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Pre-Hospital Care in ST-Segment Elevation Acute Myocardial Infarction

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Abstract

The key to proper management of patients with ST-segment elevation acute myocardial infarction (STEMI) is immediate treatment of the lethal arrhythmias, primary ventricular fibrillation (VF), and rapid access to reperfusion treatment. These two aspects condition the final prognosis of patients in such a manner that they have become the principal reference elements to improve the care of STEMI.

VF is responsible for early mortality [1] in the first few hours of onset and basically affects the group of patients who do not manage to reach hospital, those who die having received no healthcare assistance. This is a very large group of patients, with considerable percentage weight on the enormous total fatalities of this disease, [2] and also with an enormous impact on years of potential life lost, as it affects the younger age group within the population with STEMI, with a relation between out-of- and in-hospital mortality in age groups under 50 years, between 50 and 54 and between 55 - 59 years being 15.6, 6.7 and 4.7 respectively [3]. In this sense, it is important to stress that a very significant proportion of patients with STEMI treated with early defibrillation in the out-of-hospital setting are later discharged from hospital [4].

Immediate VF treatment is, logically, a type I indication in all the Clinical Practice Guidelines (CPG), as are also the means used to facilitate the immediate application of this treatment: information for patients on early recognition of symptoms, existence of medical emergency services (MES) with easy telephone access and a rapid response for in situ care [5,6]. It is easy to deduce that defibrillation is one of the key mandates, if not the primary, that justify the need for proper pre-hospital care.

The next basic prognostic factor is the re-establishing of blood flow in the artery responsible for the AMI (ARA) as soon as possible. The efficacy of useful treatments, pharmacological and mechanical reperfusion, is clearly and widely supported with evidence in the different Clinical Practice Guidelines [5,6]. In general, the use of one or other method, primary Percutaneous Coronary Intervention (pPCI) or chemical intravenous fibrinolysis, is conditioned by two aspects:

1. Delays in the effective application of treatment: time from onset of symptoms to infusion of drug in the case of fibrinolysis and inflation of balloon in primary PCI (pPCI). The early application of treatment is directly related to patient survival [7,8]. In the first three hours, both treatments are very effective, with certain differences favouring one over the other depending on the specific studies conducted [9]. Over three hours from onset, there is a clear benefit of pPCI over fibrinolysis, even questioning the use of fibrinolytic agents as opposed to the transfer to a centre with available PCI, unless this option is not viable [10]. We understand a centre with available PCI as a hospital with the real possibility of pPCI at the moment the patient arrives and that is capable of conducting the procedure in accordance with parameters compiled in the CPG (time, efficacy and safety). Therefore, a centre may be useful at certain times or for 24 hours if it has an on-call hemodynamic service, or it may temporarily cease to be useful for various reasons (saturation of unit, organisation problems, etc.). In any case, it would never be justified in this period, to cause delays that would delay

commencement of the final treatment to a period outside this optimal window [11,12].
2. Availability of resources. The specific application of these treatments is mediated in real life by the availability of resources. The majority of data from the records from AMI indicate that pPCI is used in times clearly higher than the recommendations. The same happens with fibrinolysis when restricted to the hospital setting [13-15], clearly highlighting that advances in this area are exceedingly slow [16]. In this context, out-of-hospital fibrinolysis (ohF) has become a recommended option in the CPG [5,6], where structured emergency pre-hospital services exist capable of establishing a specific STEMI care programme. Likewise, pPCI should be established based on a consensus between different Health services. In both cases, pPCI or ohF programmes require continuous monitoring and evaluations in terms of the possible results of the strategies adopted using mortality as the reference point.

Starting with these preliminary considerations and from recent experiences conducted in our country [4, 17], a common strategy may be established for the management of patients with STEMI that would meet the following goals:

1. To strictly and suitably apply the set of general recommendations of CPG (type I recommendations)
2. To favour the conducting of early reperfusion in a greater number of patients, promoting the extension of out-of-hospital fibrinolysis and referral to a centre with immediate availability of pPCI.
3. To monitor and assess the management conducted with special attention to the results and safety of patients.

In the present order of events, the classes of recommendation (R) and levels of evidence (LE) of the American CPG are taken as reference and as explained in annex I.

1. General measures and traditional treatment:

1.1 Continuous monitoring with possibility of early defibrillation (R I, LE A).
1.2 Oxygen. In all patients for first 6 hours (R I, LE B). Administration of high FiO2 should be avoided (except in intense desaturation or pulmonary congestion) to avoid the vasoconstrictor effects of hyperoxemia.
1.3 Aspirin. (R I, LE A). The recommended doses are between 162 and 325 mg (easier to use 250 mg). If the patient is allergic to aspirin, clopidogrel 300 mg (4 x 75 mg tablets) may be used.
1.4 Double antiaggregation. Although they have not yet reached the CPG, results of recent studies appear to open new possibilities of a double antiaggregation therapy with aspirin plus clopidogrel in these patients [18,19]. It would be particularly advisable to initiate early double antiaggregation in patients in whom a primary interventionism is considered. The dosage has not been established for clopidogrel so the regimens used in the reference studies are used: a dose of 75 mg for patients with high risk of bleeding* and full doses for other patients (300 mg).
1.5 Nitroglycerin S.L. 0.4 mg every 5 minutes up to three times (R I, LE C). Nitroglycerin I.V. if pain persists and when there is hypertension or pulmonary congestion (class I, level of evidence C). The use of nitroglycerin in any form is contraindicated when: systolic blood pressure is less than 90 mm Hg (or has dropped more than 30 mm Hg from baseline), severe bradycardia (<50 bpm), tachycardia (>100 bpm), suspected right ventricular AMI and the previous use of phosphodiesterase inhibitors (24 hours for sildenafil and 48 for tadalafil)
1.6 Analgesia (R I, LE C). Morphine (2-4 mg repeated at intervals between 5 and 15 minutes depending on pain). NSAID type analgesics should not be used.
1.7 Beta-blockers. There is no doubt about the efficacy in the case of infarction but there is doubt concerning the correct timing. Early administration (first 24 hours) in patients treated with thrombolytic agents is associated with an increase in mortality due to heart failure [20]. For this reason, its pre-hospital use is not in principle justified, except if intense pain persists despite the use of analgesia and Nitroglycerin, with ECG disturbances and signs of marked adrenergia (tachycardia and hypertension), always in the absence of contraindications (table 1).

- Heart rate < 60 s/mn
- SBP < 100 mm Hg
- Moderate to severe LV failure
- Signs of peripheral hypoperfusion
- PR interval > 0.24 seconds
- 2nd to 3rd degree AV block
- Severe COPD
- History of asthma
- Severe peripheral vascular disease
- Insulin dependent diabetes mellitus

Table 1

Beta-blockers should not be used in AMI caused by cocaine (they may increase coronary vasospasm).

** See groups at high risk of bleeding in section on anticoagulant treatment: Heparins*

Reperfusion treatment (R I, LE A). The generic indication is: patient with clinical picture compatible with ACS of more than 30 minutes and less than 12 hours duration, and ECG with elevated ST > 0.1 mV in two or more contiguous leads or newly acquired left bundle branch block, which is not altered with the administration of Nitroglycerin.

1.8 Out-of-hospital fibrinolysis. Generic fibrinolytic treatment has an indication of class I, level of evidence A in the absence of contraindications. Its out-of-hospital use is appreciated differently depending on the structure of the service that applies it. Generally, it is considered a class IIa recommendation in services where a doctor is present in the emergency team.

1.8.1 Indication:

1.8.1.1 Clinical picture compatible with ACS of more than 30 minutes since onset and ECG with elevated ST $\geqslant$ 0.1 mV in at least two contiguous leads (ST $\geqslant$ of 0.2 mV in the precordial leads V1-V3), or newly acquired left bundle branch block in which the drug infusion is conducted within the first three hours of onset of symptoms. In the absence of absolute and relative contraindications (table 2).

Absolute contraindications

- History of haemorrhagic stroke
- Known intracranial neoplasia (primary or metastatic)
- Known intracranial vascular malformation (fistula or aneurism)
- Non-haemorrhagic stroke in the previous three months
- Suspicion of aortic dissection
- Active bleeding or known haemorrhagic diathesis (excluding menses)
- Significant cranial or facial surgery or trauma in previous three months

Relative contraindications (individual assessment of risk /benefit ratio)

- Uncontrolled hypertension on admission (> 180/110 mmHg)*
- History of chronic, severe or poorly controlled HTA
- History of previous CVE or other intracerebral disease not included in absolute contraindications
- Prolonged or traumatic CPR (> 10 min) or major surgery in the previous three weeks
- Recent internal bleeding (previous 2 to 4 weeks)
- Non-compressible vascular punctures
- Pregnancy
- Chronic anticoagulant use (INR > 2-3)
- Active peptic ulcer

* In patients with low risk AMI, this would be an absolute contraindication.

Table 2

1.8.1.2 The same situation as the previous point, but in patients with a delay of more than three hours in a health area not equipped with available pPCI, or when its availability implies a total delay of over 90 minutes to balloon inflation in respect of possible start of fibrinolytic treatment.

1.8.2 Regimen. The regimen includes administration of a fibrinolytic drug in combination with anticoagulant treatment with heparin.

1.8.2.1 Fibrinolytic. Currently, the fibrinolytic agent of choice for the out-of-hospital setting is tenecteplase (TnK-tPa) which is administered as a single bolus according to weight of patient. However, other thrombolytic regimens may be used, with proven efficacy, in accordance with reference hospital.
1.8.2.2 Heparin: the use of Heparin Na or Enoxaparin is acceptable, taking the following into consideration
1.8.2.2.1 Heparin Na (non fractionated) at doses of 60 IU/kg to a maximum of 4,000 IU as an initial IV bolus, prior to infusion of the fibrinolytic agent, followed by a perfusion of 12 IU / kg/hour (up to a maximum of 1000 IU/ hour). Subsequent adjustment according to aPTT (maintain between 1.5 and 2.5 times the control time)
1.8.2.2.2 Enoxaparin (low molecular weight fractionated heparin). At doses of 30 mg IV as an initial IV bolus, prior to infusion of the fibrinolytic agent, followed by 1 mg/kg subcutaneously every 12 hours (with a maximum of 100 mg/ 12 h in the first 24 hours). In the current recommendations [5,6], it is considered contraindicated (class III) in patients with mayor risk of bleeding (aged > 75 years and in patients with renal insufficiency, considering creatinine values of 2.5 mg/dL and 2 mg/dL in men and women respectively). It use should also be limited in patients with low body weight (<70 kg) as they present a greater risk of bleeding [21]. Nonetheless, recent data appear to widen the field of use of enoxaparin in these patients provided that the administration regimen is modified. In patients with renal insufficiency, the total dose should be reduced to 1 mg/kg in 24 hours and in other at-risk groups, the initial IV bolus should be omitted and the dose adjusted to 0.75 mg/kg of weight, with a maximum of 75 mg in the first 24 hours [22]. With this regimen, the risk of excess bleeding due to enoxaparin is minimised. Although the anticoagulant regimen used should continue to be on an individualised basis which has been agreed upon with the hospital where patient is referred, with the results obtained and the ease of application, the use of enoxaparin, with the necessary adjustments, should be a model to be followed. Concerning the use of different types of heparins in the same patient, there are no data that would formally advise against this in STE-ACS, but the experience compiled in patients with non-elevated ST-segment ACS

this practice has demonstrated an increase in morbidity, making it advisable to avoid such treatment crossovers [23].

1.9 Transfer to a centre with available pPCI. (pPCI is a class I indication, with levels of evidence from A to C, depending on the type of patient, the delays in its application and the experience of the centre performing it). The transfer criteria may be divided into two groups:

1.9.1 Patients with whom a priori there is no other treatment option:

1.9.1.1 Patients who present an absolute contraindication for fibrinolytic treatment.
1.9.1.2 Patients meeting the requirements of ohF, but refusing out-of-hospital treatment or presenting insurmountable technical problems.

1.9.2 Patients in whom, due to their clinical condition, a reasonable delay is justified to favour an interventionist treatment [11], provided that this can be started within a period less than 90 minutes in relation to commencing fibrinolytic therapy.

1.9.2.1 When the delay of the fibrinolytic infusion exceeds three hours from start of symptoms.
1.9.2.2 Patients in situation of cardiogenic shock and under 75 years
1.9.2.3 Patients with hemodynamic instability or who present relative contraindications, whose solution would imply unnecessarily lengthening of "door-needle" time.
1.9.2.4 Patients with large anterior STEMI (affectation of > 4 leads)
1.9.2.5 patients with a doubtful diagnosis

Co adjuvant treatment for primary PCI. Previous treatment with anti IIb-IIIa has demonstrated that it improves permeability of arteries responsible for the infarction, demonstrating a non-significant tendency toward a decrease in mortality and re-infarction [24]. Furthermore, this early administration has been shown to be feasible in the out-of-hospital setting [25], and increasingly reinforcing its early indication in emergency departments [26]. If an inter-level pPCI protocol is established, it should include a direct transfer from the mobile ICU to the hemodynamic room, which would imply avoiding delays and intermediate steps, including in turn a protocol of specific antiplatelet treatment with the reference centre.

pPCI vs fibrinolysis in elderly patients. The strategy that should be followed in patients over 75 years is a constant topic of debate. The primary PCI or fibrinolysis indication is controversial. The majority of the data derive from partial analyses, extrapolation from large studies and population subgroups of these general studies. The preliminary results of a specific trial, SENIOR PAMI [27], do not demonstrate the superiority of one treatment over the other in the entire group, although in the sub-analysis of patients up to 80 years, there was a greater benefit of treatment with PCI as opposed to fibrinolysis. Therefore, to date, there is an insufficient basis to determine a general position, so it would appear more appropriate to adjust the management of these patients to the individual clinical conditions and the local resources, with a case by case assessment of the risk/benefit of each therapeutic option.

2. Protocol. The existence of written treatment protocols (management, transfer, etc.) is considered a class I recommendation and a C level of evidence. This protocol should contemplate a global perspective, and should have the agreement of all the professionals who intervene in the management of these patients. This consensus should include:

2.1 Acceptance of agreement between the different health levels.
2.2 Systematisation of procedures. Explaining the steps and circuits that each patient should go through, identifying the contacts necessary for the smooth and effective functioning.
2.3 Monitoring and assessment of the strategies conducted. Preferably in the form of a continuous register and evaluating basic indicators of the process and their results on mortality. Quality circle (evaluation-improvement options-intervention-evaluation). In order for this evaluation to be possible, the necessary information must be compiled (table 3):

- Personal details (with some data which would allow future follow-up, e.g. telephone number)
- Personal background: particularly on IC, diabetes and renal insufficiency.
- Times (hh:mm):
  - Time of onset of pain
  - Time of contacting with health system (calling emergency services, arrival at Emergencies)
  - Time of initiating care / time of first ECG
  - Time of starting fibrinolysis
  - Time of arrival at hospital
- Killip class
- General measures applied (defibrillation, antiaggregation agents, pain relief)
- Initial rhythm disorders and during episode
- Progression during episode (electrical or hemodynamic complications that required intervention)
- Condition on admission (symptoms, hemodynamic assessment)

Table 3

Future Lines

New working lines are opening up for the management of these patients, which involve mixed treatments and strategies, pharmacological and mechanical [28]. Among these, the results of PCI facilitated with prior treatment of full doses of Tnk are particularly attractive. The rapid opening of the ARA and also early repair of the vessel make profound pathophysiological sense. However, despite initial promising results [29,30], expectations have not been consolidated by larger studies, such as the recent ASSENT IV [31]. We shall have to await the results of other studies currently in very advanced phases [32] before opting for this type of treatment. But as things stand at the moment, mixed treatments should be considered as being currently under study and without clear indications, so that it is now necessary to specifically compile, using very rigorous criteria, all the extremes involved in the implementation of these treatments to clinical practice, as well as an exhaustive assessment.

In addition, other interesting mixed options are being included, based on rapid pharmacological reperfusion and PCI (of rescue plus / or PCI in the first 24 hours) [33]. All the strategies have the advantage of a greater applicability in the real world and may help to increase the number of patients treated in terms of quantity and quality.

Without losing sight of these lines, at present the margins for improvement are not so much based on pharmacological advances that would bring about residual benefits, but on the optimal use of the existing resources, strengthening vital aspects such as accessibility, equity and the reduction in the variability in clinical practice. It is essential to know the results of practice in the real world to design policies based on understanding and clear improvement goals [34]. Working with registers, continuous or periodic, aiming to use a common language that would aid comparison and assessment of the results [35,36].

In the near future, management of patients with STEMI should be contemplated from a global perspective, as a continuous process with different interventions and actors, from where greater advances can be gained in results from the treatment of these patients. For this, special attention should be paid to two fundamental aspects:

1. The strategic aspect: A robust network of ohF supported by and/or together with a clear increase in PCI (primary with previous pharmaceutical intervention, facilitated, rescue or prior to admission to hospital) [37], agreed upon with local resources.
2. The adequacy aspect: Indicate treatment for each patient depending on the individual risk. The clinical factors of the patient that decisively affect the final prognosis are well known [38], as well as the importance of the initial ECG, data that are gaining greater prominence [39-41] and that should be the crux of the decision-making process for the management of each patient. An exhaustive clinical and electrocardiographic assessment, two old tools conducted at the bedside are, to a large extent, key to the improvement in the care in STEMI and both are decided in the first 30 minutes of medical care, a moment in the process that in a large percentage of patients occurs in the prehospital setting.

Summary

1. Consensus and treatment protocol in each health area.
2. Description of strategies adopted.
3. Performance of out-of-hospital fibrinolysis within the first three hours of onset of symptoms, in the

absence of absolute contraindications using the regimens that minimise the risk of bleeding.
4. Transfer to a centre with an available PCI (when feasible) in all patients with delays of more than three hours and in patient groups with specific indications for primary PCI.
5. Follow up of process, flow of information and assessment of results.

ANNEX I
Recommendation Levels (taken from the CPG of ACC/AHA 2004, ref. 6)

Class I: There is evidence and/or general agreement that a given procedure or treatment is useful and effective (benefit >>>risk).
Class II: There is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.
Class IIa: Weight of evidence/opinion is in favour of usefulness/efficacy (benefit>>risk). Studies or results from registers derived from specific populations (age, gender, previous disease…) would be necessary. It would be reasonable to conduct the procedure or apply the treatment.
Class IIb: Usefulness/efficacy is less well established by evidence/opinion (Benefit $\geqslant$ Risk). Studies with wider objectives would be necessary. It would be useful to have data from registers. The treatment or procedure should be considered before being used.
Class III: There is evidence and/or general agreement that the procedure/treatment is not useful/effective and in some cases may be harmful (Benefit $\geqslant$ Risk). The treatment or procedure should not be applied.

Levels of Evidence
Level A. There is strong data on the effects produced in terms of results and size of the effects, derived from randomized controlled clinical trials or meta-analyses. There are sufficient data from specific populations (age, gender, previous disease…)
Level B. There is limited evidence on the effects produced in terms of results and size of effects, derived from a single randomized study or from non-randomised controlled clinical trials. The data from specific populations (age, gender, previous disease…) are also limited.
Level C. The recommendation is based on the consensus of experts or on series of cases or from standards of care. The data from specific populations (age, gender, previous disease…) are scarce.

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Abstract
Appropriate management of patients with ST-segment elevation Acute Myocardial Infarction (STEMI) requires, as central elements, immediate accessibility to defibrillation and early initiation of reperfusion treatment. For both these aspects, out-of-hospital emergency services play a key role in the initial care of patients with STEMI.
The aim is to construct a common basic strategy upon which local aspects may be adapted which would facilitate decision making on the treatment of these patients, maintaining the following aspects as priorities:
1. To strictly and appropriately apply the set of general recommendations of CPG (type I recommendations)
2. To favour the conducting of early reperfusion to a greater quantity of patients, promoting the extension of out-of-hospital fibrinolysis and referral to a centre with immediate availability of primary percutaneous coronary intervention.
3. To monitor and assess the management conducted, with special attention to the results and safety of patients.
Key words: ST elevation Acute Myocardial Infarction, Reperfusion Treatment, Fibrinolysis, Percutaneous Coronary Intervention

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