ALLEGATO 4

Valutazione lingua Inglese

Text #1

The introduction of low-molecular-weight heparins in the arterial field1 supports the use of indirect antithrombin drugs associated with an antiplatelet drug for the treatment of unstable angina and non-Q-wave myocardial infarction.
This finding is based on pooled data from studies designed to combine aspirin plus heparin, 2-4 and more recently dalteparin, 5 and particularly enoxaparin.

Text #2

The British Heart Foundation was founded in 1961 by a group of medical professionals, who were concerned about the increasing death rate from cardiovascular disease. They wanted to fund extra research into the causes, diagnosis, treatment, and prevention of heart and circulatory diseases.

It is a major funder and authority in cardiovascular research, education, and care, and relies predominantly on voluntary donations to meet its aims. In order to increase income and maximise the impact of its work, it also works with other organizations to combat premature death and disability from cardiovascular disease.

Text #3

The Third Danish Study of Optimal Acute Treatment of Patients with ST-segment Elevation Myocardial Infarction - Ischaemic Postconditioning (DANAMI-3-iPOST) did not show improved clinical outcome in patients with ST-segment elevation myocardial infarction (STEMI) treated with ischaemic postconditioning. However, the use of thrombectomy was frequent and thrombectomy may in itself diminish the effect of ischaemic postconditioning. We evaluated the effect of ischaemic postconditioning in patients included in DANAMI-3-iPOST stratified by the use of thrombectomy.

Text #4

Acute pulmonary embolism (PE) is a frequent cause of cardiovascular mortality worldwide[1] and represents a major threat for ageing populations. As PE is characterized by a wide spectrum of severity, risk assessment is mandatory to define the appropriate management strategy. The current guidelines of the European Society of Cardiology (ESC) propose a stepwise risk stratification approach, using a combination of clinical findings, imaging, and biochemical markers, to distinguish between patients with high, intermediate, and low risk of an early adverse outcome.

Text #5

Acute PE is a potentially life-threatening acute cardiovascular syndrome. Therefore, the decision to discharge a patient within the first hours following presentation may raise medical, ethical, and legal concerns, which underline the importance of relying on validated criteria for patient selection. Current guidelines support the use of two clinical

scores, the Pulmonary Embolism Severity Index (PESI) and its simplified version (sPESI), for the identification of patients with low-risk PE. In addition, the so-called Hestia criteria were proposed, aiming to select candidates for early discharge by taking into account general medical factors along with the patients' social and family supporting environment.

Text #6

The rates of efficacy and safety outcomes documented in HoT-PE are generally in line with those reported in previous trials. Recurrent symptomatic (non-fatal) VTE occurred within the first three months in 0.6% of the patients enrolled in HoT-PE, compared with 2.0% of those in the Hestia study and 0.6% in the Outpatient Treatment of Pulmonary Embolism (OTPE) trial; both latter trials had used VKA treatment. The incidence of major bleeding was 1.2% in HoT-PE vs. 0.7-1.8% in previous studies.

Text #7

HoT-PE is the first management study using a direct, NOAC which does not require initial parenteral heparin anticoagulation and thus offers the advantage of facilitated early discharge of patients at low risk. The results of HoT-PE support the feasibility of this strategy, since more than 95% of the study patients enrolled were hospitalized for two nights or less, and 54% were either discharged immediately or hospitalized for (only) one night after presentation. Long-term follow-up focusing on 1-year survival of the patients included in HoT-PE is still ongoing, and will also provide data on the quality of life, patient satisfaction and, in selected countries, utilization of healthcare resources.

Text #8

Some limitations of our results need to be mentioned. First, it is not possible to determine from an interventional management trial like HoT-PE how many unselected patients with PE may fulfil our eligibility criteria in clinical practice. The enrolment-to-screening ratio did not represent a pre-defined measure of this trial and there was significant heterogeneity among centres in the reported percentage of screened patients who were ultimately enrolled. For example, in 25 of the 49 study sites, the reported enrolment rates exceeded 40%. Further, we cannot exclude the possibility that some eligible patients may not have been screened for HoT-PE at some of the participating study sites.

Text #9

HoT-PE suggests that neither advanced age nor active cancer, two of the 'high-risk' items included in sPESI, mandate by themselves a prolonged hospital stay. Keeping in mind that the absolute numbers of patients with these sPESI items were small and do not permit definitive conclusions, these results are encouraging news with potential medical and socioeconomic implications for ageing societies. The strategy validated in HoT-PE may therefore be applicable to a large number of patients and countries under real-life

conditions, and that it addresses the true medical need to shorten the duration of hospitalization for patients with acute low-risk PE.

Text #10

In conclusion, early discharge with continuation of anticoagulant treatment at home was effective and safe in carefully selected patients with acute PE. Patients were identified by clinical criteria of low risk and the absence of RV dysfunction and of free-floating thrombi in the right atrium or ventricle on admission, and received the standard approved regimen of rivaroxaban for at least three months. The present trial may have a clinically relevant impact on the selection of PE patients for early discharge and ambulatory management, helping to reduce in-hospital complications and rationalize the use of healthcare resources.