

Optimization of Door-to-Balloon Time Implementing a Process Improvement Program

Optimización del tiempo puerta-balón mediante la implementación de un programa de mejora de procesos

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ABSTRACT

Background: Primary percutaneous coronary intervention has played a major role in the treatment of ST-segment elevation acute myocardial infarction (STEMI). Delay in revascularization of the culprit vessel affects patient's prognosis. Systematization within a medical institution with catheterization laboratory influences treatment delays.

Objective: The aim of this study was to analyze the impact of a process improvement program on the door-to-balloon time of patients admitted with STEMI in a center with capability to perform primary percutaneous coronary intervention on a 24/7 basis.

Methods: Patients with a diagnosis of STEMI requiring primary percutaneous coronary intervention were prospectively and consecutively included from January 2014 to May 2016. The population was divided into three periods: p1 control; p2 program implementation; p3 program operation. Patients with progressive STEMI, rescue angioplasty and Killip and Kimball D were excluded from the study. An analysis of the system was performed to detect the barriers by means of an improvement model. The process was redesigned incorporating the following strategies: ambulance preactivation for patient admission, bypassing the emergency department and catheterization laboratory activation.

Results: Three hundred and fifteen patients were included in the study (p1: 125, p2: 99, p3: 91). There were no differences in baseline population characteristics between the periods analyzed. In 27.1% of cases patients consulted directly at the emergency room, 47.7% were admitted through the emergency service and 24.6% were referred from another center without capacity to perform primary percutaneous coronary intervention.

During p3, pre-activation, bypassing the emergency department and possibility of a ready cath lab were implemented in 54.1%, 59.7% and 79.1% of patients, respectively. A significant reduction in door-to-balloon time was observed throughout the periods [p1 76 min (IQR 55-120), p2 53 min (IQR 30-89) and p3 46 min (IQR 29-59); $P < 0.01$]. The trend was maintained both during working hours [p1: 76 min (IQR 53-125), p2: 36 min (IQR 26-60) and p3: 40.5 min (IQR 21-53.5); p1 vs. p3 $p = 0.02$] as during the emergency shift [p1: 80.5 min (IQR 60.2-115), p2: 80 min (IQR 37-100) and p3: 54 min (IQR 34-62, 7); p1 vs. p3 $p = 0.01$]. Impact was obtained in the first physician contact-balloon time [p1: 149 min (IQR 105-195) vs. p3: 94 min (IQR 73.5-130); $p = 0.012$].

Conclusion: An improvement program allows a significant reduction of the door-to-balloon time in patients admitted with STEMI in a center with capability to perform primary percutaneous coronary intervention on a 24/7 basis.

Key words: Myocardial Infarction - Angioplasty - Time-to-Treatment

RESUMEN

Introducción: La angioplastia primaria ha tomado un papel preferencial en el tratamiento del infarto agudo de miocardio con supradesnivel del segmento ST (IAMcST). El retraso en la revascularización de la arteria responsable afecta el pronóstico del paciente. La sistemática dentro de una institución médica con servicio de hemodinamia influye en las demoras al tratamiento.

Objetivo: Analizar el impacto de un programa de mejora de procesos en el tiempo puerta-balón de pacientes admitidos con IAMcST en un centro con capacidad de realizar intervención coronaria percutánea primaria 24/7.

Material y métodos: Se incluyeron en forma prospectiva y consecutiva pacientes con diagnóstico de IAMcST que requirieron intervención coronaria percutánea primaria desde enero de 2014 a mayo de 2016. La población se dividió en tres periodos: p1 control; p2 implementación del programa; p3 funcionamiento del programa. Se excluyeron los pacientes portadores de IAMcST evolucionado, angioplastias de rescate y pacientes con Killip y Kimball D. A través de un modelo de mejora, se realizó un análisis del sistema para detectar las barreras. Se rediseñó el proceso incorporando las siguientes estrategias: preactivación de ambulancia por admisión, puenteo de la guardia y sala lista.

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Resultados: Se incluyeron 315 pacientes (p1: 125, p2: 99, p3: 91). No se evidenciaron diferencias en las características basales de la población entre los períodos analizados. El 27,1% de los pacientes consultaron directamente en la guardia, el 47,7% ingresaron a través del servicio de emergencia y el 24,6% lo hicieron derivados de otro centro sin capacidad para realizar intervención coronaria percutánea primaria.

Durante el p3, la preactivación, el puenteo de la guardia y la posibilidad de tener la sala lista se implementaron en el 54,1%, el 59,7% y el 79,1% de los pacientes, respectivamente. Se evidenció de forma significativa una reducción del tiempo puerta-balón a través de los períodos [p1 76 min (RIC 55-120), p2 53 min (RIC 30-89), p3 46 min (RIC 29-59); $p < 0,01$]. Tanto en horario laborable [p1: 76 min (RIC 53-125), p2: 36 min (RIC 26-60), p3: 40,5 min (RIC 21-53,5); p1 vs. p3 $p = 0,02$] como durante el servicio de urgencia [p1: 80,5 min (RIC 60,2-115), p2: 80 min (RIC 37-100), p3: 54 min (RIC 34-62,7); p1 vs. p3 $p = 0,01$] se mantuvo la tendencia. Se obtuvo un impacto en el tiempo primer contacto médico-balón [p1: 149 min (RIC 105-195), p3: 94 min (RIC 73,5-130); $p = 0,012$].

Conclusión: Un programa de mejora permite reducir significativamente el tiempo puerta-balón en pacientes admitidos por IAMcST en un centro con capacidad de realizar intervención coronaria percutánea primaria 24/7.

Palabras clave: Infarto del miocardio - Angioplastia - Tiempo de tratamiento

Abbreviations

DBT	Door-to-balloon time	PCI	Primary percutaneous coronary intervention
ES	Emergency service	STEMI	ST-segment elevation acute myocardial infarction
IQR	Interquartile range		

INTRODUCTION

Primary percutaneous coronary intervention (PCI) has become the therapy of choice for the management of ST-elevation acute myocardial infarction (STEMI) due to its high rate of coronary recanalization. However, treatment of infarction depends on time, constituting a critical factor in reperfusion and patients' prognosis. (1-3)

The time of myocardial ischemia from symptom onset to recanalization involves different stages such as: patient consultation and attention of emergency services and healthcare institutions. These stages present delays that continue to be the subject of analysis and constitute a problem worldwide.

Systematization within a medical institution capable of performing 24/7 primary percutaneous coronary intervention (PCI) influences treatment delays. (4, 5) The time elapsed from patient arrival to the healthcare center to the opening of the artery (door-to-balloon time, [DBT]) is a crucial factor that determines treatment efficacy and is considered one of the main indicators of quality of care. (6-9)

Time reductions within the healthcare system require knowledge of the specific components to be intervened in order to establish rules in the systematization of these patients' treatment.

With the purpose of reducing DBT in our institution, the diagnosis and treatment methodology was redesigned incorporating strategies generating multidisciplinary work. The aim of the present work was to analyze the improvement processes and their impact on DBT in a center with hemodynamic capability.

METHODS

From January 2014 to May 2016, patients with a diagnosis of STEMI activating the cath lab for primary angioplasty within 12 hours of symptom onset or between 12 to 24 hours of symptom persistence were prospectively and consecutively included in the study. The receiving center is private,

academic, and urban, with 24-hour cardiovascular surgery and circulatory support system availability. Patients with progressive STEMI, rescue PCI and Killip and Kimball D were excluded from the study

The population was divided into three periods. The first, pre-installation of the program (p1), from January to December 2014, the second, put into operation (p2), from January to September 2015 and the third, operational (p3), from October 2015 to May 2016.

In the second period, we formed a multidisciplinary team involving different areas that participate in the care of STEMI patients:

- Admission (administrative and security)
- External emergency department (doctors, nurses)
- Patient transfer supervisor (stretcher bearers, auxiliaries)
- Hemodynamics (doctors, nurses, technicians)

A continuous improvement model was chosen. It provides a structure that ensures the best way to achieve the goals. This model is based on four premises: 1) to define a clear objective, 2) to create correct measurements and certify the compilation of the desired information, 3) to modify the current process with ideas, 4) to test those changes. (10-12)

We defined DBT as the time from patient admission to the passage of the catheter guidewire through the coronary obstruction, according to international clinical guidelines.

In order to homogenize the criteria at an international level, the time from patient satellite hour of admission until the catheter guidewire is inserted through the culprit artery was taken as DBT. The hour of catheter guidewire passage is registered in the angiograph, providing the possibility of later audits. (13) A card was designed where the times of each intervening area were registered.

An in-depth analysis was performed of the current system at our center, detecting barriers that prolong the time from patient admission to the implementation of revascularization therapy. The working hours, where the service was in operation when a STEMI was admitted, were Monday through Friday, 7:00 AM to 8:00 PM. Out of these hours, the activation of the service was considered non-working hours.

Finally an improvement proposal was made where the

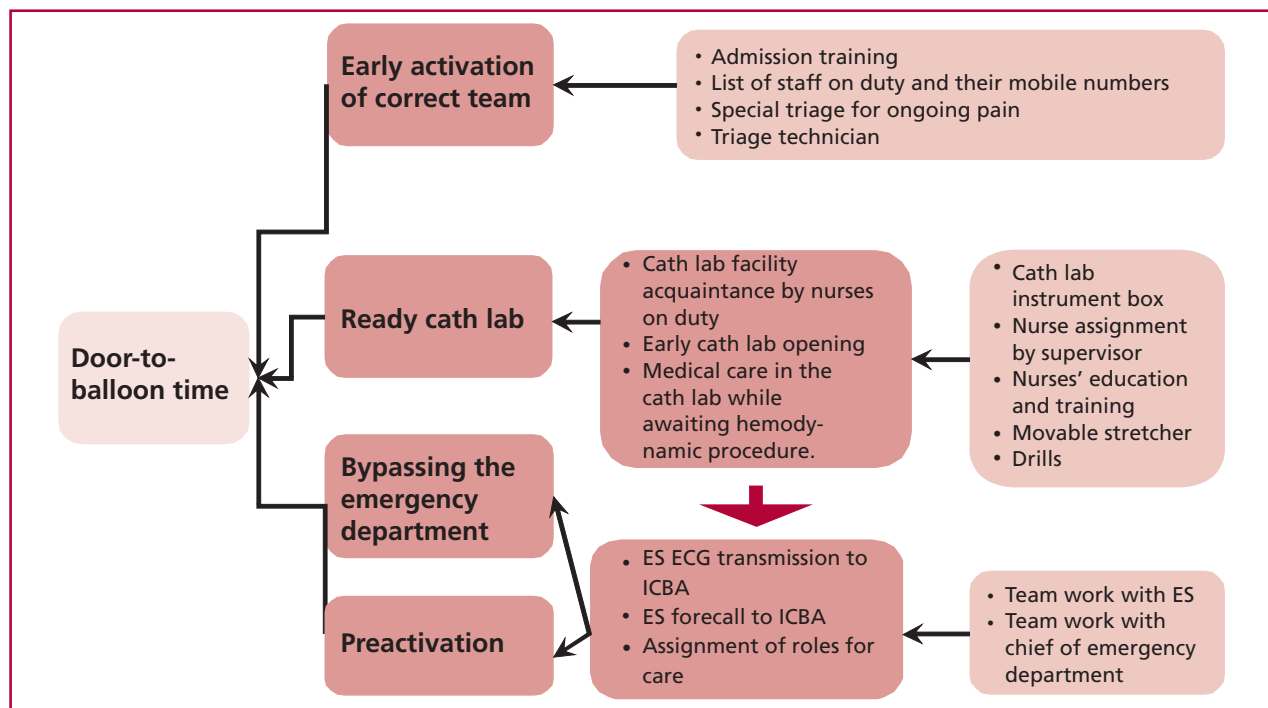


Fig. 1. Improvement proposal. ECG: Electrocardiogram. ES: Emergency service. ICBA: Instituto Cardiovascular de Buenos Aires.

following strategies were implemented (the changes applied in each strategy are detailed in Figure 1):

Ready cath lab: It includes the possibility of having the catheterization room in conditions to perform a procedure in the period when the service is closed (off-hours). It also, includes admitting and preparing the patient for the intervention, prior to the arrival of the hemodynamics team.

Bypassing the emergency department: Direct access to the cath lab of patients admitted by the emergency service (ES), once the diagnosis is made, avoiding delays and hospitalization in the emergency department.

Pre-activation through ES: Activation of the hemodynamic team after requesting transfer to the center of the patient with STEMI diagnosis, either from his home or from an institution. Interventional activation is performed by a single call to admission, both to the emergency department (emergency room) as to the interventional team, after receiving the STEMI transfer call either from a domicile or from a referral center.

Statistical analysis

Mean and standard deviation (SD) or median and interquartile range (IQR) were used to describe quantitative data. Categorical variables were described using absolute numbers and percentages. The chi-square test, t-test or Mann-Whitney test was used to compare data, as appropriate. A value of $p < 0.05$ was considered statistically significant. The Kruskal-Wallis test was used to compare multiple groups. SPSS (version 21.0 SPSS Inc., Chicago, IL) statistical package was used to perform the analyses.

Ethical Considerations

The door-to-balloon protocol was approved by the institutional Ethics Committee and Scientific Committee. In-

formed consent was requested from the patients for the use of medical information. The study members protected the privacy and confidentiality of the data in accordance with current legal regulations (Personal Data Protection Act 25,326).

RESULTS

During the three periods, 315 patients were admitted. In the first period, 125 patients were included, in the second period, 99 patients and in the third 91 patients. In 47.7% of cases the patients were admitted in our institution through the ES, while 27.1% consulted spontaneously and 24.6% were transferred from another center. The program was activated in 43.3% of cases during the hours of cath lab activity (working hours). There were no differences in the baseline characteristics of the patients in the different periods. (Table 1)

During program operation, the pre-activation strategy was implemented in 54.1% of cases, bypassing the emergency department in 59.7% and the “ready cath lab” strategy in 79.1%. The implementation of the first strategy allowed the hemodynamic team to enter the cath lab 32 minutes (IQR 7-50) before the patient’s arrival to the institution. Without using this strategy, the hemodynamic team was activated from the emergency department after patient assessment, and the delay in reaching the center was 28.6 minutes (IQR 8.5-40). After starting with the implementation of the pre-activation strategy, 5 patients with false activation were received in period 2

and 4 patients in period 3.

Bypassing the emergency department, significantly reduced the stay in this service prior to revascularization (bypassing the emergency department 5 minutes vs. non-bypassing the emergency department 33 minutes, $p=0.023$). Finally, the ready cath lab strategy allowed reducing by 10 minutes patient's stay in the emergency department (IQR 4.2-13, $p=0.034$).

Door-to-balloon time had a significant reduction across the three periods (Figure 2). Within this time, the strategies impacted by decreasing time on a first sub-step, "door-to-cath lab time" [p1: 30 min (IQR 12-62), p2: 24 min (IQR 5-45), p3: 11.5 min (IQR

5-27.7), $p=0.003$], as well as on the "hemodynamic room entry-to-catheter guidewire passage" time [(p1: 32 min (IQR 23-45), p2: 26 min (IQR 19-40), p3: 22 min (IQR 13-34), p1 vs. p3 $p = 0.032$).

Door-to-balloon time reduction was observed both in patients who spontaneously consulted at the emergency department: [p1: 107 min (IQR 81.7-135), p2: 84.5 (IQR 62.2-100), p3: 54.5 (IQR 36-70.7)], as in patients admitted through the ES (p1: 80 min (IQR 53-111.7), p2: 44 (IQR 28-80), p3: 40 (IQR 24-57), $p=0.036$) (Figure 3).

Both during the hours with active cath lab [p1: 76 min (IQR 53-125), p2: 36 min (IQR 26-60), p3: 40.5

	Period 1 (n = 125)	Period 2 (n = 99)	Period 3 (n = 91)	p
Age, years	61 (54-65)	62,4 (58-70)	60,1 (53,1-70,7)	0.794
Hypertension, %	59.5	69	56.3	0.573
Dyslipidemia, %	56.8	55.2	50	0.846
Diabetes, %	17.3	15.6	14	0.781
Smoking (%)	32.4	31	43.8	0.509
FH, %	13.5	17.2	21.9	0.658
Prior PCI, %	16.2	6.9	25	0.161
Prior CABGS, %	2.7	0	3.1	0.646
Prior AMI, %	16.2	3.4	18.8	0.170
KK A-B, %	88	90	93.4	0.798
Previous STEMI, %	45.6	50.5	49.4	0.612
ES, %	48.8	48.4	50.5	0.252
Direct consultation, %	24.8	28.2	22.1	0.174
Transfer from another institution, %	26.4	23.4	27.4	0.398
Prepaid health insurance, %	61.6	59.5	64.8	0.421

Table 1. Baseline characteristics according to the period

FH: Family history. PCI: Percutaneous coronary intervention. CABGS: Coronary artery bypass graft surgery. AMI: Acute myocardial infarction. KK: Killip and Kimball classification. STEMI: ST-segment elevation acute coronary syndrome. ES: Emergency service.

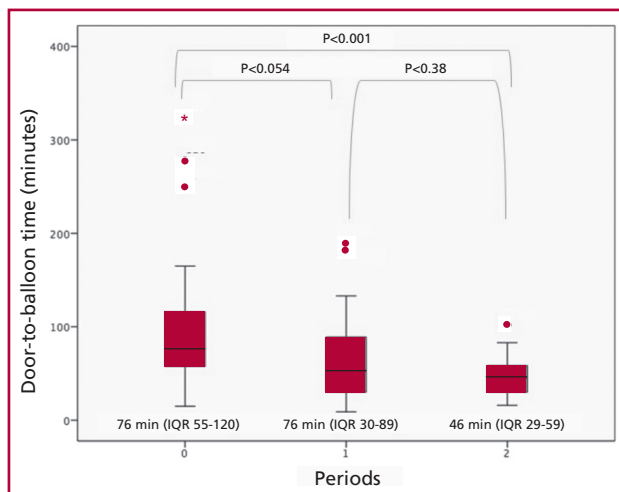


Fig. 2. Door-to-balloon time according to the program period

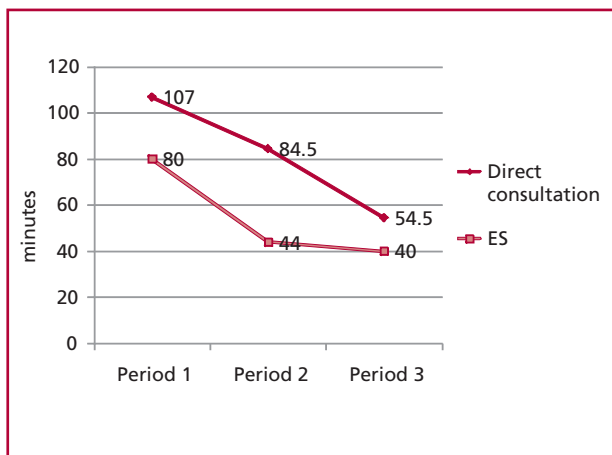


Fig. 3. Door-to-balloon time and activation of the healthcare system. ES: Emergency service

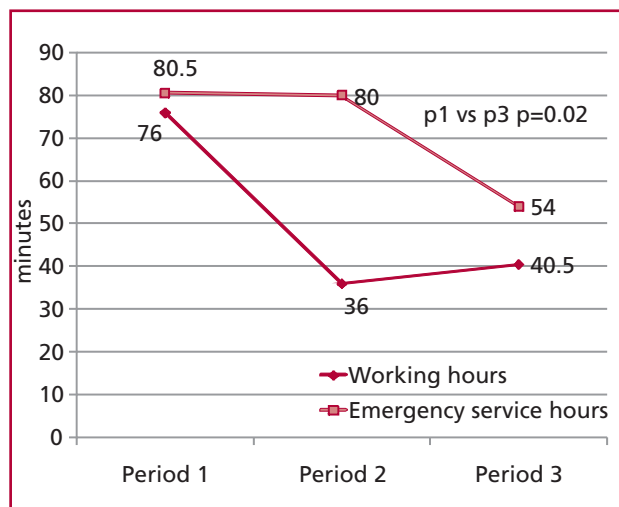


Fig. 4. Door-to-balloon time in working versus emergency hours. p1: Period 1. p3: Period 3.

min, (IQR 21-53.5), p1 Vs p3 $p=0.02$] as during the emergency service hours [p1: 80.5 min (IQR 60.2-115), p2: 80 min (IQR 37-100), p3: 54 min (IQR 34-62, 7), p1 vs p3 $p=0.01$] DBT was significantly reduced. (Figure 4)

Finally, the strategies that were incorporated demonstrated a positive impact on ischemic time, i.e. from the first medical contact to revascularization (catheter guidewire passage) [p1: 149 min (IQR 105-195) p3: 94 min (IQR 73.5- 130), $p=0.012$].

DISCUSSION

The implementation of a door-to-balloon program in an institution with capability to perform PCI allowed understanding the particular delays of the center, recognizing the barriers and implementing an improvement process which significantly reduced the time to reperfusion.

Over the years, several registries have positively reflected an increase in the utilization rate of suitable pharmacological treatments and the use of mechanical reperfusion thanks to scientific evidence and the constant work of cardiologic societies. In our country, there have been local initiatives to assess health quality of care in the public health system of the Autonomous City of Buenos Aires as well as in the Multicenter SCAR Registry (Acute Coronary Syndromes in Argentina). This has stimulated multiple centers to identify time delays in STEMI; however, the conclusion in these registries shows the low compliance to the appropriate times for the use of reperfusion treatments leaving a great opportunity for improvement. (14-17)

The delays in STEMI reperfusion therapy show several components, such as the time between the onset of symptoms and the contact with the healthcare system, the time elapsed between the patient's first medical contact and arrival to a healthcare center

and the time to reperfusion after being hospitalized. The latter, being sensitive to improvement processes, is the focus of our research. These improvement processes are initiated by a coordinated and multidisciplinary working team (administrators, nurses, doctors) that allow implementing a protocol, evaluating its evolution, auditing the process and continuously monitoring the improvement in the quality of care. We understand by quality, the extent by which healthcare services provided to individuals increase the likelihood of achieving the desired health outcomes and are in line with timely, patient-centered and cost-effective professional knowledge. Quality could be measured throughout the entire assistance process and/or by the final results of clinical practice. (9, 18) This measurement allows comparing the medicine offered in relation to the recommendations made by clinical guidelines; developing strategies within a program to achieve the proposed goal. Thus, through knowledge of the barriers in our system, improvement strategies that seek to overturn these limitations have been implemented. By means of these strategies we have transformed a serial and rigid system of actions into a process with parallel actions, achieving them in a shorter period of time.

When generating improvement strategies, resources sometimes limit start-up and normal operation. However, in our experience, we recommend changes in the processes, highlighting education directed to the different sectors involved, creating a new culture of rapid reperfusion. It is also worth noting that these strategies are applicable in other healthcare systems, provided they are carried out in a context of programs that start from the institution after analyzing the barriers of the center to implement it. This last point is of great importance as different systems and institutions present different obstacles.

The first link of this race against time is the individual performing the admission, either from referrals from another center, ambulance or direct patient consultation, communicating immediately to the triage staff in the direct consultation or communicating to the medical staff of the emergency department, thus elucidating the probable type of acute coronary syndrome to be received. This first action is correlated with the following strategies: after patient diagnosis and reception in the PCI center, it is vital that the rest of the process be continued in the cath lab. With this premise, the "nursing staff available in the institution" was trained to open and prepare this lab.

This allows discounting delays by specialized hemodynamic staff not present in the center, during non-working hours. It also allows avoiding a significant delay in the emergency department of patients who arrive with the ES. Conversely, bypassing the emergency department is a strategy that causes a certain aversion when implemented. This is described in previous publications, where its adoption by the centers is low, secondary to great staff mobilization and

commitment. (19, 20) The adaptation by the medical and non-medical staff required a period of education and set-up, including the security staff team. This staff receives the ambulance identified with the STEMI patient and with the certification of the doctor on duty bypasses the emergency department.

It is well known in the literature that the time elapsed between the arrival to the center and a ready cath lab is the period that most extends DBT. (21) Although notably, strategies are more oriented towards the patients that arrive through the ES, the implementation of immediate triage to the patients with “pain in course” and the prompt mobilization to the cath lab, also allows a reduction in time to reperfusion treatment, both in working and non-working hours.

The use of the “first medical contact-to-balloon” time included in the guidelines became important when evaluating which reperfusion strategy is most effective, besides representing more accurately the time of the medical system. Undoubtedly, it is an indicator of quality of care that includes the time in which the patient contacts the healthcare system and the need for urgent reperfusion is indicated. As we have shown in our experience, a program that engages the different areas of a center efficiently presents a significant scope, which involves the time of the system prior to contact with the receiving center.

We are aware that the optimal treatment of STEMI should be based on the use of networks between hospitals with diverse levels of complexity connected by an efficient ambulance service. This type of network reduces treatment delays and increases the amount of patients receiving reperfusion. (14, 22-24) Working teams in scientific societies through the Stent for Life Argentina initiative are struggling to improve the access of patients with STEMI to a quality reperfusion treatment with the aim of reducing morbidity and mortality.

However, in order to achieve these goals, it is vital to begin with the internal organization of our centers, with a view to being incorporated into these networks by efficient work.

Limitations

This is a study of limited scope due to specific characteristics of the centers included. The most effective strategies for increasing the proportion of patients receiving reperfusion and reducing delays in primary PCI may be different in other healthcare systems. As already mentioned, although all the patients referred to our center during the study period were included, providing a good representation of operation in the “real world”, a selection bias in relation to the type of patient being treated cannot be ruled out. In fact, we do not know the actual incidence and characteristics of infarcts treated with effective fibrinolysis or not treated with any reperfusion therapy in that period.

CONCLUSIONS

The implementation of an improvement process reduces the time of action in the care of patients with STEMI. The good functioning of this protocol is confirmed by consistent results under a multidisciplinary team.

Conflicts of interest

None declared.

(See authors' conflicts of interest forms on the website/Supplementary material).

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