

**1027 Cost-Effectiveness of Intracoronary Stents**

Sunday, March 29, 1998, 5:00 p.m.-7:00 p.m.  
 Georgia World Congress Center, West Exhibit Hall Level  
 Presentation Hour: 5:00 p.m.-7:00 p.m.

**1027-47 Cardiac Interventional Procedures Performed in Europe During a Four Year Observation Period From 1992 to 1995**

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**Background:** An annual survey on percutaneous cardiac interventions has been conducted by the European Society of Cardiology since 1992. The purpose of this study was to analyze the trends in cardiac interventions during this observation period.

**Methods/Results:** A questionnaire was distributed through the national societies of cardiology to 35 member states of the European Society of Cardiology. The questionnaire contains a detailed listing of all percutaneous cardiac interventions. The results of this survey are summarized in the table below:

	1992	1993	1994	1995
Cath's	883 888	766 822	822 887	1032 782
PTCA's	117 720	183 720	324 722	272 100
Stents	3 211	0 444	21 500	70 056
PTCA/CABG	1.1	1.2	1.3	1.6

**Conclusions:** 1. The number of coronary angiograms increases at an annual rate of 15%. 2. The number of PTCA's increases at an annual rate of 20%. 3. Coronary stenting is the fastest growing procedure in interventional cardiology. 4. PTCA continues to surpass CABG as revascularization procedure.

**1027-48 Application of Critical Pathways in the Introduction of New Medical Technology: The Intracoronary Stent as a Model**

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After the initial research breakthrough, new medical technology can be further developed, improved, and adapted to new indications. By standardizing and optimizing the care process, critical pathways (CP) may facilitate the introduction of new medical technology and the rapid implementation of changes in ancillary care. The development of intracoronary stenting, with the evolution in per-procedural care and anticoagulation regimen, is a useful paradigm. We report our experience with intracoronary stenting as a model for CP application. Between 8/10/93 and 3/31/97, 494 consecutive patients underwent intracoronary stenting for stable or unstable coronary syndromes during 4 phases of CP evolution (Periods A through D). During that time, tighter blood pressure control was implemented, sheath removal practices were revised and the peri-procedural anticoagulation regimen was progressively liberalized from one that included dextran, IV heparin, warfarin at a target INR of 3-4, dipyridamol and ASA (A), to a final regimen that contained neither post-procedure heparin nor warfarin (D2). As treatment algorithms evolved, vascular complication rate (VC), blood transfusion rate (Txf) and post-procedure length-of-stay (LOS) decreased significantly without a consequent increase in the rate of subacute stent thrombosis (SST).

Period (n)	A (30)	B (9)	C (18)	D1 (146)	D2 (291)	p
Txf (%)	40.0	22.2	16.7	15.1	4.1	<.001
VC (%)	16.7	0	5.6	5.5	2.7	0.008
LOS (days)	9.8 ± 7.7	5.8 ± 0.8	4.6 ± 1.5	5.5 ± 6.3	2.2 ± 3.9	<.001
SST (%)	0	0	0	1.4	0.7	0.869

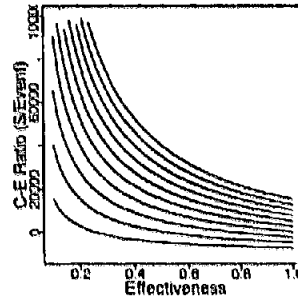
The observed reduction in complication rates and LOS was likely the result of changes in anticoagulation regimen. The CP proved instrumental in facilitating the rapid and controlled introduction of changes in the care process and in tracking the effects of those changes on clinical outcomes.

**1027-49 Cost of Clinical Restenosis and Cost-effectiveness of Therapy to Prevent it**

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Restenosis, a major limitation of PTCA, increases cost by adding resource

use, especially repeat procedures. Recently restenosis has been defined clinically, and for this study was defined as death, myocardial infarction, additional PTCA or CABG after successful, uncomplicated therapy. Charges for additional hospitalizations were determined from the UB92 forms, and reduced to cost by departmental cost to charge ratio. Cost are expressed 1996 dollars. Between 1988 and 1995 there were 5,795 patients suitable for study with cost data available. The cost of clinical restenosis (n = 1,131 or 19.5%) was \$9,633 (25% to 75% range \$7,453 to \$11,813). There was limited ability to predict clinical restenosis (area under ROC curve 0.60) and even less to predict the cost (r<sup>2</sup> = 3.05). Thus a suitable preventive therapy will probably be used in all possible patients. If the effectiveness of preventive therapy is 50% and the cost of therapy \$2,500, it will cost \$16,000 per event prevented; if cost of therapy is \$1,000, cost per event prevented falls to \$633.



The figure is a two way sensitivity analysis of effectiveness of preventive therapy from 10% to 100% and each line from bottom to top, is an isobar of cost from \$500 to \$5000 in \$500 steps. Cost effectiveness (C-E) improves with lower cost of therapy and improved effectiveness. Restenosis is likely to remain a problem after PTCA until inexpensive, highly effective preventive therapy is available.

Cost effectiveness analysis may help guide the choice of therapy and in setting policy over use of scarce resources.

**1027-50 Costs and Effects of Stent Implantation Versus Balloon Angioplasty**

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**Background:** The Benestent II study is designed not only to assess safety and efficacy of the heparin coated Palmaz-Schatz stent but also to investigate the balance between the costs and effects.

**Methods:** Cost effectiveness is estimated at one year after randomization. Direct medical costs are calculated by multiplying detailed resource utilization data with US cost estimates. Effects are expressed in terms of event free survival including death, MI, stroke and all re-interventions as events. Cost effectiveness is expressed in terms of incremental cost effectiveness ratio's. Subgroup analyses concern LAD, vessel size >3 mm and stable/unstable angina

**Results:** Event free survival is estimated at 88.8% after stent implantation and at 79.0% after PTCA. The additional costs per additional event free survivor are estimated at \$14,473 (95% CI: 5 - 1,523-\$94,073). Subgroup analysis shows more favorable results for stent implantation in LAD lesions, in lesions with vessel size >3 mm, and in patients with unstable angina. Cost savings are expected for patients with a lesion in the LAD and a vessel size >3 mm (\$11,481 for stent implantation versus \$14,558 for PTCA). Here, the upper 95% limit of the incremental cost effectiveness ratio is estimated at \$3,119.

**Conclusion:** A strategy of stent implantation in all patients is more effective but also more costly than a strategy starting with PTCA (and a strict definition of bail out stenting). Appropriate patient selection (LAD, vessel size >3 mm) however, may lead to cost savings.

**1027-51 Clinical, Resource and Cost Benefits of the RESTORE Study Applied to US Population**

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RESTORE, a randomized efficacy study of tirofiban for outcomes and restenosis, evaluated the effectiveness, resource utilization and cost of IIb/IIIa

platelet inhibition in patients with acute coronary ischemic syndromes undergoing angioplasty. RESTORE demonstrated a 30% risk reduction in the composite endpoint of death, MI and repeat procedures ( $p = 0.016$ ) at 7 days and at 30 days ( $p = 0.052$ ). To project the clinical, resource and cost (initial and 30 day) benefits observed in RESTORE to the entire US population (USP), the National Hospital Discharge Survey (NHDS) was utilized to identify a cohort of patients meeting RESTORE eligibility criteria. NHDS PTCA estimates for the US population for 1994 were approximately 404,000. Morbidity and resource utilization rates from RESTORE were applied to the USP PTCA estimates to determine the population incremental benefits of tirofiban therapy compared to placebo. An estimated reduction of approximately 6464 MI's and 7272 emergency repeat angioplasties would also be avoided at Day 7. A commensurate reduction of \$175.7 Million in initial hospitalization costs and \$787.8 Million in overall costs, excluding drug procurement cost, would be expected with tirofiban therapy. Tirofiban confers the aforementioned clinical advantage with substantial cost offsets during the initial hospitalization and 30 days post hospitalization.

**1027-52 Cost-effectiveness of Abciximab After Coronary Stenting: A Decision-analytic Model**

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*Background:* Abciximab (AB) has been shown to improve outcomes after

balloon angioplasty but at an increased cost. Whether its benefits apply after coronary stenting (CS) and at what cost is not known.

*Methods:* We developed a model to predict the cost-effectiveness (CE) of AB use in planned CS. Baseline assumptions were derived from published data, and included the annual probability of cardiac death for pts with coronary disease (range 0.6%–2.9% depending on anatomy, LV function and diabetes); the relative risk (RR) of cardiac mortality due to per-procedural CK elevation (8% increase per 1-fold rise in the ratio of peak CK/normal); and the RR of per-procedural CK elevation with AB (0.48). The probability of per-procedural CK elevation (pCK) in pts undergoing CS (10%) was based on data from the Stent Anti-thrombotic Regimen Study (STARS). We assumed an AB cost of \$1,400 and that per-procedural CK elevation would affect cardiac mortality for 5 years.

*Results:* The baseline analysis for a 60 year old man showed a CE ratio of \$620,000 per year of life saved (YOLS) for low risk pts (1-vessel disease, no diabetes, normal ejection fraction) and of \$167,000/YOLS for high risk pts (multivessel disease, diabetes, and low ejection fraction). Sensitivity analysis showed that major determinants of CE were the cost of AB and pCK. At a spending threshold of \$50,000/YOLS, AB would be preferred in high risk pts if pCK was  $>35\%$  or if it cost  $\leq$  \$400. For low risk pts, achievement of a favorable CE ratio required both a pCK  $>35\%$  and a net AB cost  $\leq$  \$400.

*Conclusion:* The use of AB adjunctive to CS does not appear cost-effective in routine use. Achievement of CE ratios comparable to other medical practices requires targeting of pts at high risk for late cardiac events and per-procedural CK elevations.