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Vascular Acoustic Emission Parameters Better Identify and Characterize Angioplasty-Induced Injury

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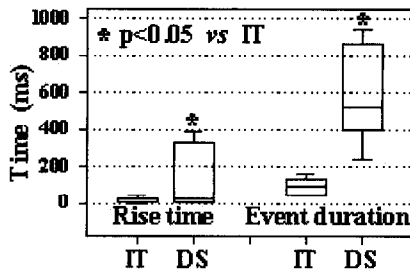
Background: We have previously demonstrated that atherosclerotic (ATH) arterial tissue emits sound (vascular acoustic emissions, VAE) as it undergoes mechanical disruption and that VAE can be used to distinguish plaque fracture from deleterious (dissection) events during balloon angioplasty (BA).

Purpose: To determine if time-domain analysis of VAE can be used to more accurately characterize BA events.

Methods: A ceramic piezoelectric transducer was mounted inside a test fixture. Post-mortem human iliofemoral arteries (n=20) exhibiting varying degrees of ATH (normal, fatty streaks to diffuse fibrous plaques) were also mounted on the fixture and subjected to pressurization with saline to simulate BA. Simultaneous recordings of the pressure and VAE signal (amplified 150x) were digitized. Based on the pressure waveform, events in the VAE signal were classified as being due to an intimal tear (IT) or due to a dissection (DS) (sharp pressure drop) and confirmed pathologically. Each VAE signal was decomposed into its constituent events. Two time-domain parameters for each event were calculated - the rise time (T_r) and the event duration (T_d).

Results: Both T_r and T_d were able to distinguish dissections from intimal tears.

Conclusions: We have demonstrated that an acoustic emission sensor with time-domain signal analysis can be used to separate types of vascular injury and provides a convenient method for real-time monitoring and optimization of balloon angioplasty and stent placement.



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Cerebrovascular Accidents After Percutaneous Coronary Interventions: Incidence, Predictors, and Outcomes

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Background: Cerebrovascular accidents (CVA) following percutaneous coronary intervention (PCI) are rare but often devastating. We sought to identify the incidence, predictors, and clinical implications of in-hospital CVA in this setting.

Methods: We reviewed the data on 31,397 PCIs that occurred between May 1993 and May 2002 at William Beaumont Hospital. CVA was defined as a transient ischemic attack (TIA), ischemic stroke, or hemorrhagic stroke. The 338 patients that also underwent coronary artery bypass graft surgery (CABG) during the index hospitalization were excluded. None of the excluded patients suffered a CVA prior to CABG. The remaining 31,059 PCIs comprised the study group. Clinical and angiographic characteristics, and in-hospital outcomes of patients who suffered a CVA were compared to those who did not.

Results: CVA occurred in 90 patients (0.3%). There were 59 (66%) ischemic strokes, 19 (21%) hemorrhagic strokes, and 12 (13%) TIAs. Patients with CVA were older (70±12 versus 65±12 years, $P<0.0001$) and more likely to undergo PCI for urgent or emergent indications (88% versus 53%, $P<0.0001$). The strongest independent predictors of CVA were thrombolytics prior to PCI (OR 4.5, 95%CI 2.2-9.4, $P<0.0001$), heparin use before PCI (OR 2.3, CI 1.4-4.0, $P<0.0025$) or after PCI (OR 3.3, CI 1.9-5.5, $P<0.0001$), low creatinine clearance (OR 1.14 per 10 ml/min decrease, CI 1.04-1.23, $P=0.0028$), past CVA (OR 2.3, CI 1.3-4.1, $P=0.0045$), and diabetes (OR 1.9, CI 1.2-3.1, $P=0.0090$). Patients that suffered a CVA had a significantly higher rate of in-hospital mortality (26% versus 1.5%, $P<0.0001$) and longer length of hospital stay (13±15 versus 3.3±5.2 days, $P<0.0001$). In a multivariate analysis, CVA was a strong independent predictor of in-hospital death (OR 9.06, CI 4.81-17.1, $P<0.0001$).

Conclusions: CVA following PCI, although rare, is associated with high rates of in-hospital death and longer length of hospital stay. Patients that receive thrombolytics or heparin are at particularly increased risk.

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Effect of Diabetes Mellitus on the Predictive Value of Myocardial Fractional Flow Reserve

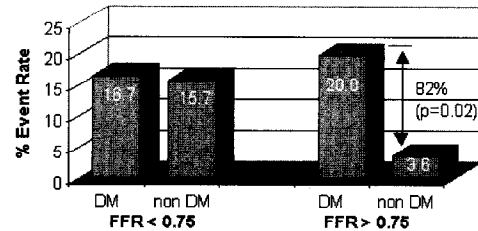
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Background: Fractional flow reserve (FFR) < 0.75 correlates with positive stress tests. Diabetes (DM) is associated with microvascular dysfunction that can potentially create falsely high FFR.

Method: All patients undergoing FFR evaluation between 6/00 and 6/02 were included. Demographic and clinical data were collected by chart review. Quantitative angiographic analysis was performed independently. Clinical events were defined as death, MI, or tar-

get vessel revascularization (TVR).

Results: 156 patients were eligible for analysis. 30% had DM. Baseline demographic data were comparable between DM and non-DM patients except: more female patients in the DM than the non-DM group (48.9% vs. 31.8%; $p=0.05$) and increased hyperlipidemia in the DM group (76.6% vs. 60.9%; $p=0.06$). Percutaneous coronary intervention (PCI) was performed in close accordance with FFR. 97% of patients with FFR < 0.75 received PCI, 91% of patients with FFR > 0.75 did not. When FFR was < 0.75 and PCI performed accordingly, the follow up event rate was low in both groups (16.7% vs. 15.7%; $p=NS$). When FFR > 0.75 and PCI was not performed, DM patients had more clinical events (all TVR) than the non-DM patients (20% vs. 3.6%; $p=0.002$).

Proportion of Patients with Events at Follow-Up

Conclusions: FFR > 0.75 in DM patients with moderate stenoses did not ensure good outcomes after conservative therapy to the same extent as in non-DM patients. This may reflect increased plaque instability or falsely elevated FFR in DM. A higher FFR threshold value for DM patients may be warranted.

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Trends in Door to Balloon Times Among High-Risk Patients Undergoing Primary Angioplasty

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Background: Long delays in performing Primary PCI (PPCI) in STEMI patients are associated with an increase in mortality. Current AHA/ACC Guidelines define an optimal 'door to balloon' time of <= 90 minutes for these patients.

Methods: This study was designed to evaluate differences among STEMI patients who underwent PPCI within the 'early' or recommended time of <= 90 minutes and those 'late' patients treated <= 120 minutes in interventional hospitals with cardiac surgery capability. Data from NRM1 4 was analyzed in 30,763 patients. High risk was defined as Systolic BP < 100mmHg, Pulse > 100 bpm, Age > 75+ years, anterior/septal location, Killip Class IV, TIMI or NRM1 high risk score.

Results: Overall, less than one-third (32.2%) of high risk patients had 'door-to-balloon' times within the recommended <=90 minutes. Moreover, just over half of patients (56.9%) had door to balloon times of <= 120 minutes.

	<=90 min.	<=120 min.
Patients (#)	10,962	19,801
75+ years (%)	23.9	47.3
SBP < 100 mmHg (%)	34.8	58.4
Pulse > 100 mmHg (%)	22.1	44.6
Killip Class IV (%)	27.5	51.6
Anterior/Septal (%)	27.9	52.4
TIMI High Risk (%)	19.6	39.5
NRM1 High Risk (%)	27.9	52.0
Teach/NoTeach (%)	26.0/31.1	48.7/55.9
Staff Beds(<151/>350,%)	36.6/29.0	63.4/52.9
Trends - 1998 (%)	28.3	52.5
1999 (%)	29.7	53.5
2000 (%)	30.9	55.4
2001 (%)	32.2	57.5

Conclusions: Rapid performance of Primary PCI in High Risk STEMI patients, although a highly recommended AHA/ACC Guideline, has not been achieved in a majority of patients. Even within the High Risk group, times to treatment did not vary markedly among subsets of patients. Most disturbing was the minimal improvement over the past four years.

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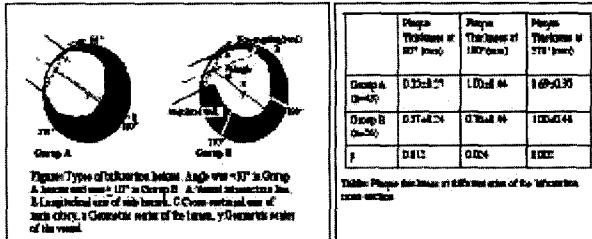
Atheroma Distribution at Coronary Bifurcations: Impact of Side Branch Angulation: An Intravascular Ultrasound Study

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Background: Asymmetric plaque distribution has been observed at coronary bifurcations. We sought to determine the relationship between the take-off angle of the side branch in the cross-sectional plane and circumferential distribution of atheroma at major coronary bifurcation sites.

Methods: Sixty-nine bifurcation lesions with angiographically <50% diameter stenosis were included in this study. An IVUS cross-section containing the main artery and the proximal part of the side branch analyzed for each lesion. We defined 2 types of bifurcation lesions according to the relation between the side branch and main artery in cross-sectional plane. Lesions were in Group A if longitudinal axis of the side branch was toward the center of the main artery and were in Group B if this axis was angulated toward the edge of main vessel instead of center (figure). In order to compare plaque distribution between the groups, plaque thickness at 90°, 180° and 270° were measured by centering the geometric center of the lumen and were expressed clockwise from the side branch

Results: Thirty-eight % of the lesions were in group B. Plaque distribution around the side branch was different in groups. Maximum plaque thickness was at 180° in group A and at 270° in group B (table).



Conclusion: The side branch take-off angle in the cross-sectionally plane influences the plaque distribution in bifurcation lesions. In angulated take-offs, atheroma close to the ostium may pose a higher risk for side branch occlusion during coronary interventions.

1005-213 Percutaneous Interventions in Radial Artery Grafts: Clinical and Angiographic Outcomes

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Background: As arterial grafts are replacing venous grafts for coronary artery bypass surgery (CABG), there has been an increasing demand for percutaneous interventions (PCI) for these conduits. While PCI of internal mammary artery (IMA) grafts has been extensively reported, experience with radial artery grafts is limited. We sought to evaluate the outcomes of 22 patients who underwent PCI of aortocoronary radial grafts.

Methods: We analyzed the baseline clinical and angiographic characteristics, and 12-month outcomes of 22 consecutive patients (26 lesions) who underwent PCI of radial grafts between January 1998 and December 2001.

Results: All patients presented with unstable angina, the majority (82%) within 14 months of CABG. Angiographic success was achieved in 96%. The lesion location was evenly distributed; proximal anastomosis 9/26 (35%), shaft 10/26 (38%), and distal anastomosis 7/26 (27%). Stents were deployed in 50% of lesions. There were no procedural complications or in-hospital cardiac events. Clinical follow-up was available in all patients, with angiographic follow-up in 77%. The mean follow-up was 392 ± 363 days. There were no deaths or myocardial infarctions; 16 patients (73%) had stable angina. Restenosis occurred in 10/22 (45%) patients or 10/26 (38%) lesions. Ninety percent of restenosis occurred within 7 months. Restenosis occurred in 7/9 (78%) of proximal anastomosis, 3/10 (30%) shaft, and 0/7 (0%) distal anastomosis. 5/10 (50%) of these restenotic lesions were treated with balloon alone.

Conclusion: Percutaneous revascularization of radial grafts can be performed safely with high procedural success. However, compared to the published experience in IMA grafts, radial graft interventions have a higher restenosis rate, particularly at the proximal anastomosis.

POSTER SESSION

1005A Outcomes and Coronary Intervention

Sunday, March 30, 2003, 9:00 a.m.-11:00 a.m.
McCormick Place, Hall A
Presentation Hour: 9:00 a.m.-10:00 a.m.

1005A-210 Survival Following Percutaneous Coronary Interventions Versus Coronary Artery Bypass Graft in Northern New England

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Background: BARI reported that nondiabetic patients with multivessel coronary disease had comparable 5 year survival with PCI or CABG. We examined the generalizability of these findings using consecutive cases of nondiabetic patients in Northern New England. **Methods:** Patient characteristics and long-term survival were compared for PCI and CABG patients with multivessel disease, excluding those with diabetes, cancer, 1VD, left

main >= 50%, prior CABG, or emergencies. Cox proportional hazards models were used for adjusted comparison of 5-year survival.

Results: From 1992-1996, 6,272 patients met study criteria (31.3% PCI, 68.7% CABG). CABG patients were more likely to be > 70, to have 3VD, COPD, EF < 40%, LVEDP > 22, but less likely to require urgent procedures. Adjusted in-hospital mortality was higher for CABG than for PCI (1.57% v 0.05%, p=0.002). Overall, CABG was associated with a small improvement in survival compared to PCI (Table). However, 5-year survival was comparable for patients with 2VD. The improved survival associated with CABG was confined to patients with 3VD, 91.2% of these had CABG.

Conclusion: Like BARI, we found similar survival for patients with 2VD in PCI and CABG. Unlike BARI, we found a survival benefit for CABG over PCI for patients with 3VD. This may reflect unmeasured differences in patients introduced by our registry setting or procedural characteristics, such as completeness of revascularization. This observation may be used to inform physician and patient decision making.

Patients	N (%PCI)	Adjusted HR PCI v CABG	95% CI	p=	5 Yr Survival PCI, CABG (%)
2VD	3890 (44.5)	1.24	0.91, 1.69	0.167	88.6, 88.7
3VD	2382 (9.8)	1.87	1.17, 3.01	0.009	84.4, 94.7
All	6272 (31.3)	1.36	1.05, 1.78	0.021	89.6, 91.6

1005A-211 Vascular Disease Independently Predicts Worse Outcome After Percutaneous Coronary Intervention: Results From the NHLBI Dynamic Registry

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Background: While vascular disease (VD) is considered a risk factor for adverse outcome after coronary artery bypass grafting (CABG), it is unknown whether VD predicts poorer outcome after percutaneous coronary intervention (PCI). This multi-center study utilizing the NHLBI Dynamic Registry was designed to determine whether the current practice of PCI in patients with VD is associated with worse outcome when compared to patients without VD. **Methods:** VD was defined as a history or presence of stroke, transient ischemic attack, claudication, vascular bypass, amputation or aortic aneurysm. The incidences of death, myocardial infarction (MI), CABG, repeat PCI and repeat revascularization were prospectively collected on 4,629 consecutive patients who underwent PCI in 17 centers between July, 1997 and February, 1998 and February and June, 1999. Procedural, in-hospital and one-year outcomes in patients with VD (n=554) were compared to patients without VD (NVD, n=4,075). **Results:** VD patients were more likely older, female, smokers and white, and were more likely to have multi-vessel disease, reduced ejection fraction, hypertension, diabetes, heart failure and hypercholesterolemia. While rates of stenting were equivalent between VD and NVD patients (71.5% vs. 73.0%, p=NS), total angiographic success was lower in patients with VD (89.5% vs. 93.2%, p<0.01). VD patients had more death (2.7% vs. 1.3%, p<0.05), MI (4.7% vs. 2.6%, p<0.01), CABG (2.2% vs. 1.1%, p<0.05), stroke (1.1% vs. 0.2%, p<0.001) and major entry site complication (6.7% vs. 3.5%, p<0.001) during the index hospitalization. At one-year, VD patients continued to have more death (10.5% vs. 4.5%, p<0.001) and MI (9.2% vs. 5.2%, p<0.001). After adjusting for clinical, demographic, and angiographic differences, VD was independently associated with worse death/MI (OR 1.4, 95% CI 1.1-1.8) and death/MI/CABG (RR 1.3, 95% CI 1.1-1.6) at one year. **Conclusion:** Patients undergoing PCI with vascular disease have more co-morbidities than patients without. After adjusting for these co-morbidities, vascular disease remains an independent predictor of worse outcome at one year and should be considered when choosing a revascularization strategy.

1005A-212 First Multi-Center Experience With a Novel Low-Profile Filter-Wire Distal Protection Device (Interceptor) During Saphenous Vein Graft Stenting

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Atheroembolism commonly follows stenting of saphenous vein graft (SVG) conduits and may contribute to adverse clinical outcomes. Filter distal protection devices (DPD) offer advantages over the FDA approved balloon occlusive device which include maintenance of coronary flow, angiographic visibility and single operator use. Potential limitations include device profile, filter pore size and single use capability. A novel 0.039 inch nitinol wire filter DPD (Interceptor™) was deployed during SVG stenting in a multicenter trial.

Methods: Patients (n=25) with mean age 71 years (85% male, 40% diabetic, LVEF <= 40, 38%) undergoing stenting of SVG (mean age 10 years) de novo stenoses (mean lesion length 3.5 mm; thrombus 72%; >B2 ACC/AHA lesion class 68%) with Interceptor™ DPD were analyzed. TIMI flow pre-procedure (28% TIMI 2, 72% TIMI 3) was improved post-procedure (8% TIMI 2, 88% TIMI 3). Procedural and hospital outcomes are summarized (Table)