Door-to-balloon time in primary percutaneous coronary intervention for patients with ST-Segment Elevation Myocardial Infarction
An audit from the Accident and Emergency department of Mater Dei Hospital, Malta.

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Abstract
Introduction: Over the past years Primary Percutaneous Coronary Intervention (PCI) has emerged as an effective treatment strategy for acute ST-Elevation Myocardial Infarction (STEMI).1 The survival rate with Primary PCI however is dependent on the time to treatment,2 thus, given the time dependency of survival in patient with STEMI undergoing Primary PCI, the American College of Cardiology and American Heart Association (ACC/AHA) in their management guidelines of acute myocardial infarction also endorsed by European Society of Cardiology (ESC) have established a door-to-balloon time of 90 minutes as a gold standard for Primary PCI.4 The aim of this audit is to measure and compare this key performance measurement for quality of care of patients with STEMI in the Maltese Islands.

Methods: This audit was conducted at the only PCI-capable hospital in Malta – Mater Dei Hospital. All the patients coming in through the Accident and Emergency Department with an ST-elevation Myocardial Infarction or a new onset Left Bundle Branch Block (LBBB), thus eligible for a Primary PCI, were included in this audit. This was a prospective audit between January 2012 and December 2012 and using a proforma, data was collected primarily to map out the Door-to-Ballon times for Primary PCI during that period. This data was also used to pinpoint areas were time delays occur when dealing with STEMI cases.

Door-to-Ballon times from pre-hospital diagnosis of STEMI using the MRX was also audited and compared to times of in-hospital STEMI diagnosis.

Results: During the 12 months duration of the audit, 157 patients were recorded in the CathLab Database as having had an Emergency Primary PCI. Recorded in the audit were 135 patients of which 123 were STEMI patients eligible for a Primary PCI and 12 STEMI patients not eligible for Primary PCI and thus not included in the audit. The Mean Door-to-Ballon times of all 123 patients was found to be 101.45 minutes. Data analysis showed that the times during ’Office Hours’ (8am to 5pm) were statistically significantly less than those of ’After hours’ (5pm to 8am) (N=123, p<0.001) and those with a Door-to-Ballon time of more than 90 minutes, data analysis showed the number of such cases were statistically significantly less during ’Office Hours’ (N=36, p=0.02). With pre-hospital ECG diagnosis of STEMI, data analysis showed that with MRX, Door-to-Ballon times are significantly less when compared to those during ’Office Hours’ and ’After Hours’ (N=57, p=0.003 and N=66, p<0.001 respectively).

Conclusion: From the results obtained, local achievement to remain well within the standards suggested by the ACC/AHA and ESC of Primary PCI ≤ 90 minutes for STEMI was not reached, however several factors contributing to delays and strategies to minimize delay were pointed out in order to further improve the local practice and thus lowering mortality rates associated with STEMI.

Key Words
Primary Percutaneous Coronary Intervention, ST segment elevation Myocardial Infarction, STEMI, Acute Coronary Syndrome, Door-to-Ballon time.

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Introduction

Over the past years Primary Percutaneous Coronary Intervention (PCI) has emerged as an effective treatment strategy for acute ST-Elevation Myocardial Infarction (STEMI). The benefits of Primary PCI when compared to Thrombolytic therapy include a reduction in the frequency of total stroke and haemorrhagic stroke; a reduction in the frequency of reinfarction and an increase in the frequency of infarct related artery patency thus improving in-hospital and long term survival.¹

The survival rate with Primary PCI however is dependent on the time to treatment. In the Global use of Strategies To open Occluded arteries in Acute coronary syndromes (GUSTO-IIb) substudy,² the lowest 30-day mortality rate was observed in patients undergoing Primary PCI within 60 minutes from presentation to the emergency room, whereas the highest mortality rate was observed in patients undergoing Primary PCI >90 minutes from presentation to the emergency room (1% vs 6.4%). Similar data were reported in an analysis of data from the National Registry of Acute Myocardial Infarction (NRMI) – with the lowest mortality rate observed in patients undergoing PCI within 60 minutes and significantly higher mortality rates in patients undergoing PCI beyond 120 minutes.³ Thus given the time dependency of survival in patient with STEMI undergoing Primary PCI, the American College of Cardiology and American Heart Association in their management guidelines of acute myocardial infarction have established a door-to-balloon time of 90 minutes as a gold standard for Primary PCI.⁴ This door-to-Balloon time has also been adopted as a key performance measurement for quality of care of patients with STEMI by the European Community. In fact guidelines on myocardial revascularization of the European Society of Cardiology (ESC)⁵ and the European Association for Cardiothoracic Surgery (EACTS) developed with the special contribution of the European Association for Percutaneous Cardiovascular Interventions (EAPCI) have placed this golden number as a benchmark for better performance in STEMI patients.

In 1997 Caputo et al ⁶ reported the effect of a detailed quality improvement intervention aimed at reducing Door-to-Balloon time in a single institution. The intervention included avoidance of re-evaluation of the patient; education of emergency room staff, transport personnel and cardiology staff on the importance of rapid diagnosis of myocardial infarction and rapid transport to the catheterization laboratory; immediate activation of the CathLab team on notification of a patient with suspected acute MI and requisition for the CathLab team to be in hospital within 30 minutes. A significant reduction in Door-to-Balloon time, and in particular a marked reduction for the 'after hours' cases, was observed after implementation of the intervention. Action through systematic intervention can result in significant improvement in care for patients with acute myocardial infarction and the Door-to-Balloon time can be favourably influenced if the complex system surrounding it is understood and modified.

This audit measures and also compares this key performance measurement for quality of care of patients with STEMI in the Maltese Islands. With one PCI-capable hospital in Malta catering for the whole population, the objective was to make sure that the gold standard Door-to-Balloon time of 90 minutes is being respected and to explore other ways with which efficiency and speed can be further improved.

Methods

Study Design

This audit was conducted at the only PCI-capable hospital in Malta – Mater Dei Hospital – and all the patients coming in through the Accident and Emergency Department with an ST-elevation Myocardial Infarction or a new onset Left Bundle Branch Block (LBBB), thus eligible for a Primary PCI, were included in this audit.

This prospective audit was run for 12 months, from January 1st 2012 to December 31st 2012. A proforma was available at the A&E Department for data collection for eligible patients. All Emergency Physicians had a formal introduction and explanation on what type of data collection is needed on the proforma prior to the start of this audit. Appointed personnel at the Catheterization Lab were also involved in this audit so that balloon times recorded on the CathLab Database could be later accessed and recovered using patients’ identification numbers.

Measures and Data Collection

From the proforma at the Accident and Emergency Department the following information was collected:

- Identification Number, Date, Sex and Age
- Time of onset of symptoms
- Time of arrival at the A&E Department
- Time of First Medical Contact and Grade
- Time of further Medical contact (if needed) and Grade
- Time of Cardiologist contact
- Time of Cath-Lab team contact
- Time of PCI initiation

In cases where old notes were requested to aid in the diagnosis (ex: new LBBB), the time of request...
and the time these were made available were recorded on the proforma. Time of Primary PCI initiation was obtained using the Catheterization Lab Database, where all patients with a STEMI who were treated with a Primary PCI were recorded. Eligible patients which were not recorded on the proforma for various reasons were tracked down using the CathLab Database and the relevant time data was retrieved using both the PAS system and Accident and Emergency documentation sheets.

Primary PCI in Mater Dei Hospital is available 24/7, however the CathLab team and Cardiologists are on hospital premises during office hours, hence the cut-off time taken in this audit, to differentiate between “Office Hours” and “After hours” was taken to be 5pm. Thus ‘Office Hours’ from 8am to 5pm and 'After hours' from 5pm to 8am.

In June 2012 the Mater Dei Pre-hospital team which is also run by the A&E Department, introduced the Philips HeartStart MRX monitor/defibrillator on ambulances attending to patients with chest pain, which basically is a pre-hospital electrocardiogram nurses can perform en-route to hospital. The ECG can be dispatched to the A&E Department before the patient arrives to hospital and in cases of STEMI the Cardiologist and CathLab team can be mobilized even before the patient arrives to the A&E. Data from patients with a STEMI where the MRX was used were also included in this audit.

The Mean Door-to-Balloon times for STEMI patients was the primary measure in this audit with \( p \) value measurements using Chi-square goodness-of-fit test and Mann-Whitney U test, for any statistical significance between office hours, after hours and MRX door-to-Balloon times. Other analysis in this audit include mean measurements for patients age and presentation time to A&E from onset of symptoms, first medical contact and CathLab team response time.

Results

During the 12 months duration of the audit, 157 patients were recorded in the CathLab Database as having had an Emergency Primary PCI. Recorded in the audit were 135 patients of which 123 were STEMI patients eligible for a Primary PCI and 12 STEMI patients not eligible for Primary PCI and thus not included in the audit (figure 1).

Twenty-two cases of STEMI patients having a Primary PCI could not be included in this audit due to missing identification numbers on the proforma and/or missing Primary PCI initiation times on the database. MRX data was limited to only 5 cases from a total of 18 cases due to inaccurate or absent documentation mainly identification numbers.

The Mean age of patients presenting with a STEMI to the Accident and Emergency Department was 58 years (\( SD=10 \)) (Figure 2). The mean first medical contact was of 6 minutes (\( SD=5 \)) and the mean time of presentation of patients from onset of symptoms to A&E attendance was of 4 hours (\( SD=2.9 \)). The mean CathLab team response from contact to receiving the patient was of 40 minutes during 'Office Hours' that is between 8 am and 5 pm and 51 minutes in the 'After Hours' that is between 5 pm and 8 am.

Figure 1: Total STEMI’s needing PPCI in 2012 – 157 Patients

Total STEMI’s recorded in Audit – 135 Patients

Of the 123 patients with a STEMI eligible for Primary PCI, 57 patients (46.3%) presented during 'Office Hours' and 66 patients (53.6%) presented 'After Hours' (Figure 3).

The Mean Door-to-Balloon times of all 123 patients was found to be 101.45 minutes. Seventy percent of cases had a Door-to-Ballon time of less than 90 minutes and thirty percent, more than 90 minutes (\( SD = 95 – 500 \) minutes).

A Chi-square goodness-of-fit test was used to examine if there was a statistical difference in the number of STEMIs presenting before 5pm ('Office Hours', \( N=66 \)) and after 5pm ('After Hours', \( N=69 \)) (Figure 4 and Figure 5). No significant difference was found (\( N=135, p=0.796 \)).

A Mann-Whitney U test was used to examine if there was a difference in the Door-to-Ballon times of Primary PCIs for STEMIs presenting during 'Office Hours' and those presenting 'After hours'. The test showed that the times for the 'Office Hours' were statistically significantly less than those of 'After Hours' (\( N=123, p<0.001 \)).
**Figure 2:** Mean age group presenting with STEMI

**Figure 3:** Presentation of STEMI patients
**Figure 4:** Door-to-Balloon time 'Office Hours'

**Figure 5:** Door-to-Balloon times 'After Hours'
Chi-square goodness-of-fit test was used to examine if there was a statistical difference in the number of STEMI patients who had a Door-to-Balloon time longer than 90 minutes in the 'Office Hours' (N=11) and 'After Hours' (N=25) categories. The test showed the number of such cases were statistically significantly less in 'Office Hours' category (N=36, p=0.02).

As mentioned earlier, in June 2012 the MRX was introduced on ambulances attending to patients with chest pain. A total of 18 MRX ECG's showing a STEMI were recorded, of which however only 5 could be used in the audit, since the omission or erroneous input of the identification number on the actual rhythm strip, made it impossible to trace or match it to patients on the CathLab database or A&E documentation sheets. Of the 5 cases audited, the Mean Door-to-Balloon time was 35 minutes (Figure 6).

A Mann-Whitney U test was used to examine if there was a difference in the Door-to-Balloon times of Primary PCIs for STEMI patients that were diagnosed before arrival of the patient to A&E with MRX and the ones diagnosed after arrival to A&E. The test showed that the times for the MRX cases where statistically significantly less (N=118, p<0.001). A Mann-Whitney U test was also used to examine if there was a difference in the Door-to-Balloon times of Primary PCIs for STEMI patients that were diagnosed before arrival of the patient to A&E with MRX and the ones diagnosed after arrival to A&E during 'Office Hours' and 'After Hours' separately. In both cases the times for the MRX patients were significantly less (N=57, p=0.003 and N=66, p<0.001 respectively).

Discussion
The results from this audit showed that the mean Door-to-Balloon times for patients with STEMI needing Primary PCI was above the 90 minute mark set as standard by the ACC/AHA and ESC.

Contributing significantly to this mean were the 30% of STEMI patients with a Door-to-Balloon time well above the 90 minute mark. The encouraging part in this audit however was that 70% of STEMI patients had a Door-to-Balloon time less than 90 minutes. Having said that 30% is still significantly high and in the local setting where transfer delays of patients with a STEMI from one hospital to the other is not an issue, and relative short distances patients need to travel to hospital, in-hospital performance and efficiency of A&E and Cathlab teams are the major contributing factors for this result.

The first striking result that emerged from this audit is the statistical difference between Door-to-Balloon times achieved during 'Office Hours' and those achieved 'After Hours'. Taken separately the mean Door-to-Balloon times during 'Office Hours' is 89.2 minutes while that of 'After Hours' is 111.14 minutes. From the data recovered, all those with a Door-to-Balloon time over 90 minutes (30% of patients) were analyzed to try to pinpoint the causes of delays (figure 7). Seventy-five percent of delays were due to time lost by A&E trainees (BST/HST) to contact a medical Higher Specialist Trainee when a STEMI was diagnosed. Twelve percent of delays was time lost from Foundation Year doctors to involve a senior A&E doctor. Six percent were delays in First Medical Contact and another six percent were delays in contacting a cardiologist. Requesting old ECG's for diagnosis of new LBBB summed up a very small number of patients (N=2), however, delays to manually retrieve old notes resulted in delayed Door-to-Ballon times for those patients. All mentioned delays were much more common in the 'After Hours' category.

Another striking result that emerged from this audit, was the use of MRX. Although the population taken was very small, prehospital ECG diagnosis of STEMI with early cardiologist and Cathlab team mobilization before the actual patient arrives at A&E, resulted in shorter door-to-balloon times. Previous studies have shown that performing ECG en route to the hospital can reduce Door-to-Balloon time, and the American National Heart Attack Alert Programme Coordinating Committee has recommended increased use of such electrocardiographic services.

Keeping Door-to-Balloon times as low as possible is of huge importance when it comes to morbidity and mortality as the mortality benefit achieved with primary PCI in STEMI patients is diminished by treatment delays.
Some factors that can improve locally the mean Door-to-Balloon times for patients with a STEMI include:

- Direct contact with the cardiologist whenever a STEMI is diagnosed, therefore avoiding intermediators and re-evaluation of the patient.
- Having well trained and experienced A&E doctors on the shopfloor who can diagnose early, patients with STEMI even with subtle ECG changes.
- Having well trained nursing staff who can triage early, patients with features of myocardial infarction, and performing early Electrocardiograms in patients with atypical chest pains.
- More training to prehospital personnel on how to use the MRX.
- Having a digital database of ECG's available for the Emergency Physician, comparable to the present PACS for X-rays, to access past ECG's of the patient.
- Having an in-hospital CathLab team with cardiologist cover capable in performing Primary PCI especially 'After Hours'.
- Training to CathLab teams to maintain response times of 30 minutes or less especially 'After Hours' if an in-hospital team cannot be obtained.

**Figure 7: Causes of Door-to-Balloon time >90 minutes, (30% of STEMI patients audited)**

**Figure 8: Door-to-Balloon Times**
In figure 8 a histogram of frequency against door-to-ballon times shows clearly several outliers which had an effect on the final mean measurement presented in this audit. If these were to be excluded, that is 12 patients having times greater than 180 minutes the mean would be below the suggested time by the ACC/AHA and ESC, however it was decided not to exclude them from the audit since:

- these patients amount to 10% of those with door-to-ballon times greater than 90 minutes of the 30% mentioned earlier and
- the reason for this delay in these patients were the same as the other patients with times greater than 90 minutes but less than 180 minutes as mentioned above, with the exception of coming in A&E at peak hours when the department is flooding with patients.

I firmly believe that the management of a patient with STEMI should be equal whether he presents during busy or less busy hours.

Conclusion

In conclusion this audit has looked at 123 patients over a 12 month period to determine the local Door-to-Balloon times in Primary Percutaneous Coronary Intervention for patients with ST-Elevation Myocardial Infarction. From the results obtained, local achievement to remain well within the standards suggested by the ACC/AHA and ESC of Primary PCI ≤ 90 minutes for STEMI was not reached, however several factors contributing to delays and strategies to minimize delay were pointed out in order to enhance the local practice and thus lowering mortality rates associated with STEMI.

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References