have a better insight in the mechanism of balloon angioplasty (PTA) of the superficial femoral artery (SFA). The EPISODE trial (Evaluation Peripheral Intravascular Sonography on Dotter Effect) is a multicenter study evaluating whether IVUS is a better predictor of the outcome after PTA of the SFA than standard angiography. We studied 41 patients (pts) with angiographic successful PTA (26 M, 15 F; mean age 70 ± 8 yr). Of each patient, the smallest free lumen area seen on IVUS before and after PTA was selected. Qualitative analysis included lesion morphology and geometry before PTA and dissection, plaque rupture and internal elastic lamina rupture after PTA. Quantitative analysis included free lumen area (FLA), free lumen diameter (FLD), media-bounded area (MBA) and percentage area stenosis (%S) before and after PTA. Success or failure at 1 month and at 6 months was defined using a combination of clinical and objective vascular laboratory criteria, including ankle/brachial index and duplex.

At one month success of PTA was evidenced in 30 pts and failure in 11 pts. After 6 months success was seen in 19 pts (46%; Group I) and failure in 22 pts (54%; Group II). No differences in outcome could be demonstrated on the basis of qualitative IVUS findings before and after PTA. Quantitative data before PTA of both groups were not significantly different. After PTA both groups showed a significant increase in FLA and FLD and a significant decrease in %S. Significant differences were encountered between the Group I and II for FLA (13.0 vs 9.7 $mm^2$ and FLD (4.0 vs 3.5 mm), whereas no significant differences were encountered in MBA and %S.

*Conclusion:* The present study indicates for the first time that the presence of a narrow free lumen site within the lumen evidenced by IVUS following PTA is the most common mechanism underlying restenosis. Given the high incidence of failures seen at 1 month it is likely that rest-stenosis rather than restenosis may be the underlying mechanism to the failures evidenced.

8:45

## 734-2 Prognostic Significance of Left Main Coronary Artery Disease Detected by Intravascular Ultrasound

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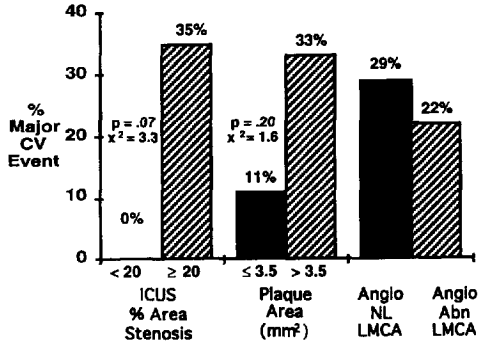
Intracoronary ultrasound (ICUS) has detected left main coronary artery (LMCA) disease that is silent by contrast angiography. The prognostic importance of ICUS detected LMCA disease is unknown. To determine the long-term outcome of LMCA disease detected by ICUS, long-term clinical followup was obtained in 30 consecutive patients. ICUS LMCA evaluation was performed immediately following successful PTCA of the LAD or LCX. Mean followup was 3 years (range 2–4 yrs). ICUS and quantitative angiography were analyzed for predictors of clinical outcome. Angiographically, 21 patients had normal LMCA and 9 were insignificantly abnormal; by ICUS 23 had >20% area stenosis. Major cardiovascular (CV) events occurred in 9, including 6 CABG, 2 cardiac deaths and 1 MI. No significant difference in age, LVEF, number or location of arteries involved were noted between those with and without events.




*Conclusions:* ICUS may predict cardiovascular prognosis in patients with angiographically silent LMCA disease. Patients with ICUS determined left main area stenosis >20% appear to have a higher incidence of major clinical cardiovascular events at long-term followup.

9:00

## 734-3 The Safety of Intracoronary Ultrasound: Data from a Multicenter European Registry

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The clinical use of intracoronary ultrasound (ICUS) is growing, serving as a useful adjuvant to contrast angiography, and providing additional information to assist with catheter based interventions. Despite the increasing use of this technique, it remains an invasive procedure which the safety has not been definitively established. Data was collected from multiple European centers performing intracoronary ultrasound examinations under the auspices of the Subgroup on Intravascular Ultrasound of the Working Group on Echocardiography of the European Society of Cardiology. Information was obtained about the number of exams performed, complications related to imaging, patient's age and CAD risk factors, indication for exam, concomitant procedures performed, catheter size and location, and any adverse clinical consequences related to ICUS imaging. Twelve centers (mean 59 patients, range 3–140) submitted information about their experience with ICUS. A total of eight (1.1%) complications were reported in a total of 718 examinations. All complications occurred during ICUS exams in patients with atherosclerotic coronary disease with a diagnosis of unstable or stable angina who underwent PTCA. Four cases of transient vessel spasm were seen, all of which resolved after administration of nitroglycerin. Two cases of vessel dissection were noted when imaging after PTCA, and thought to be "possibly" related to the ultrasound catheter. Two cases of guidewire entrapment after distal advancement of the transducer were reported, requiring the catheter and guidewire to be withdrawn. No adverse clinical consequences due to ICUS imaging were reported. There was no difference in frequency of complications between centers assessed by Chi square ($p = 0.232$).

*Conclusion:* Intracoronary ultrasound examinations can be performed safely with a very low rate of acute complications.

9:15

## 734-4 Can Intracoronary Ultrasound Improve PTCA Results?: Preliminary Core Lab Ultrasound Analysis from the CLOUT Pilot Study

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The CLOUT Pilot Study hypothesis is that intracoronary ultrasound (ICUS) guidance can maximize the potential of balloon angioplasty through the safe application of carefully chosen oversized balloons. PTCA was performed until success was obtained using standard angiographic criteria. ICUS was then performed and, based on the degree of reference segment disease, balloons were upsized from 0.25 to 0.75 mm (mean 0.4 mm) regardless of the angiographic results. There have been no complications using this strategy in the initial 14 of a planned 100 patients. ICUS measures were performed using semiautomated programs at a core laboratory.

*Results:* In the reference segment, ICUS revealed a mean lumen diameter of 2.60 ± 0.35 mm and plaque thickness of 0.78 ± 0.11 mm; on average 54.75 ± 11.05% of the reference vessel was occupied by atheroma. At initial ICUS evaluation after angiographically successful PTCA, the lesion had a minimal lumen diameter (MLD) of 1.78 ± 0.22 mm and lumen area of 3.14 ± 0.88 $mm^2$. Following balloon upsizing, the lesion MLD increased to 1.95 ± 0.15 mm (8.7% gain, $p < 0.02$) and lumen area to 3.76 ± 0.63 $mm^2$ (16.7% gain, $p < 0.01$). When compared to the reference segment lumen area, the lesional %lumen area reduction improved from 38.14 ± 16.74% to 25.91 ± 12.17% ($p < 0.01$). Lumen improvement occurred primarily by expansion of the total vessel area (12.08 ± 3.01 $mm^2$ to 12.51 ± 3.11 $mm^2$, p = ns). As expected, there was a large degree of residual atheroma (68.62 ± 7.47% cross sectional narrowing). After routine PTCA, only 5 of 12 patients reached a target MLD of 75% of the reference lumen diameter. Following balloon upsizing, 8 of 12 had reached this criteria.

*Conclusions:* ICUS guided balloon upsizing based on the degree of reference segment disease may be safely performed and results in significant improvement in luminal cross sectional area above that achieved by angiographic guidance alone. This may potentially lower restenosis rates if these initial gains are sustained long term.

9:30

## 734-5 Mechanims of Radiofrequency Thermal Balloon Angioplasty. A Study with Intracoronary Ultrasound

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Radiofrequency thermal balloon angioplasty (RF) may be performed with very low balloon pressures, decreasing barotrauma, and a lower incidence of dissections has been reported. In order to study the mechanism responsible for dilation after RF, we have imaged with intracoronary ultrasound (ICUS) [mechanically rotated transducer; 20–30 MHz; 3.5–4.8F], 12 lesions, of a total of 31 included in a prospective protocol designed to evaluate the usefulness of RF. In 11/12 lesions we were able to obtain interpretable images, and these are the subject of our study. In 9/11 (81%) of the lesions, imaging was attempted both before (Pre), and after (Post) RF and in 2 the ICUS catheter could not cross the lesion previous to RF. Plaque on IVUS was considered hypoechogenic (n = 4, 36%), fibrotic (n = 4, 36%) or calcified (n =