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NIR TOP trial fails to show equivalency of gold-fused and basic NIRflex stents, raising questions about radiopacity and QCA

EuroPCR NEWS Paris, France -The **NIR[®] TOP** trial, comparing the NIRflex[™] and gold-plated NIRflex Royal[™] stents (Medinol Ltd, Tel Aviv, Israel) has failed to reach its primary end point of equivalence between the two stents. Presenting the results at the **2003 EuroPCR** meeting, **Dr Sigmund Silber** (Dr Müller Hospital, Munich, Germany) noted that the disappointing results for the gold stent on quantitative coronary angiography (QCA) might raise methodological concerns about using QCA analysis for dense radiopaque stents.

The trial results also add to the limited clinical trial data for the NIRflex stent, already available in Europe but still in pre-FDA approval studies in the US. As Silber explains, the NIRflex Royal is identical in design to the basic NIRflex stent, but subjected to a "fused-gold" process to increase its radiopacity on angiography without increasing strut thickness. Gold is one of several avenues being explored by stent manufacturers responding to operators' calls for enhanced visibility to improve stent placement.

Royal stent fails to top uncoated cousin

The NIR TOP trial randomized 305 patients to either the NIRflex or NIRflex Royal stent, who were then examined at six months by QCA to assess the primary end point of equivalent minimal luminal diameter (MLD). Silber reported that at six months, MLD was 1.61 mm in the patients who received the Royal stent vs 1.81 mm in the basic stent (p=0.002). Secondary end points determined by QCA, including late loss and binary restenosis, were also nonequivalent, although clinical outcomes, including target lesion revascularization rates and MACE, were not significantly different.

Strikingly, results from a small subset of patients who underwent IVUS, which would not be affected by the radiopacity of the fused gold struts, did not demonstrate nonequivalence between the two stents, raising the possibility that comparing QCA measurements of devices with very different radiopacity on QCA may not be possible under the currently used parameters.

In his concluding remarks, Silber noted, "It is fair to say that angiographic data after six months suggest no equivalence, so the primary end point of this trial was not reached, the MLD was not equivalent. But the clinical end point, which was a secondary end point, suggests that they are equivalent and the IVUS substudies, in a small number of patients, also showed equivalence."

He continued, "We have methodological concerns about QCA, and it is very important to note that QCA may be influenced by these highly radiopac stents and this really requires further research. We really need to look at the algorithms to know exactly what QCA does with this stent. It may be that QCA just does not fit with a radiopaque stent."

On the other hand . . .

Looking on the bright side, Silber pointed out that NIR TOP was really the first randomized, controlled trial for the basic NIRflex stent, which produced "unexpectedly good" results, a six-month late loss of 0.65 mm and a low restenosis rate of 17.8%.

Tellingly, in an electronic survey of the audience following Silber's presentation that asked delegates how important radiopacity was in their work, more than half the respondents replied that radiopacity would be "nice to have" but was not essential.

Israel-based Medinol is best known for its feud in 2001 with Boston Scientific (Natick, MA), which had previously obtained all of the stents used in its TAXUS program from Medinol before launching its own EXPRESS stent. Medinol sued Boston Scientific for fraud, alleging that the American company had copied its NIR stent before dropping Medinol as a supplier. Ironically, Boston Scientific's NIRoyal™ Elite Monorail™ coronary stent system, which incorporates a Medinol-manufactured stent with gold plating, was approved by the FDA in February 2001.

Related links

1. [Boston Scientific, Pfizer under scrutiny in US investigations](#) [*HeartWire* > *MediaPulse*; May 17, 2002]
2. [Medinol versus Boston Scientific stent battle escalates](#) [*HeartWire* > *MediaPulse*; Oct 24, 2001]

Shelley Wood
shelley@conceptis.com