Cutting Balloon Angioplasty

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Following seven years of experience with the Cutting Balloon, many advances have been made in the types of lesions treatable with this device, as well as various techniques associated with its unique characteristics. Due to this long experience with Cutting Balloon, and the rate at which IVUS is used in Japan, clarification and documentation of the dilatation mechanism of Cutting Balloon's microsurgical blades has taken place.

In a study at Toho Ohashi Hospital comparing Cutting Balloon vessel expansion ratios with that of POBA, the ratio was 1.09 vs. 1.17 ($p<0.05$), respectively. Due to this reduction in vessel expansion, lumen gain for Cutting Balloon also showed an advantage over the conventional balloon (63% gain for CB vs. 48% gain for POBA). Because of these advantages it was also reasoned that stenting following Cutting Balloon would present with lower restenosis rates due to the plaque reduction associated with Cutting Balloon.

Dr. Colombo reported extremely interesting data along these lines in 1998 that prompted further investigation by Japanese collegues. His presentation stated that as the percentage of residual plaque area increased, the neointimal area also greatly increased. At less than 40% residual plaque area, the neointimal area was 9.2%, however, as the residual plaque area increased to more than 60% the neointimal area grew to 29.9%. This was a very strong argument to pursue Debulking Stent, in this case Cutting Stent.

Three centers in Japan participated in this study with favorable results for the Cutting Balloon cohort. At Toho Ohashi Hospital, the restenosis rate and TLR for Cutting Balloon + Stenting were 12.9% and 10.3%, while for the POBA + Stenting group were 22.7%(p=NA) and 18.7%(p=NA). Toyohashi Higashi Hospital experienced similar results with the Cutting Balloon + Stenting group having a restenosis rate and TLR of 19.2% and 12.3%, while POBA + Stenting had 26.9%(p=N.S.) and 24.6%($p<0.03$) respectively. Nagoya 2nd Red Cross presented with IVUS findings for Neo-Intimal Hyperplasia at MLD Site and found that the CB + Stent group had 32.4% plaque area, while POBA + Stent had 50.3% plaque area($p<0.01$). It was following these results that the REDUCE III trial, Cutting Balloon followed by Stenting, was started in an effort to get randomized, multi-center experience. Preliminary results from REDUCE III will presented as soon as they become available.