

冠動脈分岐部病変に対するステント留置技術の比較(Abstract 5034)

BBK II: 側枝にステント留置が必要な冠動脈分岐部病変にはキュロットステントが好ましい

BBK II: Culotte stenting preferred for coronary bifurcations when stenting of the site branch is needed

側枝にステント留置が必要な冠動脈分岐部病変には、TAPステント術に対しキュロットステント術を用いた治療の方が優れている、とのBBK IIトライアルの結果が2016年ESC Congressで発表され、同時に*European Heart Journal*に掲載された。一次エンドポイントは、9か月後のフォローアップ定量的冠動脈造影により評価した、分岐部病変の最大ステント径狭窄率であった。結果、キュロットステント群とTAPステント群の平均最大径狭窄率は、それぞれ21%対27% ($p=0.038$) であり、キュロットステント群が有意に優れていた。この差のほとんどすべては、側枝の狭窄率の差によるものであった。

Full Text

Coronary bifurcations are best treated with a technique known as culotte stenting, as opposed to T-and-protrusion (TAP) stenting, when there is need for a side-branch stent according to results of the BBK II (Bifurcations Bad Krozingen) trial.

The findings, presented at ESC Congress 2016, with simultaneous publication *The European Heart Journal*, are the first randomized results directly comparing these two commonly used techniques.

Coronary bifurcations lesions have to be treated in about 20% of all percutaneous coronary interventions, and so far several different technical approaches have been recommended, explained investigator Miroslaw Ferenc, MD, PhD from the University Heart Center Freiburg, in Bad Krozingen, Germany.

"Treatment is often challenging and requires a high level of interventional qualification. This is the first head to head comparison of the two most commonly used techniques in patients needing side branch stenting and having suitable anatomy for both techniques, and it not only provides angiographic follow-up but also demonstrated a clear signal with respect to clinical outcome.

"There was a statistically significant difference in the primary study endpoint favoring culotte stenting. The lower angiographic restenosis rate in the bifurcation lesion after culotte stenting as compared with TAP stenting was also associated with lower rate of target lesion revascularization (TLR) in the first year after PCI."

The study included 300 patients with stable or unstable angina and/or a positive stress test who were undergoing percutaneous coronary intervention and side-branch stenting of a coronary bifurcation lesion.

During the procedure, if a side branch stent was needed and the lesion was deemed amenable for both stenting techniques, patients were randomized to either TAP stenting ($n=150$) or culotte stenting ($N=150$).

The primary endpoint was maximal in-stent percent diameter stenosis of the bifurcation lesion assessed by follow-up quantitative coronary angiography at 9 months.

This showed a significant advantage to culotte stenting which resulted in a mean maximal percent diameter stenosis of 21% versus 27% in the TAP stenting group ($P=0.038$), said Dr. Ferenc.

This difference in the primary endpoint was driven almost entirely by differences in the side branch, where the mean percent diameter stenosis was 16% in the culotte arm versus 22% in the TAP ($P=0.029$). In contrast, there were no differences between techniques in the percent diameter stenosis in the main branch.

There were other important differences in favor of culotte stenting, added Dr. Ferenc.

These included a highly significant difference in binary in-stent restenosis at the bifurcation lesion (6.5% after culotte vs. 17% TAP; $P=0.006$) as well as a 6% vs. 12% target bifurcation lesion revascularization rate at 1 year (which just missed reaching statistical significance: $P=0.069$). Again, both of these outcomes were driven by differences in the side, as opposed to the main branch, he said.

Death, target vessel myocardial infarction, and stent thrombosis were infrequent at 1 year, and did not differ significantly between the two study groups.

"Given the clear results of this trial together with the same trend for hard clinical endpoints, culotte stenting has now to be seen as the preferred approach for coronary bifurcations, when stenting of the site branch is needed," said Dr. Ferenc.

"Interventional cardiologists can use now culotte stenting with more confidence knowing that this technique is associated with a very low angiographic restenosis rate and lower rate of TLR as compared with TAP stenting - even though it is slightly more challenging and requires appropriate training."

This trial was exclusively supported by an unrestricted grant from the University Heart Center Freiburg - Bad Krozingen. Dr. Ferenc receives speaker honoraria from Boston Scientific, Biotronik, Abbott, and Medtronic.

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