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**Predictors of the reduction of treatment time for
ST-segment elevation myocardial infarction in a
complex urban reality. The MoMi² survey**

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Predictors of the reduction of treatment time for ST-segment elevation myocardial infarction in a complex urban reality. The MoMi² survey.

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Abstract:

Aims: To achieve a rapid and effective reperfusion of infarct related artery in a complex urban reality.

Methods and results: A net that connects the territory to 23 hospitals, by a centralized coordination of the emergency resources has been activated in the Milan urban area to obtain a real time knowledge of critical resources availability and to transmit a 12 lead ECG to the admitting Coronary Care Unit. During the survey periods, data related to 627 patients have been collected. Most of the patients (73%) were treated with primary PCI, 45 (7%) with thrombolysis, 105 (17%) didn't receive any reperfusion therapy. 57% patients arrived to hospital with rescue units; in 23% of all cases, a 12 lead ECG was tele-transmitted to the hospital of destination before patient arrival. The modality of hospital presentation was the most critical determinant of door-to-balloon time. The shorter one (49.5 minutes) was that of patients transported by means of Advanced Rescue Units with 12 lead ECG tele-transmission and activation of a fast track directly to the Cath Lab.

Conclusions: Pre-hospital ECG recording is the most critical factor necessary to keep door-to-balloon time within suggested limits in a large urban area where most of STEMI patients are treated with PCI.

Key words: coronary reperfusion, door-to-balloon time, STEMI, acute myocardial infarction

Introduction

The main goal in ST elevation acute myocardial infarction (STEMI) is to achieve a rapid and effective reperfusion of infarct related artery (1-3). This may be difficult in complex urban reality where traffic congestion, early and appropriate symptoms recognitions as well as transport to alerted and specialized centres for primary percutaneous coronary interventions (PCI) are only a few of the factors that can cause a delay.

A net that connects the territory to hospitals, by a centralized coordination of the emergency resources has been activated in the Milan urban area to promote the best utilisation of different reperfusion strategies, to reduce the delay to treatment and to increase the global number of patients undergoing coronary reperfusion with a door-to-balloon time less than 90 minutes (4-6). The main characteristics of the network strategy include the sharing of a pre-hospital triage and therapy protocol, real time knowledge of critical resources availability and the possibility of standard 12 lead ECG tele-transmission to admitting Coronary Care Unit (CCU).

It has been previously shown that the modality and timing of admission and availability of 12 lead ECG tele-transmission were some of the critical factors determining in-hospital delay of treatment. However, previous experiences have been performed in contexts surrounding a single hub and spoke model (7,8) or involving a small hospital number (9,10) with a limited rate of tele-transmitted ECG (11).

Since 2001 in the urban area of Milan and neighbourhoods has been operating a network among 27 hospitals and 118 Dispatch Centre (national free number for medical emergencies). All of them, with the Health Country Government Agency, planned a shared protocol of STEMI management

based on the time of onset of the symptoms and risk stratification. On site recording and tele-transmission of 12 lead ECG was strongly recommended and supported by adequate training.

Between June '06 and June '07 we performed three surveys lasting from 30 to 60 days called MoMi². The one **Month Monitoring Myocardial Infarction in Milan** project was designed to analyse all the time to treatment and admittance modality of patients with STEMI, referred to the Emergency Room (ER) and treated within 6 hours from symptom onset.

Methods:

Structure and organisation: Milan urban area is a complex territory with high density of population (2.9 million resident and a million commuters daily) and a great number of hospitals (n = 27).

Twenty-three of them have a cardiology division and a CCU; 18 offer a 24 hour available Cath Lab for primary PCI, 5 are completed with a Cardiac Surgery unit.

The Dispatch Centre of the pre-hospital Emergency Medical System (118) in Milan is coordinating about 60 Basic Rescue Units (number variable on different time of the day), mostly endowed with automatic external defibrillator as well as 10 Advanced Rescue Units (9 cars and one helicopter), carrying medical and nursing staff. Advanced Rescue Units are sent, if available, in response to calls for chest pain or symptoms related to heart attack according to a Dispatch Center pre-defined protocol. They are able to record 12 lead ECG through LIFEPACK 12 defibrillator system (Medtronic, Minneapolis, USA) and to send it to 118 Dispatch Center via GSM. On the basis of LIFEPACK automatic reading or medical interpretation, the Dispatch Center doctor can decide to transmit the ECG by phone or by fax to the network Hospital identified as the hospital of destination on the basis of distance and availability of critical resources. Pre-hospital treatment refers to a shared protocol. The list of participating hospitals is presented in the appendix.

Planning of the study and data collection: From June 2006 to June 2007 three survey periods of a single (June and December 2006) or two month (between June and July 2007) duration were made,

involving all patients with a diagnosis of STEMI who were referred to one of the 23 hospitals of the network.

For each patient the following information were collected: age, gender, clinical presentation (symptoms, infarct localization, Killip Class), modality of access to hospital (spontaneous, by Basic Rescue Units, by Advanced Rescue Units provided with or without ECG tele-transmission capability), pre-hospital time (time of the call to 118, time of arrival of rescue units at patients' site; time to arrival to the hospital (door), time to first ECG, time to balloon inflation, activation of a fast track (directly to Cath Lab); type of therapy (thrombolysis, PCI, no therapy) and, finally, hospital outcome.

Statistical Analysis: Data analysis was restricted to patients with STEMI treated with primary PCI and was primarily focused on the study of the distribution of the door-to-balloon time. Data are expressed as median (first – third quartiles) for continuous variables and as percentage for categorical ones. A non parametric statistical analysis (12), has been implemented to detect a stochastic order of door-to-balloon time distribution stratified with respect to some covariates (sex, age, Killip class, way and time of admittance in the hospital, time of first ECG, fast track). A similar analysis was then conducted stratifying the door-to-balloon time separately with respect to four different relevant covariates: Tele-transmission of ECG: yes vs. no; Time of the first ECG: less than or equal to 10 minutes vs. greater than 10 minutes; Fast Track utilisation: directly to Cath Lab or not and Timing of hospital admittance: working days between 8.00 a.m. to 6:00 p.m. (on hours) vs. working days between 6:00 p.m. and 8:00 a.m. and no-working days (off hours).

The patients have been also divided in two groups according to the value of door-to-balloon time: group “a” if less than or equal to 90 min; group “b” if greater than 90 min, respectively. A *random forest* analysis (13) applied to Classification and Regression Trees (CART) (14) predictors was then performed in order to assess the discriminatory power of the covariates using Gini's impurity index to split group “a” and “b”.

Finally, a comparison longitudinal study (two – way ANOVA) of the door-to-balloon time distributions stratified with respect to the two factors (different monitoring periods and different way of hospital admittance) was also performed. Analysis have been carried out using R® software (version 2.3.1).

Results:

During the three survey periods, data related to 627 patients have been collected. Most of the patients (73%) were treated with primary PCI, 45 (7%) with thrombolysis, 105 (17%) didn't receive any reperfusion therapy. In-hospital mortality for the whole population was of 4.8%. The study population was restricted to 459 treated with PCI. Mortality in these patients was 4.14%. Clinical data and organizational aspects related to the study population are presented in Table I. It should be noted that the characteristics of population including sex, age, MI site and clinical presentation are well in keeping with the current epidemiology of STEMI. Of interest was the finding that the percentage of patients arriving at the ER with rescue units was 57%. In 23% of total cases, a 12 lead ECG was tele-transmitted to the hospital of destination before patient arrival. Table 2 shows additional relevant data in relation to patients' presentation (56 % of patients reached the ER within two hours from symptom onset), door-to-balloon time (median 80 minutes with 57% patients treated within 90') and time of execution of the first in-hospital ECG (median 8 minutes, with 57% patients within 10').

Door-to-balloon time predictors: The non parametric statistical analysis detected a stochastic order of door-to-balloon time distribution in respect to some relevant covariates. Of interest was the finding that the modality of presentation to the ER ($p < 0.0001$) was the most critical one. As indicated in Fig. 1, the distribution of door-to-balloon time varied in relation to the different modalities of hospital transportation. The shorter time (49.5 minutes) was that of patients transported by means of Advanced Rescue Units with 12 lead ECG tele-transmission. This time was

significantly smaller than that of all other patients including those transported with Advanced Rescue Units but without 12 lead ECG transmission. A similar analysis was then conducted stratifying the door-to-balloon time separately with respect to four different relevant covariates: tele-transmission of 12 lead ECG, timing of first in-hospital ECG, utilization of a fast track and timing of hospital admission (see methods). Table 3 summarizes the p-values of one-sided Wilcoxon sum rank tests conducted to detect a stochastic order between the corresponding door-to-balloon time distributions that are presented in Fig. 2. It is evident that all these factors were significantly associated with shorter door-to-balloon times.

To further investigate the relationships between the above covariates and door-to-balloon time, patients were divided in two groups in relation to a value less than or equal to 90 min (Group a) or greater than 90 min, (Group b) to assess the discriminatory power of the covariates taken into consideration. In Figure 3 the discriminate power of each variable is proportional to the length of the corresponding bar: the analysis shows that the time of first ECG that included both tele-transmitted ones and all first in-hospital ECG, was the most significant discriminate between group “a” and “b”. According to a classification tree using Gini’s impurity index a patient was attributed to group “a” if the time of the first ECG was less than 9.5 minutes, otherwise to group “b”. Finally, a longitudinal study of comparison of the door-to-balloon time distributions stratified with respect to single survey timings and modality of hospital admission was performed (see Figure 4). Data analysis indicated that the first factor (monitoring period) was not statistically relevant (p-value of F test on this factor = n.s.) while the second factor (way of hospital admittance) was again markedly significant (p-value of test F on this factor < 0.0001). There was no statistical evidence of interaction between the two factors but only a decreasing trend in the variability of the distributions as long as time increased.

Discussion

The experience of the Milan network for Cardiac Emergency shows how networking strategy that coordinates territory, rescue units and hospitals in a complex urban area with high technological and medical resources, improves health care of patients with STEMI and provides the opportunity to collect and analyse data in order to optimise resources. There was a great number of patients treated with reperfusion therapy (80%) with a low hospital mortality (4.14%), an extensive use of PCI (73%), and a continuous attempt to reduce door-to-balloon time. Almost 60% of patients met the guidelines recommendations with a door-to-balloon time smaller than 90 minutes (10,15).

These results not only confirm the clinical relevance of a networking strategy (10) but also indicate that attempts to reduce any reperfusion delay are associated with a lower mortality rate (5).

Our data show that the door-to-balloon time is greatly influenced by organizational pre-hospital and in-hospital elements. In particular, we found that timing of the first ECG, mode of transport to hospital, pre-alert, direct fast track to the Cath Lab and presentation at hospital during work time, were all elements predictive of a door-to-balloon time smaller than 90 minutes (10,15). Of particular interest was the finding that execution and transmission of pre-hospital ECG (23% of patients) as well as triage within 10 minutes from ER presentation (63% of pts) were the two most important predictive factors in reducing door-to-balloon time (16).

Admission mode: The admission mode had relevant influence on the door-to-balloon time because the receptivity and hospital response were different in terms of triage and direct transportation to the Cath Lab (fast-track) for patients whose arrival was anticipated or was managed by an Advanced Rescue Unit. Regarding this point, it is interesting to note that there was, as expected, a significant difference between self-arriving patients and those who were managed by 118, while, among this latter group, there were no major time differences between those who were accompanied by a basic or by an advanced rescue unit, if the on site ECG were not transmitted. Thus, alerting of the cardiology team of the receiving hospital through a call of 118 Dispatch Centre and ECG transmission made possible to activate the Cath Lab (room preparation, staff activation etc.),

organise a fast track, and reduce the in-hospital time (10,15,16). Our results are well in keeping with the observation of Bradley and coworkers (15) who reported that Cath Lab activation either by the ER or during rescue transportation were two factors together with the presence of a cardiologist in the hospital were major determinant of a reduction in the door-to-balloon time. Of interest was the finding that recording of a 12 lead ECG on site was effective only when used to activate the Cath Lab. More recently, Lee May et al. (17) reported the results of an integrated-metropolitan-area approach where trained paramedics independently triaged and transported patients directly to a designated primary PCI center. Also in Ottawa experience, a pre-hospital 12 lead ECG was recorded by advance care paramedics before transportation. Milan protocol was different in relation to the greater number of involved hospital, the central role of 118 Dispatch Center and the possibility of transmitting the 12 lead ECG from patients' site to the Dispatch Center and from the Dispatch Center to the alerted hospital. Thus, the importance of a pre-hospital diagnosis appears therefore not limited to patients with STEMI complicated by cardiogenic shock (8) or patients transferred to an interventional reference center for PCI (9) but also involves unselected patients transported to local alerted hospital. In this context we extended the positive results of previous studies (8-10) which were based on experiences made in less complex areas, pertaining to one or a few centres and often in non-urban regions with significant distances by providing a model for network coordination of a large number of hospitals in an high population urban areas, with shorter distances and reduced travel time from territory to hospital.

Even if not tested in our survey where most of the patients were treated with PCI, recording and transmitting a 12 lead ECG in the pre-hospital phase of STEMI could also determine beneficial effects areas where PCI is not the selected revascularisation strategy and patients are treated with thrombolysis by allowing either a safer pre-hospital administration or by reducing the in-hospital delay (18,19).

Fast Track: Another important organizational aspect was the activation of a fast track program in most of the participating hospital. This allowed the transport of patients directly to the Cath Lab avoiding emergency room staying, reducing or cancelling time due to patient reevaluation, ECG recording, cardiologist consulting and internal transfer time. This process was only possible when a validated interaction between Advanced Rescue Units, 118 Dispatch Centre and alerted hospital was in function and could completely benefit from 12 lead ECG tele-transmission. It's a common experience that those who arrive at hospital off hours have a longer door-to-balloon time if an alerting program is not active. During this period of the day it is necessary to activate the Cath Lab team and await for the arrival of on call staff. It's particularly in this time frame that the pre-alert system through a call of 118 Dispatch Centre and ECG tele-transmission could give the best results by starting Cath Lab activation before the patient's arrival to the hospital (15).

First ECG: In our study, we also evaluated the impact of the first (either recorded at patients' site or on hospital admission) ECG execution time in relation to other organizational aspects and found that this was the most important factor in order to reduce door-to-balloon time. It should be noted that recording of a 12 lead ECG at patients' site caused a small delay in transport time but allowed, in addition to the activation of hospital pre-alerting system, an appropriate diagnosis STEMI and beginning of a territory targeted therapeutical strategy which could include drugs such as aspirin, heparin, beta-blocker, nitrates, thrombolytics and platelet inhibitors. The 49% of self presenting patients receive an ECG in hospital within 10 minutes.

Milan network: To facilitate comparison with other European and North American experiences, it is important to recall that within the Milan Cardiac Emergency network a high percentage of patients arrived at the ER within two hours from symptom onset and received first aid by the pre-hospital Emergency Medical System, which provided advanced rescue units in 56% of cases and ECG tele-transmission in 40% of referred patients (in fact the 23% of total patients). The high density of

hospitals with 24h/24h active hemodynamic facilities made it possible not only to treat most of STEMI patients with primary PCI but also to obtain a door-to-balloon average time lower than those described in literature. Thrombolysis regarded a limited number (8%) of cases. Another aspect peculiar to our network was that transfers to other hospital were relatively rare 6%. This was due to the fact that territorial triage by the 118 Dispatch Centre avoided inappropriate transfer of patients to hospital, which even closer were without temporally receptive capabilities, whereas the use of advanced rescue units guaranteed protected transportation. Thus, we were able also during night time to transfer all patients to hospitals with suitable and available resources. In our opinion, this factor may have contributed to the small mortality rate observed in our study. Thus, appropriate triage of STEMI patients appears of critical importance not only for patients living in areas without immediate PCI facilities but also in large metropolitan areas where alerted hospitals can be reached in relatively short times (20).

The possibility of transporting patients with basic and advanced rescue units supplied with automatic external defibrillators and ambulance personnel trained to perform cardio pulmonary resuscitation manoeuvres, gave the opportunity of treating pre-hospital cardiac arrest when this occurred at home or during transportation. In our experience this was a relatively rare case (3.8%) and all of them were successfully treated.

As to the use of different survey periods to validate the advantages and limits of the Milan network, it is worth noting that analysis of data collected during short periods of time, and on different observation points has already been proven in terms of both reliability and easy implementation. Also in our case, collected data were in accordance with STEMI epidemiology and presented constant features over time. Moreover, repetition of data collection during three periods of time (MOMI² 1-2-3) allowed a continuous updating and a joint debate over collected data by the operators thus facilitating system optimisation.

Study limitation: it is important to recall that this was an observational study aimed to evaluate the role principal factors determining revascularisation delay in patient with STEMI in a great urban area. There was no attempt to influence patients' management in regard to the revascularisation modalities or concomitant therapy.

Conclusions: Our study indicates the efficacy of an emergency cardiac network in a large urban area in which several cardiac structures impinge on. A simple instrument such as pre-hospital ECG recording and tele-transmission is the most critical factor necessary to keep door-to-balloon time within suggested limits also in a situation where most of STEMI patients are treated with PCI. Our data also indicate the importance of increasing the number subjects with STEMI who turn to the 118 Dispatch centre at early time in order to alert the system and further reduce any delay in the revascularisation process. The possibility of implementing 12 lead ECG transmission also in basic rescue units is the further step of Milan network organisation that will be tested in the next years.

Conflict of Interest: none declared'.

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Figure legends:

Figure 1: Flanked boxplot of distributions of Door to Balloon times stratified by different modalities of admittance in the hospital. The red line corresponds to 90 minutes. BRU: basic rescue units; ARU: advanced rescue units.

Figure 2: Flanked boxplot of distributions of door-to-balloon times stratified by different covariates. The red line corresponds to 90 minutes.

Figure 3: Discriminant power of different variables: ECG recording and tele-transmission was markedly superior to modality of admission, activation of a Fast track and time of the day in determining a door-to-balloon time < 90 minutes.

Table I: Clinical settings and baseline characteristics of the study population

Age	64 (54 – 71)
Male (%)	342 (75%)
Female (%)	117 (25%)
Anterior MI (%)	52%
Killip >2	9%
Symptoms (%)	
Chest pain/discomfort	97%
Syncope	1.1%
dyspnoea	2.2%
Pre-hospital Cardiac Arrest (%)	4.4%
Modality of hospital admittance (%)	
Spontaneous	43%
Managed by 118 Dispatch Center	57%
BRU	44%
ARU	16%
ARU+teleECG	40%

BRU: basic rescue units; ARU: advanced rescue units.

Table II: Timing from symptom onset to hospital; door-to-balloon and first 12 lead ECG recording.

Time (min):	
Symptoms to ER	102 (60 – 190)
Door-to-Balloon	80 (51 – 119)
Door to first ECG (min)	
if done in ER	8 (4 – 17)
if done on the ground	-22.5 (-34.75 – 0)

Data are expressed as median (first-third quartile). ER: Emergency room.

Table III. Test on distributions of Door to Balloon times stratified by different covariates.

Covariate	p-value
Tele ECG	<0.00001
Time of first ECG	<0.0000001
Fast Track	<0.000001
Time of hospital admittance	<0.0001

Figure 1
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Time Door to Balloon

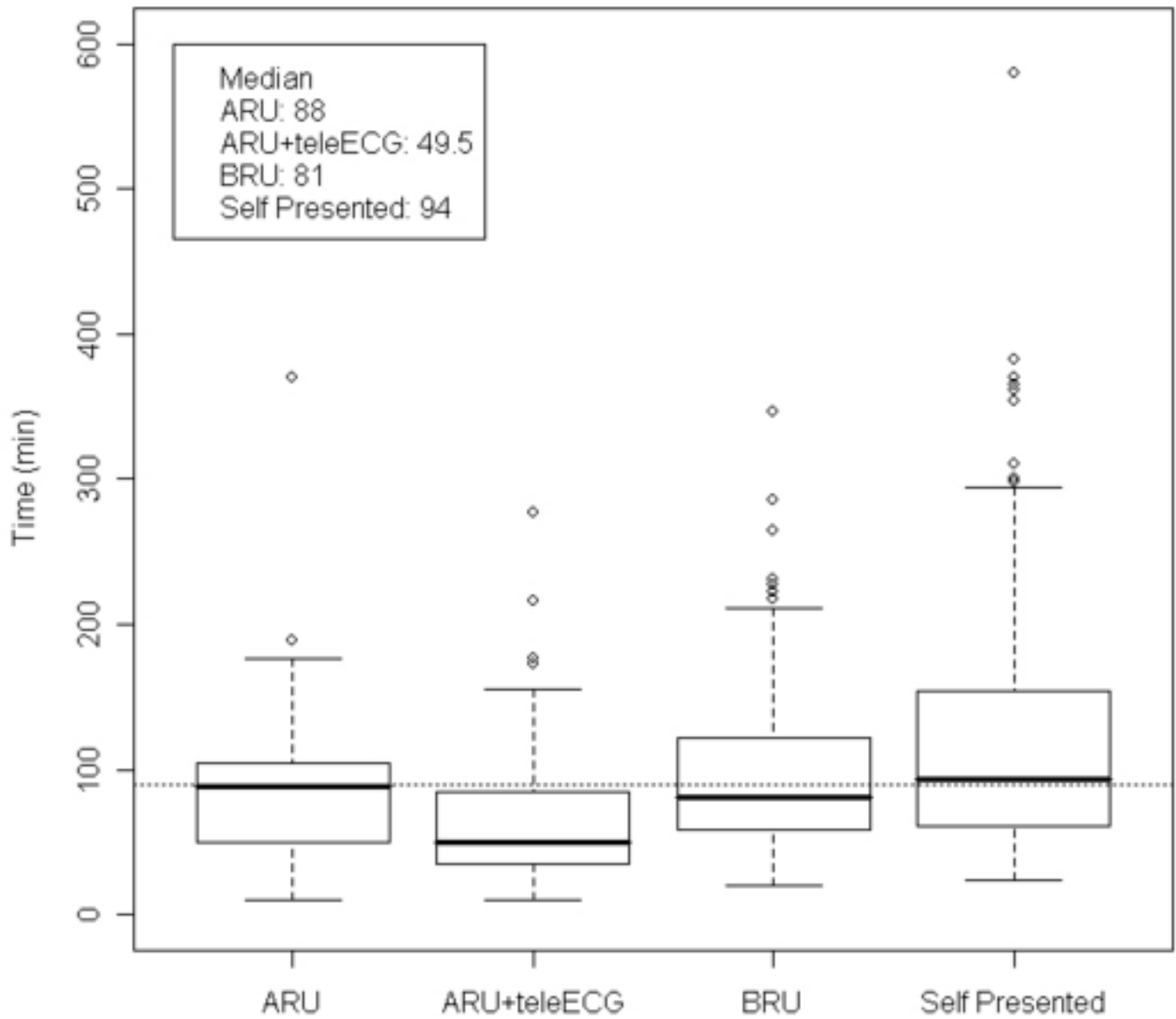


Figure 2

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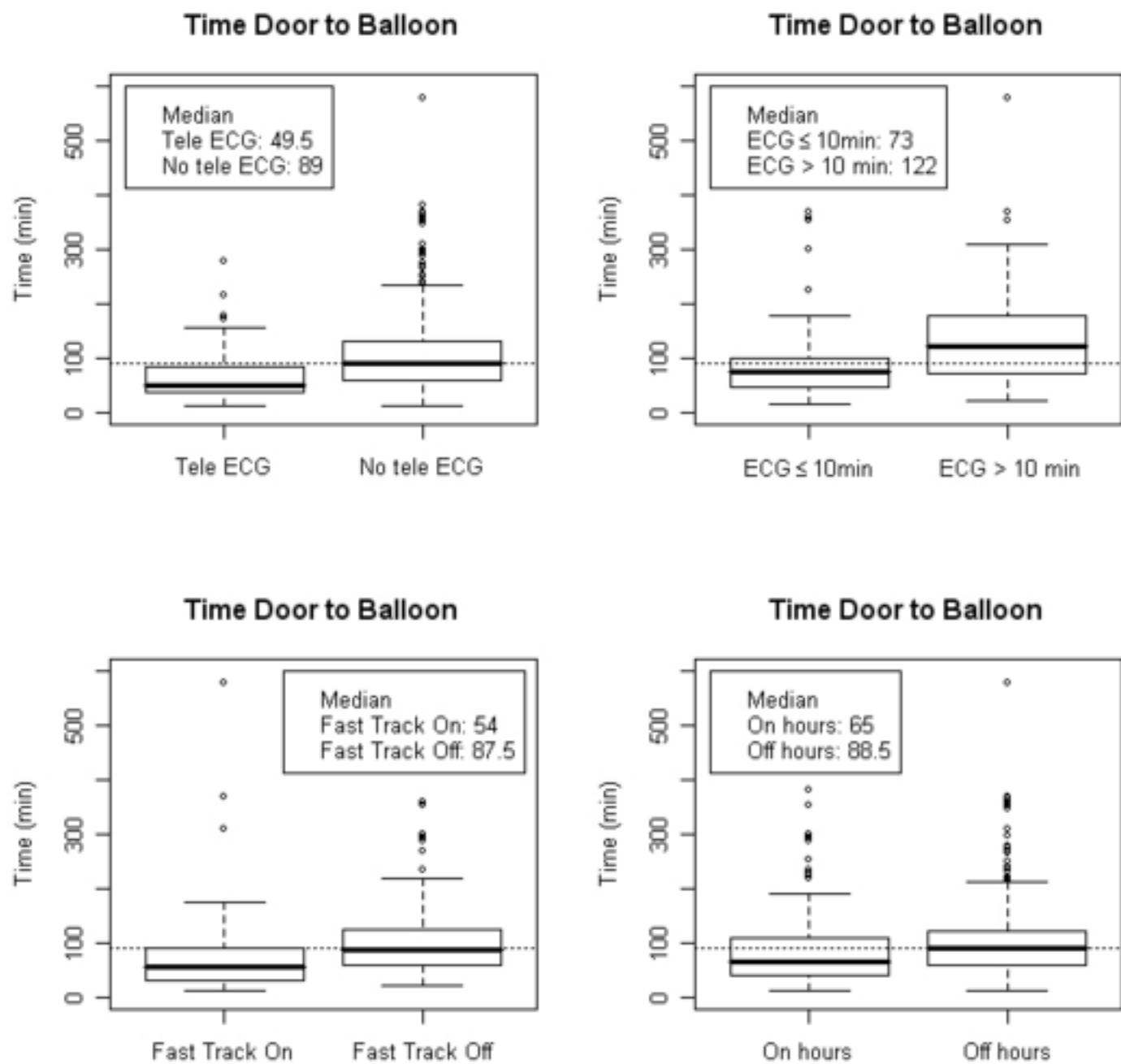


Figure 3
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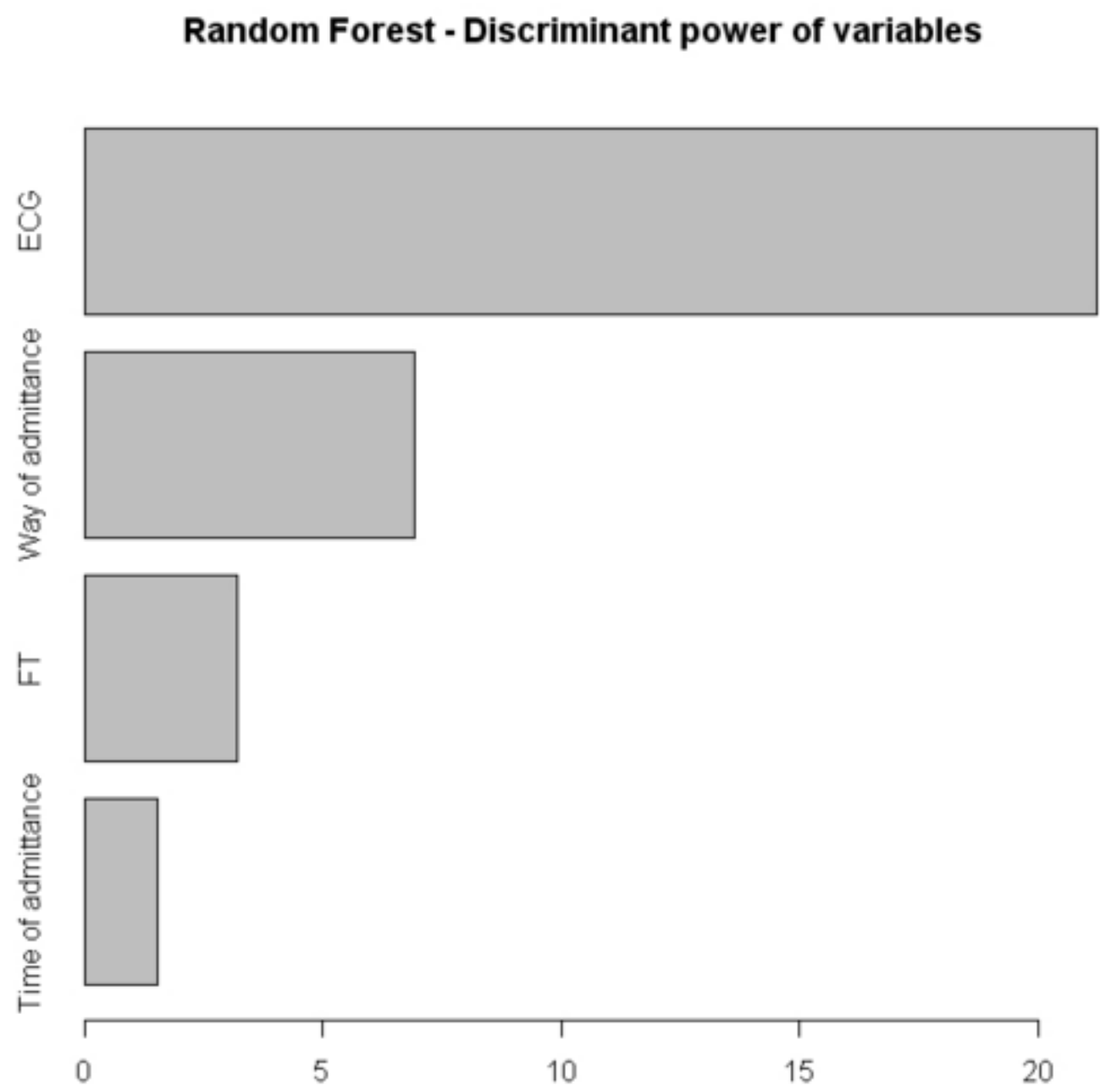
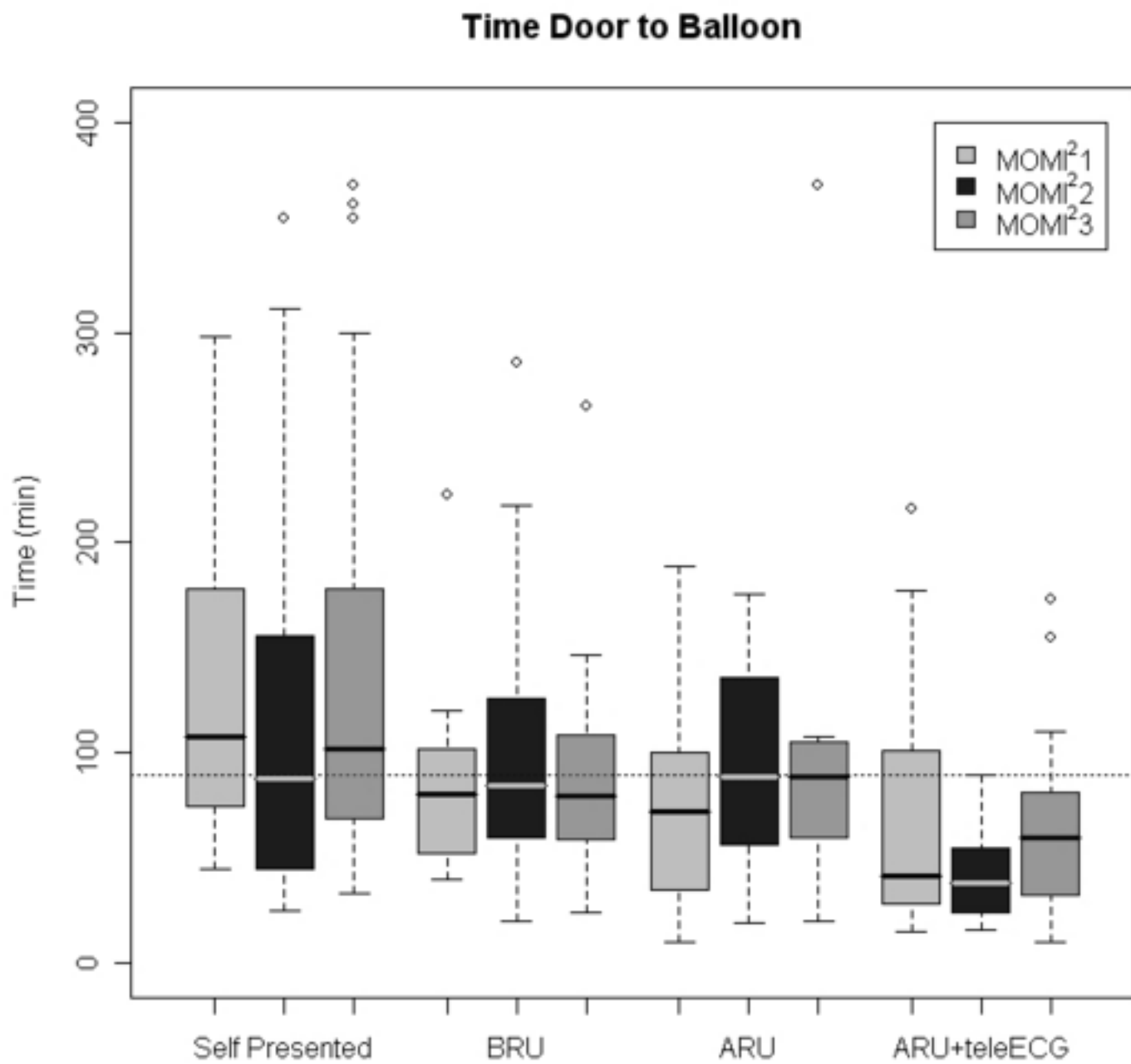


Figure 4
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