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Abstract

Background: We report the preliminary data from a regional registry on ST-elevation myocardial infarction (STEMI) patients treated with primary angioplasty in Apulia, Italy; the region is covered by a single public health-care service, a single public emergency medical service (EMS), and a single tele-medicine service provider.

Methods: Two hundred and ninety-seven consecutive patients with STEMI transferred by regional free public EMS 1-1-8 for primary-PCI were enrolled in the study; 123 underwent pre-hospital electrocardiograms (ECGs) triage by tele-cardiology support and directly referred for primary-PCI, those remaining were just transferred by 1-1-8 ambulances for primary percutaneous coronary intervention (PCI) (diagnosis not based on tele-medicine ECG; already hospitalised patients, emergency-room without tele-medicine support).

Time from first ECG diagnostic for STEMI to balloon was recorded; a time-to-balloon <1 h was considered as optimal and patients as timely treated.

Results: Mean time-to-balloon with pre-hospital triage and tele-cardiology ECG was significantly shorter (0:41±0:17 vs 1:34±1:11 h, p<0.001, –0:53 h, –56%) and rates of patients timely treated higher (85% vs 35%, p<0.001, +141%), both in patients from the ‘inner’ zone closer to PCI catheterisation laboratories (0:34±0:13 vs 0:54±0:30 h, p<0.001; 96% vs 77%, p<0.01, +30%) and in the ‘outer’ zone (0:52±0:17 vs 1:41±1:14 h, p<0.001; 69% vs 29%, p<0.001, +138%). Results remained significant even after multivariable analysis (odds ratio for time-to-balloon 0.71, 95% confidence interval (CI) 0.63–0.80, p<0.001; 1.39, 95% CI 1.25–1.55, p<0.001, for timely primary-PCI).

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Conclusions: Pre-hospital triage with tele-cardiology ECG in an EMS registry from an area with more than one and a half million inhabitants was associated with shorter time-to-balloon and higher rates of timely treated patients, even in 'rural' areas.

Keywords
Tele-cardiology, pre-hospital electrocardiogram, pre-hospital triage, ST-elevation, acute myocardial infarction, primary coronary angioplasty, emergency medical service

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Introduction

Time to reperfusion is crucial in reducing the necrotic zone[1] and improving prognosis[2] in patients with acute myocardial infarction (AMI). Several strategies were therefore implemented over time with the aim to increase the rates of subjects with AMI who receive reperfusion within the benchmark 'golden hour'.[3–5]

Pre-hospital triage with electrocardiogram (ECG)[6] and tele-medicine support[7–9] are among these strategies. Such organisational expedients, however, risk failure when not matched with institutional networks specifically aimed at ST-elevation myocardial infarction (STEMI) treatment with primary PCI. Therefore, several networks for primary PCI models have been proposed so far: some cover a relatively small geographic area,[10] some, based on the work of paramedics and many emergency medical service (EMS) agencies, rely on computer algorithm interpretation that identifies AMI;[11,12] best results are available when larger areas are covered by a primary PCI network[13] and pre-hospital ECGs are read by a physician with a single EMS.[14–16]

Data on pre-hospital ECG triage are also currently available from our country,[17] Italy, but too often they relate to a single catheterisation laboratory, smaller areas and populations.[18,19]

We therefore report the preliminary data (provinces of Bari and Barletta/Andria/Trani (BAT)) on time-to-balloon and timeliness of treatment coming from a regional registry on STEMI patients treated with primary angioplasty in Apulia, Italy, a region with four million inhabitants. The region is covered by a single public health care service, a single public EMS, and a single tele-medicine service provider.

Methods

The provinces of Bari/BAT (5363 km^2 (3825+1538 km^2 respectively) contain about 1,637,778 inhabitants (1,246,222+391,556 respectively). The regional network for primary PCI in STEMI was started in Apulia in January 2012. Eight PCI intervention laboratories providing 24/7 service are located in the Bari/BAT provinces (six in Bari, one in Acquaviva and one in Andria, Figure 1).

Two hundred and ninety-seven consecutive patients with STEMI transferred by regional free public EMS 1-1-8 ambulances and crews for primary PCI from 1 October 2012–30 April 2013 were enrolled in the 'Apulia Regional Registry on STEMI of 1-1-8 EMS' and in the study.

The telephone number 1-1-8 is the Italian public free service for general medical or surgical emergencies, with the aim of an immediate diagnosis of critical diseases in order to avoid emergency room delay-to-diagnosis. Final hospitalisation is arranged by teams of physicians and 1-1-8 district central, connected by mobile phone: direct admission to a critical care unit is arranged according to the level of care needed. Patients are discharged from the ambulance and not transported at all in the case of normal findings. According to Italian legislation, 1-1-8 crews usually include a physician skilled in emergency medicine and/or nurses and the ECG should be preferably read by a cardiologist.

All crews of regional 1-1-8 EMS (n=154) are therefore equipped with a CardioVox P12 12-lead ECG recorder (Aerotel, Holon, Israel): the device may record a complete 12-lead ECG which is read by a cardiologist available 24/7 after (mobile-) telephone transmission to a unique regional medicine support 'hub', located in Bari, capital city of Apulia, Italy. Paramedics and physicians, as 1-1-8 personnel, may be shown back ECGs on smart-phones connected with the tele-cardiology hub. Logistic support for the tele-medicine hub was provided by Cardio On Line Europe S.R.I., Bari, Italy, as described elsewhere. A cardiologist available 24/7 within tele-cardiology hub promptly reads the ECGs sent by EMS personnel from all over Apulia. In the case of STEMI, the patients are immediately addressed to the nearest catheterisation laboratory for the appropriate treatment.

The 1-1-8 ambulances are also committed to inter-hospital transfer of patients with STEMI from a 'spoke-hospital' without primary PCI capability to a 'hub-hospital' where primary PCI can be performed 24/7.

Patients enrolled in the study were therefore divided in two groups, those diagnosed with pre-hospital ECG delivered by tele-medicine support (118-TeleC) and controls not diagnosed with STEMI but just transferred by

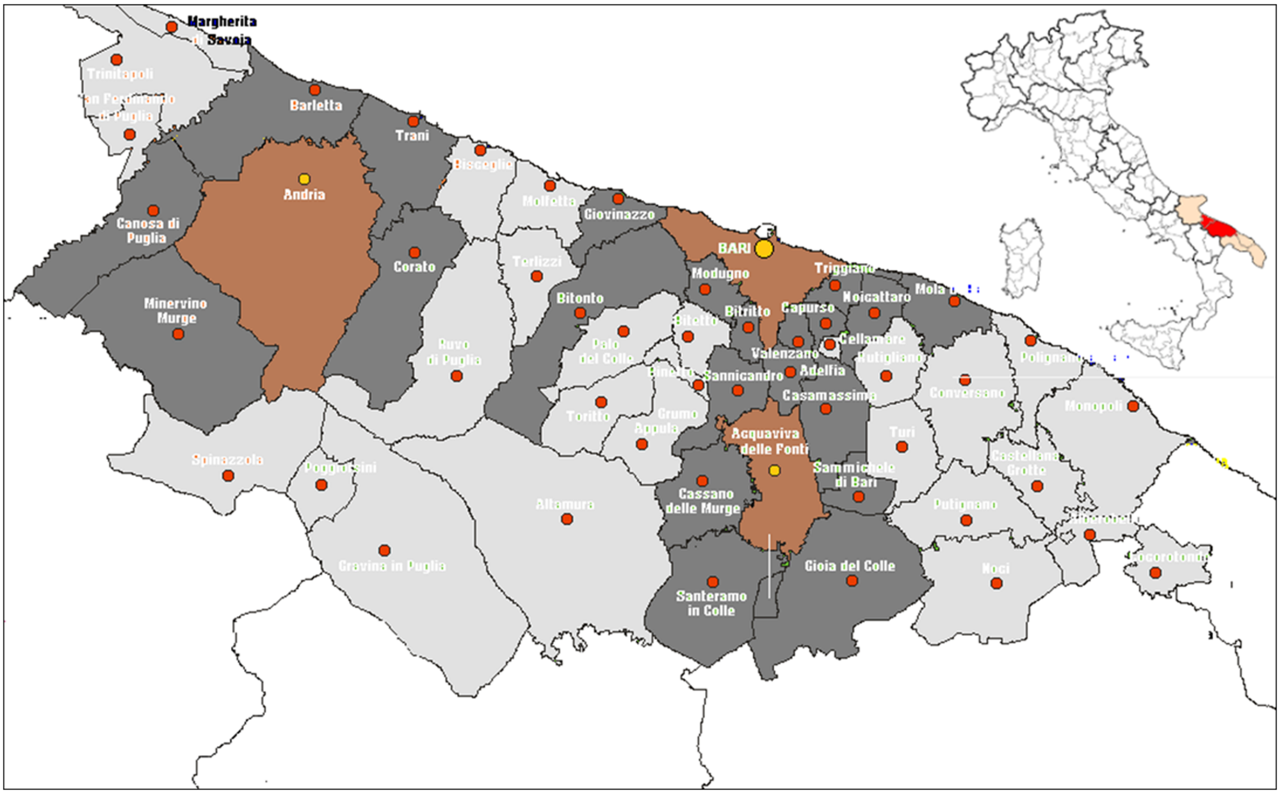

Figure 1. Bari and Barletta/Andria/Trani provinces, Apulia, Italy. In brown, cities with a catheterisation laboratory available 24/7 for the network for primary PCI in ST-elevation myocardial infarction; in dark grey, towns immediately closer ('inner' zone); in light grey, towns not immediately close to towns with 24/7 catheterisation laboratory for primary PCI.

1-1-8 crews (118-Transf). Subjects in the latter group are those diagnosed with STEMI in emergency departments without tele-medicine support and PCI facilities or already hospitalised not in a PCI hub-hospital when the diagnosis of STEMI was done: in such patients the 1-1-8 service was used just for patient transfer to the catheterisation laboratory for primary PCI. Subjects with a diagnosis of STEMI done in PCI-capable hospitals, and therefore not needing 1-1-8 transfer, were not enrolled in the registry.

The towns in the Bari-BAT provinces were also divided into two groups: those with an on-site catheterisation laboratory able to perform primary PCI 24/7 (primary PCI hub) or those with an immediately closer primary PCI hub ('inner' group), and the others not with a primary PCI hub or not immediately closer to a primary PCI hub ('outer' group) (Figure 1).

Time from first ECG diagnostic for STEMI to balloon in the catheterisation laboratory was recorded for all patients. A time-to-balloon <1 h was considered as optimal and patients were considered as treated in a timely way if within this ideal time. The diagnosis of STEMI was based on current European Society of Cardiology guidelines.[20] Distances and standard transfer-times were calculated on the Google Map internet site (www.google.it/maps).

The study was authorised by local Health Authority (Agenzia Regionale Sanità Puglia) and conforms with the principles of the Declaration of Helsinki.

Statistical analysis

Continuous variables were reported as mean±standard deviation and compared with Student's *t*-test, dichotomous variables were reported as percentages and compared with the χ^2 test. Correlations were tested with Pearson's test. The odds ratio (OR) with 95% confidence interval (CI) was also calculated. Correction for principal confounders was performed in a multivariable analysis. A p value <0.05 was considered as statistically significant.

Results

Population characteristics are given in Tables 1 and 2: 41% of patients who underwent pre-hospital ECG with telecardiology support, 32% of patients came from the 'inner' zone (Tables 1 and 2).

Several characteristics were significantly different when comparing the 'inner' zone with the 'outer' zone (Table 3): in particular time-to-balloon, rates of subjects treated within 1 h, and, obviously, the distance between

Table 1. Population characteristics.

	297		123	Tele-cardiology	174	Controls	p
	Mean	SD	Mean	SD	Mean	SD	
Age	67.0	13.8	69.4	13.1	65.2	14.0	<0.05
Female	26% (77)		35% (43)		19% (32)		<0.01
Inner vs outer	32% (95)		60% (74)		13% (23)		<0.001
On-time treatment	56% (166)		85% (105)		35% (61)		<0.001
Time-to-balloon	1:13	1.01	0:41	0:17	1:34	1:11	<0.001
Km distance	30.1	18.1	20.9	21.4	36.5	11.7	<0.001
Drive distance	0:28	0.11	0:22	0.13	0:32	0:08	<0.001

SD: standard deviation.

Table 2. Comparison of 'inner' vs 'outer' zones.

	96	Inner zone	201	Outer zone	p
	Mean	SD	Mean	SD	
Age	66.8	14.1	67.1	13.7	n.s.
Female	25% (24)		26% (52)		n.s.
Pre-hospital triage with tele-cardiology	77% (74)		24% (48)		<0.001
On-time treatment	92% (88)		39% (78)		<0.001
Time-to-balloon	0:39	0:20	1:29	1:08	<0.001
Km distance	8.5	7.2	40.3	11.5	<0.001
Drive distance	0:14	0.04	0:34	0:07	<0.001

n.s.: not significant; SD: standard deviation.

Table 3. Impact on time-to-balloon and timely reperfusion of pre-hospital triage with tele-cardiology electrocardiogram (ECG) according to 'inner' vs 'outer' zone.

	74	Tele-cardiology	22	Controls	Inner	49	Tele-cardiology	152	Controls	Outer
	Mean	SD	Mean	SD	p	Mean	SD	Mean	SD	p
Age	68.6	13.0	61.6	16.2	<0.05	70.6	13.2	65.8	13.7	<0.05
Female	31% (23)		9% (2)		<0.05	41% (20)		21% (32)		<0.01
On-time treatment	96% (71)		77% (17)		<0.01	69% (34)		29% (44)		<0.001
Time-to-balloon	0:34	0:13	0:54	0:30	<0.001	0:52	0:17	1:41	1:14	<0.001
Km distance	7.1	7.2	15.9	12.8	<0.001	41.7	18.7	39.7	7.7	n.s.
Drive distance	0:13	0:04	0:18	0:07	<0.001	0:35	0:11	0:34	0:05	n.s.

n.s.: not significant; SD: standard deviation.

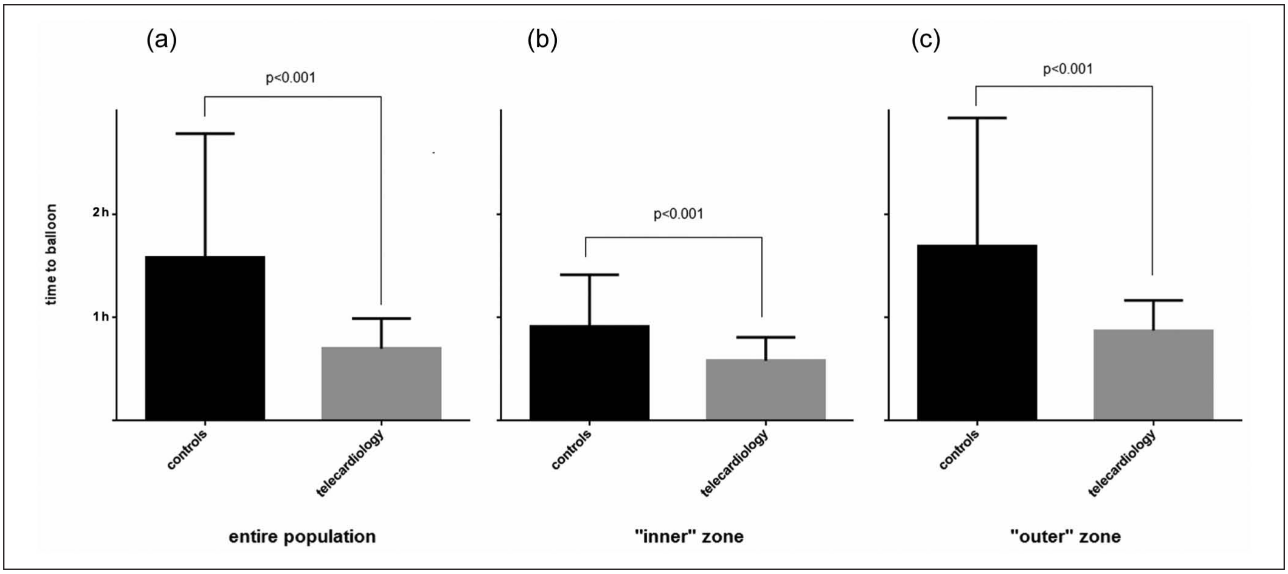

Figure 2. Time from electrocardiogram (ECG) diagnosis of ST-elevation myocardial infarction (STEMI) and catheterisation laboratory entrance (time-to-balloon); (a) entire population, (b) 'inner' zone, (c) 'outer' zone.

the place of diagnosis and PCI hub. Even the use of pre-hospital triage with tele-cardiology ECG was lower in the 'outer' zone.

No difference in terms of time-to-balloon and rates of timely reperfusion was found according to patients' age or gender, while distance from catheterisation laboratory was significantly related to time-to-balloon (OR 1.5, 95% CI 1.3–1.6, $p<0.001$), and rates of timely reperfusion (OR 0.6, 95% CI 0.5–0.6, $p<0.001$).

In the 118-TeleC group with the use of pre-hospital triage with tele-cardiology ECG, mean time-to-balloon was significantly shorter than 118-Transf group (0:41±0:17 vs 1:34±1:11 h, $p<0.001$, –0:53 h, –56%) (Figure 2(a)), and rates of patients treated within 1 h after first medical diagnosis higher (85% vs 35%, $p<0.001$, +141%) (Figure 3(a)).

The 118-TeleC group was characterised by lower time-to-balloon both for patients from the 'inner' zone (0:34±0:13 vs 0:54±0:30 h, $p<0.001$) and in the 'outer' zone (0:52±0:17 vs 1:41±1:14 h, $p<0.001$; –0:49 h (–48.5%) in the 'outer' zone vs −0:20 h (–37%) in the 'inner', $p<0.05$) (Figure 2(b) and (c)). Rates of patients treated within 1 h after first medical diagnosis in the 118-TeleC group were significantly higher both in the 'inner' zone (96% vs 77%, $p<0.01$, +30%), and in the 'outer' zone (69% vs 29%, $p<0.001$, +138%) (Figure 3(b) and (c)).

In the multivariable analysis, pre-hospital triage with tele-cardiology support was associated with lower time-to-balloon (odds ratio 0.71, 95% CI 0.63–0.80, $p<0.001$, Figure 4) and higher rates of patients treated within one hour from ECG diagnosis (odds ratio 1.39, 95% CI 1.25–1.55, $p<0.001$, Figure 5).

Discussion

Preliminary data on the Bari/BAT provinces coming from the Apulia regional 1-1-8 EMS Registry on STEMI show that pre-hospital triage with tele-cardiology ECG is associated with shorter time-to-balloon and higher timeliness of reperfusion. These results are achieved both in cities with a catheterisation laboratory immediately available 24/7, in closer areas, and in further external areas where primary PCI for STEMI needs longer ambulance transfer. The benefit of pre-hospital triage with tele-cardiology ECG is particularly remarkable in those 'peripheral' areas where any delay in diagnosis could further increase total delay to treatment which is inevitably linked to geographic distance from the catheterisation laboratory.

To the best of our knowledge, these are among the first data on the effectiveness of pre-hospital triage with tele-cardiology ECG in such a large population (more than one and a half million inhabitants), with a single EMS provider and a single tele-medicine service provider.

Data from a larger registry on much wider areas from our country have been already published, showing that pre-hospital ECG is associated with a trend of reduced 30-day mortality (5.3% vs 7.9%).[17] This benchmark registry (LombardIMA)[21] was the model for the Apulia registry on STEMI, though the Apulia registry on STEMI patients was an EMS (1-1-8) based registry; that means that transportation times were perfectly described while STEMI patients who directly entered a hospital with primary PCI capability (presumably a small fraction of total STEMI patients)[22] were missed by the registry. However, in just 12% of patients from the LombardIMA registry the pre-hospital

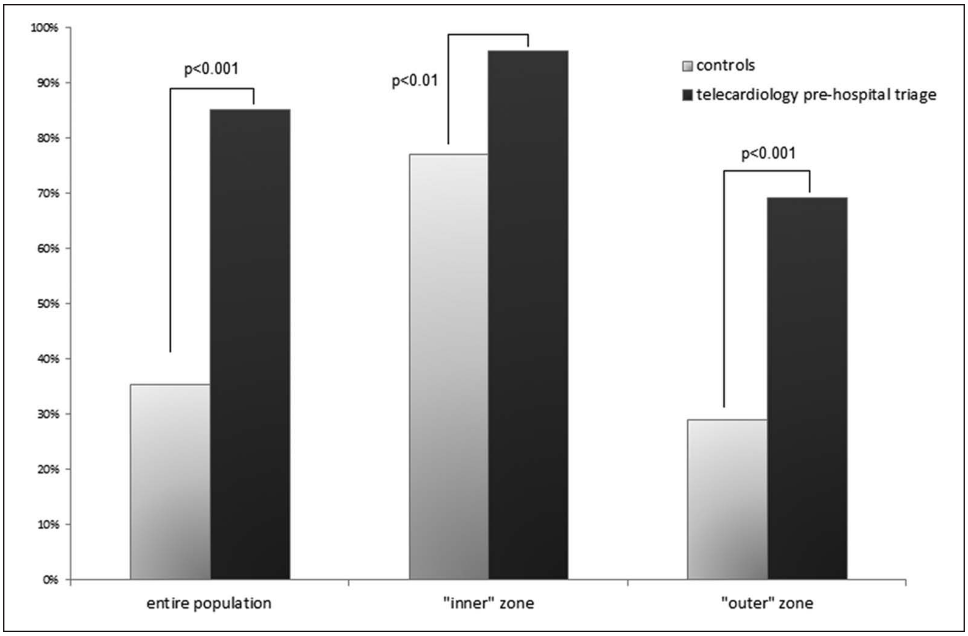

Figure 3. Rates of subjects treated within 1 h after first electrocardiogram (ECG) diagnosis of ST-elevation myocardial infarction (STEMI).

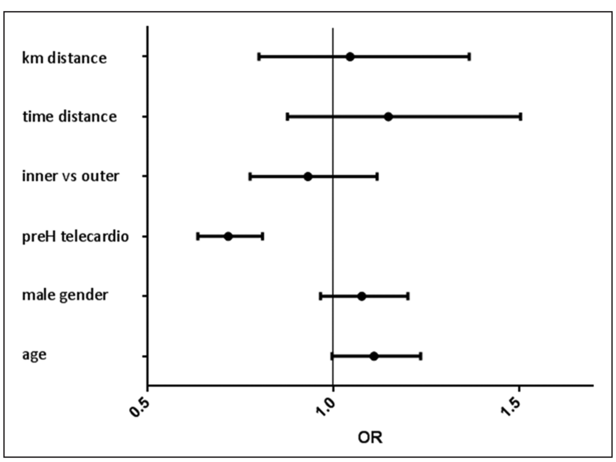

Figure 4. Multivariable analysis showing predictors of time-to-balloon in subjects with ST-elevation myocardial infarction (STEMI): pre-hospital triage with tele-cardiology support is associated with significantly lower time-to-balloon. OR: odds ratio; preH: pre-hospital.

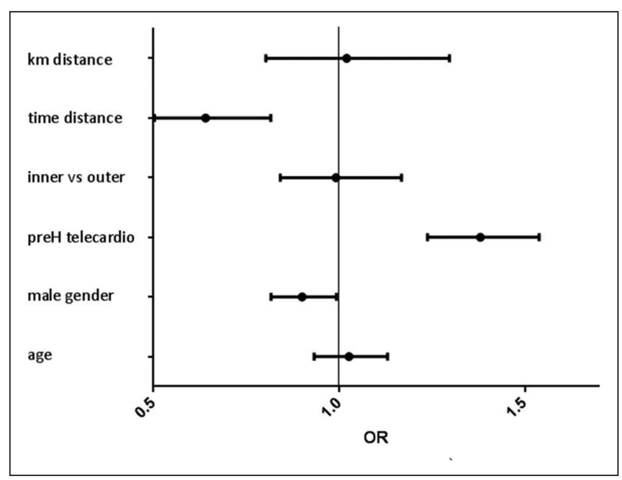

Figure 5. Multivariable analysis showing predictors of timeliness (within 1 h) time-to-balloon in subjects with ST-elevation myocardial infarction (STEMI): pre-hospital triage with tele-cardiology support is associated with higher rates of STEMI patients treated within 1 h after medical diagnosis. OR: odds ratio; preH: pre-hospital.

ECG was available; unlike the Lombardia region, Apulia provided all 1-1-8 EMS crews with a 12-lead ECG recorder since 2004. More than half a million ECGs have been sent to the tele-cardiology hub to be read so far, aiming at a pre-hospital diagnosis of acute cardiovascular disease as fast as possible.[7–9,23,24] Use of the pre-hospital 12-lead ECG in cases of suspected AMI has been advocated and recommended by guidelines[20,25] and scientific statements;[26] however, its use is still low.[27]

A lower mortality was found when pre-hospital ECG triage was used to bypass any emergency department delay.[28,29] An impressive reduction in STEMI mortality was reported by Chan et al. with a pre-hospital triage strategy: –59% relative risk reduction at 30 days, –62% at one year, even though very high mortality rates characterised the control group in this study.[30] Pre-hospital ECG was associated with a lower mortality even in subjects with STEMI and cardiogenic shock.[18] In another study by the same authors, patients with pre-hospital triage showed a lower rate of severely depressed left ventricular systolic function.[31]

In keeping with other reports, we found that pre-hospital ECG was associated with a decrease in balloon time.[27–29,32] In a cohort of patients scheduled for admission to a local hospital and subsequent transfer to an interventional centre for primary PCI, those diagnosed pre-hospital had shorter treatment delays compared with those diagnosed in-hospital, both in terms of initial admission to a local hospital, and to an even larger extent in terms of referral directly to the interventional centre.[14] In the MonAMI project, the performance of pre-hospital 12-lead ECG triage and emergency department activation of the infarct team significantly improved door-to-balloon time and resulted in a greater proportion of patients achieving guideline recommendations.[33] After ambulance-based diagnosis of STEMI, direct transport to an intervention centre with pre-hospital notification of the catheterisation laboratory more than tripled the proportion of patients treated within the time window of the guidelines.[34] Time-to-balloon was an independent predictor of post-procedural thrombolyis in myocardial infarction (TIMI) flow grade 3, which underscores the need to reduce treatment delays.

North Carolina, USA, has adopted a statewide STEMI referral strategy that advises paramedics to bypass local hospitals and transport STEMI patients directly to a PCI-capable hospital, even if a non-PCI-capable hospital is closer.[13,35] In a multivariable model, increases in differential driving time and cardiac arrest were associated with a lesser likelihood of being taken directly to a PCI centre, whereas a history of PCI was associated with a higher likelihood of being taken directly to a PCI centre. Patients sent directly to a PCI centre were more likely to have times between first medical contact and PCI within guideline recommendations, and a significantly shorter time to reperfusion.

The best way to interpret pre-hospital ECGs is still matter of debate. In a small population from San Diego, a pre-hospital electrocardiographic diagnosis of STEMI based on an automated computer algorithm markedly reduced the door-to-balloon time.[12] In a small single-centre study, pre-hospital activation of the catheterisation laboratory by EMS personnel based on automated ECG interpretation achieved a significant reduction in dispatch-to-reperfusion time and first medical contact-to-reperfusion time.[36]

However, accuracy of automated ECG interpretation is quite poor[36,37] and, according to current guidelines on ECG interpretation, a physician overview and confirmation is usually required after automated interpretation.[38]

Other authors showed, against an historical control cohort, that catheterisation laboratory activation and emergency department bypass by trained paramedics and pre-hospital ECG could improve the rates of STEMI patients re-perfused within 90 min.[39] Paramedic-referred primary PCI was shown as a safe and feasible strategy for treating STEMI that is associated with rapid and effective reperfusion and very low in-hospital mortality.[40] However, it has also been shown that paramedic readings could limit the efficacy of pre-hospital triage. In a large population from Netherlands 12-lead pre-hospital ECG was interpreted by the paramedics with the help of a computer algorithm. In case of a non clear-cut case of a patient with STEMI a contact with the cardiologist of the nearest hospital was often required.[34] Poor accuracy of paramedic ECG reading could be avoided by direct transmission of the pre-hospital 12-lead ECG directly to the attending cardiologist's mobile telephone for rapid triage and transport to a primary PCI centre, bypassing local hospitals and emergency departments.[16,41]

In an ideal scenario depicted by current guidelines on STEMI treatment, a consultation between cardiologist and on-field EMS personnel should be pursued[20] and all ECGs should be read by a cardiologist. This ideal scenario of widespread use of pre-hospital ECG and direct referral for primary PCI bypassing the emergency department would be best accomplished in a regional network with a single regional EMS[20] and, we add, with a single tele-medicine hub which allows all the ECGs to be read by a cardiologist. According to a pooled analysis of 10 independent, prospective, observational registries involving 72 hospitals from the USA, large regional STEMI-receiving centre networks and 9-1-1 with pre-hospital ECG triage may provide entire communities with timely access to quality STEMI care.[42]

In our registry about half of the patients with STEMI that we enrolled were triaged with pre-hospital ECGs: such higher rates have been rarely reported before. In the National Cardiovascular Data Registry on Acute Coronary Treatment and Intervention Outcomes Network registry on more than 7000 patients who were transported by EMS from 1 January 2007–31 December 2007, only 27.4% received a pre-hospital ECG.[27] Even lower rates of use of pre-hospital ECGs have been reported from Italy.[17] We still have a long way to go before a pre-hospital ECG is widely available in STEMI patients: tele-medicine support could be of help in bridging this gap.

It is noteworthy that the benefit of pre-hospital triage with tele-cardiology ECG was more evident in ‘outer’ areas, far from a primary PCI capable hub hospital. Preliminary data from the USA showed that the implementation of the use of pre-hospital ECG was associated with shorter first medical contact-to-balloon time even in a rural area; these data, however, come from a single centre and lack any control group.[43] More robust evidence from Denmark shows that pre-hospital electrocardiographic diagnosis and direct referral for primary PCI enables STEMI patients living far from a PCI centre to achieve a system delay comparable with patients living in close vicinity of a PCI centre.[15]

Moreover, pre-hospital triage with tele-medicine was associated with shorter time-to-balloon even considering STEMI which occurred in the same urban area where PCI hubs were located: however, subjects with STEMI treated with primary PCI who bypassed 1-1-8 because they were diagnosed in the emergency room of PCI-capable hospitals were missed by our registry.

The Apulia network for primary PCI surely shows some critical issues. Less than 30% of patients in the 'outer' area receive pre-hospital triage with tele-cardiology support. That means that several patients with chest pain suspected for AMI did not refer to 1-1-8, with a consequent significant delay to treatment. Awareness campaigns aimed at persuading people that 1-1-8 should be called in every case of suspected AMI should be launched by local health authorities.

Limitations

This is an observational study and non-randomised; no data are available on mortality, left ventricular function after reperfusion, reperfusion rates and coronary flow. Not all patients with STEMI were enrolled in this study, specifically not those who accessed primary PCI bypassing 1-1-8. Data on STEMI patients diagnosed straight away in the emergency room of PCI-capable hospitals were not reported in the registry.

Patients immediately transferred by spoke-hospitals bypassing 1-1-8 could also have been missed by the registry; missing these patients with presumably shorter time-to-balloon could have biased the time-to-balloon findings in the control group. No case of missed pre-hospital diagnosis of STEMI later requiring 1-1-8 transfer has been actually reported, although theoretically possible.

Conclusions

Pre-hospital triage with tele-cardiology ECG in an EMS registry from an area with more than one and a half million inhabitants was associated with shorter time-to-balloon and higher rates of patients treated within 1 h after first medical diagnosis, both in STEMI patients closer to a catheterisation laboratory with primary PCI capability and even more in those from more distant areas requiring longer ambulance transfer.

Conflict of interest

None declared.

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