

高感度トロポニンを用いた単回の検査でMIを除外する

HiSTORIC試験：心筋梗塞疑いに対する迅速検査により健康な患者を早期に帰宅させることが可能になる

HiSTORIC: Rapid pathway for suspected myocardial infarction enables healthy patients to go home earlier

心筋梗塞の早期除外診断は、心有害事象を増加させることなく病院滞在時間および入院を減少させる。このHiSTORIC試験のレイトブレイキングの結果がESC Congress 2019のHot Line Sessionで発表され、*Circulation*に掲載された。この試験では高感度トロポニン検査を用いて、診察時の心筋梗塞を除外する迅速な方法の有効性及び安全性を、標準的な方法と比較調査した。この検査を実地臨床でルーチンに導入することにより、救急外来滞在時間が3時間以上短縮し、救急外来から帰宅する患者の割合は追加リスクなく50%以上増加した。

Full Text

An early rule-out pathway for myocardial infarction (MI) reduces length of stay and hospital admissions without increasing adverse cardiac events, according to late breaking results from the HiSTORIC trial presented in a Hot Line Session at ESC Congress 2019 together with the World Congress of Cardiology and published in *Circulation*.

Principal investigator Professor Nicholas Mills of the University of Edinburgh, UK said: "This is the first randomized controlled trial to evaluate the efficacy and safety of an early rule-out pathway. Introducing the pathway into routine clinical practice reduced length of stay by more than three hours and increased the proportion of patients discharged from the emergency department by over 50%."

Suspected MIs account for up to 10% of all hospital attendances and 40% of unscheduled admissions. Most of these patients have not had and MI, and effective and safe pathways are needed to rule out this diagnosis in the emergency department.

The diagnosis of myocardial infarction includes measuring the concentration of cardiac troponin, a protein released into the blood when the heart muscle is injured. Guidelines recommend serial testing at presentation and 6 to 12 hours later to coincide with the peak in troponin concentration (standard care). In most hospitals, myocardial infarction is ruled out when the cardiac troponin concentration is less than the upper reference limit or 99th percentile on serial testing.

The HiSTORIC trial examined the efficacy and safety of an expedited pathway, where high-sensitivity cardiac troponin testing is used to rule out myocardial infarction at presentation, compared to standard care. Myocardial infarction is ruled out at presentation with a single test using a lower threshold of 5 ng/L. The scientific basis for this approach to risk stratification is published simultaneously in *Circulation*. If the troponin concentration is above this risk stratification threshold, cardiac troponin is measured again at three hours; myocardial infarction is ruled out if the concentration is unchanged and remains below the 99th percentile.

This was a stepped-wedge cluster randomized controlled trial in 31,492 consecutive patients with suspected acute coronary syndrome presenting to seven hospitals in Scotland. The hospital was the unit of randomization. The primary efficacy outcome was length of stay, defined as the length of time from initial presentation to the emergency department until final discharge from hospital. The primary safety outcome was myocardial infarction or cardiac death after discharge and was evaluated at 30 days and one year.

Length of stay was 10.1 hours and 6.8 hours before and after implementation of the early rule-out pathway, respectively (adjusted geometric mean ratio 0.78; 95% confidence interval [CI] 0.73–0.83; $p < 0.001$). The proportion of patients discharged from the emergency department without hospital admission increased from 53% to 74% (adjusted risk ratio 1.57; 95% CI 1.34–1.83; $p < 0.001$) after introducing the early rule-out pathway.

At 30 days, the primary safety outcome occurred in 57/14,700 (0.4%) and 56/16,792 (0.3%) patients before and after implementation of the early rule-out pathway, respectively. At one year, the primary safety outcome occurred in 396/14,700 (2.6%) and 307/16,792 (1.8%) of patients before and after introducing the early rule-out pathway, respectively.

"These results show that the use of an early rule-out pathway can be very effective, and earlier discharge is not associated with adverse cardiac event," said Prof Mills. "Most guidelines recommend ruling in and ruling out MI using a single threshold (99th percentile). Our trial demonstrates that using separate risk stratification and diagnostic thresholds allows MI to be ruled out at presentation in more patients without additional risk."

Prof Mills said the potential benefits for patients and healthcare systems are considerable. "We observed substantial reductions in length of stay and increases in the number of patients avoiding hospital admission. In the US alone, more than 20 million patients attend emergency departments with suspected acute coronary syndrome every year. Reducing length of stay by three hours could save more than \$3.6 billion annually on bed occupancy alone," he said.

This trial was funded by the British Heart Foundation (BHF) with support from a BHF Research Excellence Award. NLM reports research grants awarded to the University of Edinburgh from Abbott Diagnostics and Siemens Healthineers outside the submitted work, and honoraria from Abbott Diagnostics, Siemens Healthineers, Roche Diagnostics, Singulex and LumiraDx.

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