

## Chinese Perspectives on ESC Congress 2020 Late-Breaking Clinical Trials

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ESC Congress 2020 – The Digital Experience, held virtually because of COVID-19, didn't fail to deliver the excitement and blockbuster clinical trials that provided significant guidance for addressing aging and COVID-19 in the cardiovascular field in China.

The [REALITY trial](#) investigated whether a restrictive blood transfusion strategy for myocardial infarction patients with anemia impacts clinical outcomes and saves costs. The prospective, randomized, open-label, interventional clinical trial enrolled 668 patients hospitalized at 35 centers in France and Spain with acute myocardial infarction and anemia (hemoglobin 10 g/dL or below, but above 7 g/dL). Patients were randomly allocated to either a restrictive transfusion strategy (transfusion withheld unless hemoglobin dropped to 8 g/dL) or a liberal transfusion strategy (transfusion given as soon as hemoglobin was 10 g/dL or below). Results found that a restrictive blood transfusion strategy was non-inferior to a free blood transfusion strategy (HR: 0.79, unilateral 97.5% CI: 1.18,  $P < 0.001$ ) at the primary effective endpoint of 30-day MACE (consisting of all-cause death, non-fatal stroke, non-fatal recurrent myocardial infarction and emergency revascularization caused by ischemia). In addition, the secondary endpoints also showed no significant difference between the two strategies. Before REALITY, restrictive blood transfusion strategy was only considered "possibly" applicable to anemic acute myocardial infarction patients. Debate has long ensued over whether risk can be overcome by blood transfusion, and best blood transfusion strategy, especially considering the majority of patients that undergo transfusion cannot be matched with non-transfused patients due to their markedly different clinical profiles, and observational studies cannot reliably establish the benefits or risks. There is also wide variation in clinical practice. Based on these results, clinicians in China may be able to avoid unnecessary transfusion risk by using restrictive rather than liberal blood transfusion strategies, saving blood resources, with high-risk patients in mind.

Research on thromboembolic events and bleeding risk in COVID-19 [was presented](#) by **Yutao Guo, MD, PhD**. One team from Hospital 301 in Beijing, China observed the correlation between systemic and venous thromboembolism incidence, major bleeding and mortality, and potential risk factors and anticoagulants in 1,125 hospitalized patients diagnosed with COVID-19 during the pandemic. The study found that there were 82 cases (7.3%) of thromboembolic events (37 systemic, 45 venous events), 128 cases (11.4%) of hemorrhagic events, and 91 cases (8.1%) of deaths. Bleeding events occurred in 25 patients (30%) with thromboembolism. Old age (over 65 years old), atrial fibrillation, and abnormal liver function comprised independent risk factors for systemic thromboembolism and bleeding events, and subcutaneous parenteral anticoagulants significantly reduced the risk of thromboembolism, bleeding, and death. According to this retrospective study from China, hypodermic parenteral anticoagulants should be considered for Chinese patients with COVID-19, such as those over 65 years of age, associated with atrial fibrillation, and abnormal liver function, in order to reduce the risk of thromboembolism, bleeding and death during hospitalization.

The [POPular-TAVI \(antiplatelet therapy\) trial](#) showed that, among post-TAVR patients without indications for anticoagulation, aspirin monotherapy reduced the incidence of postoperative bleeding events and did not increase the incidence of thromboembolic events, compared with aspirin plus short-term clopidogrel therapy. The incidence of all bleeding events in the single-drug group was 15.1%, which was significantly lower than the 26.6% of all bleeding events in the combined group ( $P = 0.001$ ); similarly, the incidence of non-procedural-related bleeding events in the single-drug group was 15.1%, which was significantly lower than 24.9% in the combined group ( $P = 0.005$ ). POPular-TAVI is a landmark trial which provides excellent answers about how clinicians should choose antithrombotic strategies after TAVR; however, before putting this strategy into daily clinical practice, especially in China, we should think it over further. TAVR is still in its infancy in China, and the domestic prosthesis is not exactly the same as mainstream in the other countries. Also, the bleeding and thrombotic risk of Asian populations differs from that of European populations. Thus, we still need more evidence before simplifying anti-thrombotic therapy after TAVR in China.

Several studies presented at ESC Congress demonstrated that outpatient management or early discharge for certain patients presenting with acute pulmonary embolism (PE) may be suitable. The [HOME-PE trial](#) compared two discharge triage strategies of normotensive PE patients, and the primary outcome included the composite of recurrent venous thromboembolism, major bleeding and all-cause death at 30 days. The results indicated the HESTIA-based strategy recommended by U.S. guidelines was noninferior to the simplified Pulmonary Embolism Severity Index (PESI)-based strategy recommended by European guidelines. The rate of the primary outcome in the HESTIA group was 3.8%, vs. 3.6% in HESTIA group ( $p = 0.005$ ). On the basis of the PESI-based strategy, the rate of patients eligible for family treatment is 48.4%, higher than 39.4% in the HESTIA group. However, clinicians prefer to apply the HESTIA-based strategy for discharge, therefore refusing the PESI-based strategy. The rates of patients eligible for family treatment were similar in the two groups, and the morbidities of complications of all family treatment patients were low. The aging problem has become more serious in China, as the morbidity PE of elderly patients has increased. The PESI-based strategy proves significantly more practical for normotensive PE patients in China, not only for providing timely and suitable family therapy, but also avoiding the occurrence of nosocomial infections and adverse events, which promotes rehabilitation of patients.