FFRガイド下インターベンションは緊急血行再建術を減少させる

FAME 2 trial:冠血流予備量比ガイド下PCIは緊急の血行再建術を減少させるが死亡率や心筋梗塞発症率は低下させない

FAME 2 trial: PCI guided by fractional flow reserve reduces urgent reinterventions but not mortality or myocardial infarction

安定冠動脈疾患患者は冠血流予備量比(FFR)ガイド下でPCIを施行され可能な最良の薬物療法(MT)を行われた場合、MT単独と比較し緊急血行再建術の必要性が低い。FAME 2トライアルの最終解析が、2012年European Society of Cardiology学会で発表され*New England Journal of Medicine*オンライン版に掲載された。研究者らは、この無作為化トライアルの患者のうち75人が一次エンドポイントイベント(死亡、心筋梗塞、または緊急血行再建術)の少なくとも1つを経験したと報告した。イベント発症率はMT単独群よりもPCIとMT併用群の方が低かった(4.3%対12.7%)。FFRによる治療ガイドは緊急血行再建術施行のリスクを8分の1に減少させるのに役立った。しかし、死亡率やAMI率は治療群間で差がなかった。FFRで虚血を引き起こす病変が認められなかった患者は薬物療法のみで治療され、レジストリでフォローされた。一次エンドポイントイベント率(死亡、AMIまたは緊急血行再建術)はこれらの患者において低かった(3%)。独立したデータ安全性監視委員会がMT単独群の継続は不当であると判断したため、このトライアルは早期に中断された。

Full Text

Patients with stable coronary artery disease (CAD) had a lower need for urgent revascularization when receiving fractional flow reserve (FFR)-guided PCI plus the best available medical therapy (MT) than when receiving MT alone. The results, from a final analysis of the FAME 2 trial, were presented during a Hot Line session of ESC Congress 2012 in Munich. Treatment guided by fractional flow reserve assessment helped reduce the risk of urgent revascularization by a factor of eight.

The FAME 2 (FFR-Guided Percutaneous Coronary Intervention (PCI) Plus Optimal Medical Therapy vs. Optimal Medical Therapy Alone in Patients with Stable Coronary Artery Disease) trial was conducted at 28 centers in Europe and North America to assess the role of FFR in the percutaneous treatment of stable coronary artery disease in one or more vessels. Results were presented by the trial's coordinator Dr. Bernard De Bruyne from the OLV Clinic in Aalst, Belgium. The study, which began in May 2010, enrolled 1220 patients with stable coronary artery disease, and compared clinical outcomes, safety and cost effectiveness of percutaneous coronary intervention (PCI) guided by FFR plus best available medical therapy (MT) with MT alone.

"These statistically significant results validate the important role that FFR-guided therapy has in improving outcomes for patients with coronary artery disease.

"The FAME 2 trial provides new evidence of the role that FFR and second-generation drug eluding stents can have in improving patient care. We now know that, if a lesion is significant as determined by FFR guidance, the stenting procedure will provide a better outcome. With this new knowledge, I believe that FFR should become the standard of care for treating most patients with stable coronary artery disease and significant coronary narrowings."

Results showed that:

- By 15 January 2012, when the trial's enrollment ended, 75 of the randomized trial patients had experienced at least one primary endpoint event (including death, heart attack, or urgent revascularization). Event occurrence was lower in the PCI plus MT group than in the MT alone group (4.3 versus 12.7%).
- There was a large difference in rates of urgent revascularization between the two groups, with patients in the PCI plus MT arm less likely to receive revascularization. However, there was no significant difference in mortality or AMI rates between patients with PCI plus MT and patients with MT alone.
- Patients in whom FFR found no evidence of ischemia-producing lesions were treated with medications alone and were followed up in a registry. Primary endpoint events including death, AMI or urgent revascularization were low (3%).

The FAME 2 trial was stopped early (January 2012) after its independent data safety monitoring board (DSMB) deemed it unjustified to continue with the MT-alone arm. The DSMB found a statistically significant reduction in the need for unplanned hospital readmission and urgent revascularization when FFR-guided assessment was used to direct treatment. As a result, patients already enrolled in the trial continued to be followed, but no new patients were added.

"The trial provides new information on the benefits of coronary intervention and answers questions raised by the COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation) trial, which found no difference in outcomes between PCI plus MT and MT alone," said Dr. De Bruyne.

"The data show that in patients with stable CAD and functionally significant stenoses as assessed by FFR, FFR-guided PCI plus MT decreases the need for urgent revascularization when compared with MT alone. In contrast, in patients without ischaemia-producing lesions, outcome is favorable with MT alone."

The trial was sponsored by St. Jude Medical.

Conference News