recently, it has been the high point of advertisement campaigns by hospital systems and ultimately might be used to reward performance by payers. It is now publicly reported by the Centers for Medicare & Medicaid Services and the U.S. Department of Health and Human Services, allowing patients to compare hospitals for care of acute myocardial infarction with an online resource (1).

Given its emerging importance, it is important to assess how this measure is tracked nationally. Recently, Ellis et al. (2) introduced the “weasel clause” to highlight a number of new exclusions that result in an unknown number of patients to be systematically omitted from institutional reporting for reasons never accounted for in the seminal studies defining the importance of this measure (3). Specifically, these exclusions relate to “non-system”-based delays involving patients with difficult vascular access, delay in consent to procedure, need for intubation/cardiac arrest, and where the culprit lesion was difficult to cross. The goal of our report is to assess the prevalence of the proportion of patients who are thus excluded and describe their clinical outcomes.

We used the Blue Cross and Blue Shield of Michigan Cardiovascular Consortium database to evaluate the outcome of all patients undergoing primary percutaneous coronary intervention (PCI) for ST-segment elevation myocardial infarction in Michigan in 2010. The details of this registry have been previously published (4).

A total of 2,463 patients underwent primary PCI in 2010 at the 33 hospitals that participate in the Blue Cross and Blue Shield of Michigan Cardiovascular Consortium. Of these patients, 2,004 were eligible for reporting DTB data, whereas 447 (18.1%) would be excluded from reporting with the “weasel clause.” The main reasons for exclusion were development of cardiac arrest/need for intubation (7.8%, $n = 191$) and other causes (6.4%, $n = 157$), whereas difficulty in crossing the lesion (2.1%, $n = 51$), difficulty obtaining vascular access (1.2%, $n = 30$), and difficulty in obtaining consent (0.7%, $n = 18$) accounted for the remainder. Median DTB in those with difficult vascular access was 93 min, 93.5 min for those patients with cardiac arrest or need for intubation, 104 min in those with difficulty crossing the lesion, 104.5 min in “other” delays, and 142.5 min in those with delays obtaining consent. Median DTB for those without system delay for PCI was 68 min.

Of the study cohort, 150 patients died before hospital discharge. Of these deaths, 56% ($n = 84$) would be excluded from consideration by American College of Cardiology/National Cardiovascular Data Registry criteria. The vast majority (44% of all deaths, $n = 66$) were among those patients presenting with cardiac arrest or requiring intubation. Of all the 150 in-hospital deaths, 3.3% ($n = 5$) would be excluded for operator difficulty crossing the lesion, 0.7% ($n = 1$) would be excluded for operator difficulty

gaining vascular access, and 0.7% ($n = 1$) would be excluded for delay in obtaining consent from the patient. Finally, 7.3% ($n = 11$) of in-hospital deaths would be excluded from reporting for “other” non-system delays. In comparison, only 44% of all deaths ($n = 66$) were outside of the current parameters for exclusion and thus eligible for DTB reporting (Fig. 1).

These findings highlight the need to strongly reconsider the implications of the “weasel clause” in relation to the reporting of DTB. The results from our study would suggest that our quality improvement efforts, if developed in response to the data as reported, would miss more than one-half of the patients who end up dying from ST-segment elevation myocardial infarction.

Exclusions for reporting serve a dual purpose in allowing for fair comparisons between centers with potentially disparate patient populations as well as encouraging broad use of lifesaving services. For example, by eliminating patients with extreme characteristics or risk, exclusions allow a large volume center to be compared with a smaller one. Similarly, exclusion of higher-risk patients (with much higher probability of worsened outcome at presentation) encourages centers to offer therapies and interventions that might be withheld if their outcome were “reportable.” However, as our data show, this medical moral hazard might be obscuring the current drivers of in-hospital mortality instead of helping focus attention on them. A key consideration for the future will be to dissociate these measures of performance from reimbursement, so as to allow for comprehensive reporting and data collection without the threat of punishment.

Efforts to ensure a level playing field and minimize the negative impact of public reporting should not distract from the most important goal—reducing mortality and ensuring the optimal outcome for our patients.

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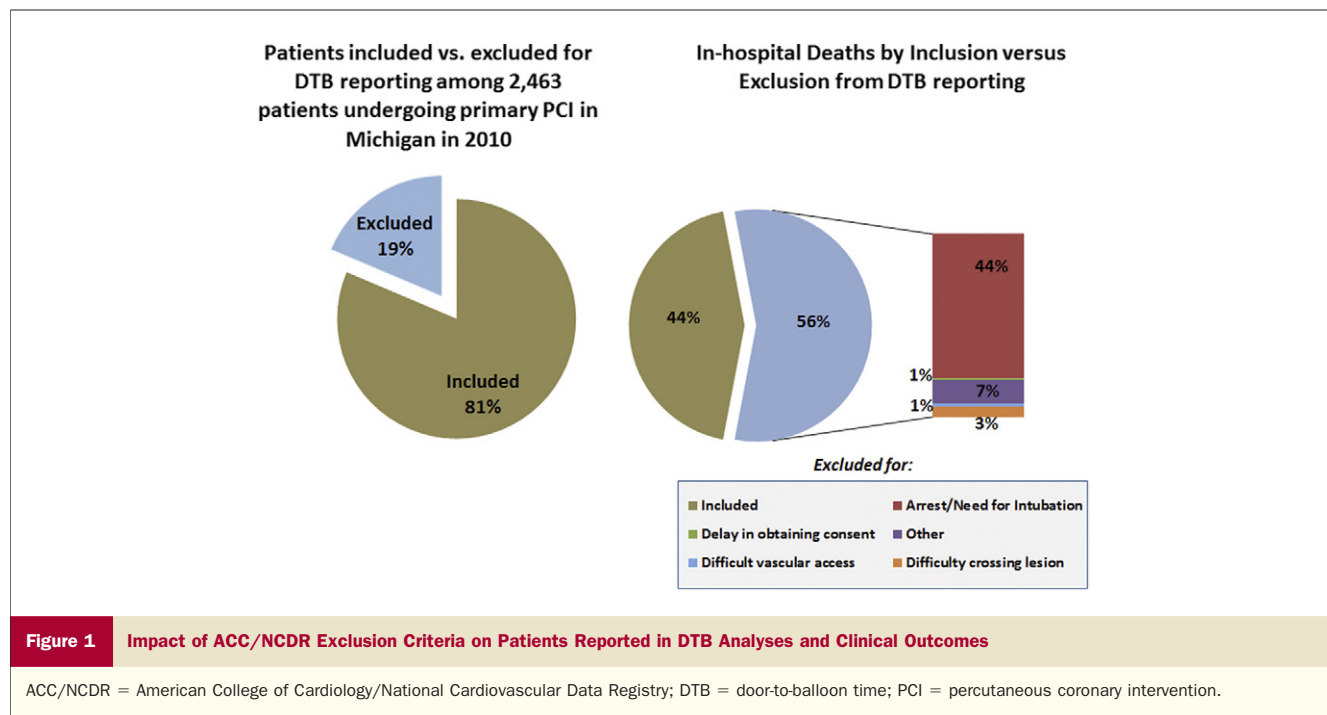
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