

| | Age >= 65 (N = 154) % (mean) | Age < 65 (N = 290) % (mean) | p-value |
|----------------------|---------------------------------|--------------------------------|---------|
| Age (years) | (69.7) | (53.9) | 0.000 |
| Male Gender | 51.9 | 73.8 | 0.000 |
| Never Smoked | 39.0 | 26.6 | 0.007 |
| Prior MI | 35.7 | 32.8 | 0.531 |
| Hypertension | 46.7 | 35.5 | 0.023 |
| Non-Q-Wave MI | 31.4 | 40.3 | 0.063 |
| Abnormal ECG | 92.9 | 94.1 | 0.597 |
| LV EF | (61.3) | (58.7) | 0.038 |
| 2-3 Vessel Disease | 50.0 | 36.0 | 0.005 |
| Angiographic Success | 95.5 | 96.4 | 0.689 |
| Events by 42 days | | | |
| Death | 1.3 | 1.4 | 0.938 |
| MI | 6.5 | 5.5 | 0.671 |
| Stroke | 0.0 | 0.3 | 0.463 |
| CABG | 1.3 | 4.2 | 0.102 |
| Death/MI/Stroke/CABG | 8.4 | 9.0 | 0.864 |

In comparison to younger pts., elderly pts having PTCA in TIMI IIIB were more often female, had not smoked, had history of hypertension and had multivessel coronary disease. The results of PTCA were equally excellent in both groups. Thus, advanced age alone does not adversely affect the results of PTCA in selected pts with acute ischemic syndromes.

1000-40

Exercise Performance Predicts Long-term Prognosis in Patients with PTCA for Multivessel Disease

Christoph Kadel, Andrea Wolf, Rainer Schröder. *University Hospital Frankfurt am Main, FRG*

The aim of the study was to evaluate whether exercise performance (watts*min) close to the time of PTCA predicts long-term prognosis in P with multivessel disease (MVD). 1031 (study group) of 1252 consecutive P with MVD and PTCA during 1977-90 underwent an exercise ECG. Exercise was performed with a constantly maintained workload and terminated at severe angina, ST↓ ≥3 mm, or at 6 min. Completeness of revascularization was established by reangiograms in 564/796 successful P. Long-term follow-up, ascertained by questionnaire in 97.9%, ranged from 2-15 (median 4.8) yrs.

Results. Univariate analyses revealed a strong correlation between exercise performance and long-term prognosis:

| | Exercise performance, watts-min | | |
|--|---------------------------------|------------|-------------|
| | 40-449 | 450-899 | 900-1380 |
| patients, n | 178 | 656 | 197 |
| 8 yr survival [#] , % | 76.5 ± 4.0 | 83.3 ± 2.0 | 96.1 ± 1.6* |
| 8 yr surv. without MI or CABG [#] , % | 42.8 ± 4.8 | 52.9 ± 2.7 | 70.7 ± 4.5* |

[#]Kaplan-Meier, *p = 0.0000 by log-rank test

Cox's multivariate regression determined exercise performance as the most important predictor of long-term survival, p = 0.0000, followed by 3VD, p = 0.001, and age, p = 0.01. Survival without MI or CABG was predicted by completeness of revascularization, exercise performance, and acute success, each p = 0.0000, and by 3VD, p = 0.02.

Conclusion. The functional parameter of exercise performance was a more powerful predictor of long-term survival after PTCA in P with MVD than angiographic parameters such as 3VD or completeness of revascularization and therefore should be considered, if algorithms for estimation of long-term outcome are designed.

1001

Local Intracoronary Thrombolysis/Experimental Stents/Vasodilators

Wednesday, March 22, 1995, Noon-2:00 p.m.
Ernest N. Morial Convention Center, Hall E
Presentation Hour: Noon-1:00 p.m.

1001-23

Localized Intracoronary Delivery of Urokinase with the Channelled Balloon: Pharmacokinetics of Drug Delivery and Washout

Joseph F. Mitchel, Daniel B. Fram, Michael A. Azrin, Laurine Bow, Tod Alberghini, Adel M. Eldin, Michael Shwedick, David D. Waters, Raymond G. McKay. *Hartford Hospital, University of Connecticut, Hartford, CT*

The Channelled Balloon is a new local drug delivery catheter which allows for simultaneous vessel dilation and local drug infusion at low pressure. In order to assess the pharmacokinetics of intracoronary urokinase delivery with

this device, ¹²³I-urokinase was delivered to 19 coronary arteries in 10 anesthetized pigs. All vessels underwent dilation at 6 atm, with simultaneous infusion of urokinase. Drug was infused at an inflation pressure of 2 or 4 atm, a balloon:artery ratio of either 1:1 or 1.2:1, and at a concentration of either 5,500 or 11,000 units/ml. Treated vessels were harvested up to 5 hrs later to quantitate intramural drug deposition and washout.

Results: Successful drug delivery was accomplished in all vessels without adverse hemodynamic, electrical, or angiographic sequelae. The efficiency of drug delivery (i.e., % of delivered drug that was intramurally deposited) ranged from 0.06 to 0.4%. Drug infusion pressure had no significant effect on drug deposition. Higher urokinase concentrations and a higher balloon:artery ratio resulted in higher intramural drug levels (p < 0.01). Urokinase deposition and washout is described below:

| | Time of Harvest | | | | |
|----------------------|-----------------|-------------|-------------|-------------|-------------|
| | 5 mins | 15 mins | 45 mins | 1 hr | 5 hrs |
| Intramural Urokinase | 21 ± 12 units | 7 ± 4 units | 5 ± 4 units | 5 ± 4 units | 2 ± 2 units |

Conclusions: Urokinase can be safely delivered at coronary angioplasty sites using the Channelled balloon. Intramural drug deposition is related to the concentration of infused drug and balloon:artery ratio. Although significant washout occurs, urokinase persists for at least 5 hours following delivery. This technique may be useful in the local dissolution of intracoronary thrombus and creates a reservoir of urokinase at an angioplasty site which may result in prolonged local thrombolysis.

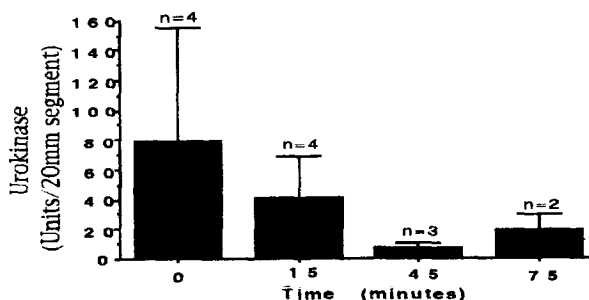
1001-24

Local Delivery of Urokinase to Porcine Coronary Arteries Using the Localmed Infusion Sleeve

Michael A. Azrin, Joseph F. Mitchel, Laurine M. Bow, Tod V. Alberghini, Gordon Grant, Aaron V. Kaplan, David D. Waters, Raymond G. McKay. *Hartford Hospital, Hartford, CT; University of Connecticut, Farmington, CT*

Local Delivery of thrombolytic agents may reduce thrombus formation after balloon angioplasty. The Localmed Infusion Sleeve enables localized infusion of urokinase to be performed at the time of balloon angioplasty without the need for catheter exchange. **Methods:** Balloon angioplasty was performed on 13 coronary arteries of 5 pigs at 4 atmospheres with a balloon to artery ratio of approximately 1.1 to 1. After angioplasty the Infusion Sleeve was advanced over the dilatation balloon and the balloon was reinflated to 2 atmospheres to appose the sleeve to the vessel wall. 50,000 Units (8 cc) of ¹²³I-urokinase was infused through the microperforations in the sleeve for 10 seconds by a computer controlled pump. The coronaries were then excised and counted in a gamma counter.

Results:



Conclusions: (1) The Localmed Infusion Sleeve enables drug infusion to be uncoupled from balloon dilatation. (2) Successful delivery of Urokinase to the vessel wall may be achieved using this device without the need for catheter exchange. (3) Persistence of urokinase within the vessel wall occurs after local delivery.

1001-25

Combined Intralesional Tissue Plasminogen Activator and Intracoronary Heparin in Patients with Unstable Angina and Coronary Thrombus Undergoing PTCA

Paul A. Gurbel, Frank I. Navetta, Brent Muhlstein, Alan N. Tenaglia, David W. Muller, Eric R. Bates, Charles J. Davidson, Michael J. Miller, Frank V. Aquirre, James B. Hermiller, Carl Tommaso, Lisa Berdan, Paul Owens, Glenn J. Beauman, Jeffrey D. Leimberger, Edwin Bovill, E. Magnus Ohman. *University of Maryland, Baltimore, MD; Duke University Medical Center, Durham, NC*

PTCA in the setting of unstable angina (UA) and coronary thrombus (CT) is associated with adverse outcomes. We performed a pilot study of intralesional tPA (20 mg) using an end-hole infusion (Tracker) catheter and intracoronary heparin (5,000 units), delivered over 20 mins, prior to PTCA in 53 pts with

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