



**Senior Medicine Rotation: Evidence-Based Medicine Project**

**Resident Name: Edwin Lee**

**Block:**

**Date: April 12<sup>th</sup> 2005**

**Case SIGNOUT:**

60yo male with CAD risk factors of HTN, DM, hypercholesterolemia, FHx CAD who present with suturing SSCP x 1 day in setting of exertion. EKG with no acute ST/T wave changes. Troponin neg x 3. Impression Unstable Angina, TIMI risk score of 3 out of 7. Pt went for cardiac cath with one vessel CAD: LCX 70% s/p Cypher stent. Post cath without any complications, Hct stable, Creatine stable. Pt is a parks worker who needs to return to work and asks you about the safety of physical activity after coronary stenting.

**Clinical Question:** Is there any evidence that early unrestricted physical activity in patients after coronary stenting is safe?

**Search Strategy**

Database: Pubmed search

“Coronary stenting” [Mesh terms] AND “Exercise” [MeSH terms] AND “Safety” [MeSH terms]  
Randomized Controlled Trial [ptyp] AND English [Lang] AND “human” [MeSH terms]

Items 1 - 3 of 3

One page.

- 1:** [Roffi M, Wenaweser P, Windecker S, Mehta H, Eberli FR, Seiler C, Fleisch M, Garachemani A, Pedrazzini GB, Hess OM, Meier B.](#) [Related Articles](#), [Links](#)  
 Early exercise after coronary stenting is safe.  
J Am Coll Cardiol. 2003 Nov 5;42(9):1569-73.  
PMID: 14607440 [PubMed - indexed for MEDLINE]
- 2:** [van Dijk D, Nierich AP, Eefting FD, Buskens E, Nathoe HM, Jansen EW, Borst C, Knape JT, Bredee JJ, Robles de Medina EO, Grobbee DE, Diephuis JC, de Jaegere PP.](#) [Related Articles](#), [Links](#)  
 The Octopus Study: rationale and design of two randomized trials on medical effectiveness, safety, and cost-effectiveness of bypass surgery on the beating heart.  
Control Clin Trials. 2000 Dec;21(6):595-609.  
PMID: 11146152 [PubMed - indexed for MEDLINE]
- 3:** [Serruys PW, Emanuelsson H, van der Giessen W, Lunn AC, Kiemeny F, Macaya C, Rutsch W, Heyndrickx G, Suryapranata H, Legrand V, Goy JJ, Materne P, Bonnier H, Morice MC, Fajadet J, Belardi J, Colombo A, Garcia E, Ruygrok P, de Jaegere P, Morel MA.](#) [Related Articles](#), [Links](#)  
 Heparin-coated Palmaz-Schatz stents in human coronary arteries. Early outcome of the Benestent-II Pilot Study.  
Circulation. 1996 Feb 1;93(3):412-22.  
PMID: 8565157 [PubMed - indexed for MEDLINE]



**Senior Medicine Rotation: Based Medicine Project (Cont)**

**Early exercise after coronary stenting is safe.**

**Roffi M, Wenaweser P, Windecker S, Mehta H, Eberli FR, Seiler C, Fleisch M, Garachemani A, Pedrazzini GB, Hess OM, Meier B.**

Journal of the American College of Cardiology 2003, Nov 5;42(9):1569-73

**Introduction**

Case reports of acute ischemia linked to exercise stress testing after coronary stenting have been described. These reports have led to uncertainty among patients and physicians about resumption of normal physical activity after coronary stenting. This was a randomized controlled trial of comparing the incidence of clinical stent thrombosis at 14 days in patients with or without exercise stress test the day after coronary stenting.

Group	Criteria or definition	n
Population screened.	Single tertiary care center in Switzerland	1000 (788 males, 212 females)
Inclusion criteria	Status post percutaneous coronary intervention of stenosis >50% disease	
Exclusion criteria	<p><b>Clinical exclusion criteria:</b> recent or ongoing MI (within one week), symptomatic heart failure, severe valvular heart or pulmonary disease, or inability to exercise</p> <p><b>Periprocedural exclusion criteria:</b> Symptomatic main vessel or side branch occlusions, <i>access site-related complications</i>, persistent chest pain or new ST-segment deviation, or final coronary flow less than TIMI grade 3.</p>	
Treatment group	Early symptom limited exercise stress testing	
No treatment group	No exercise stress testing	

**Primary endpoints:** Clinical stent thrombosis at 14 days defined by one of the following: angiographically documented stent thrombosis, sudden death, any MI, or urgent target revascularization.

**Secondary endpoints:** Any one of the following *vascular access site-related complications*: pseudoaneurysm, DVT or PE, need for surgical repair of access site, need for blood transfusion, or presence of hematoma requiring hemostasis measures/prolonged hospital stay/surgical revision.

- Are the Results of the Trial Valid?
  - Randomized? Yes, randomization occurred at the end of the coronary procedure, in the absence of the above mentioned exclusion criteria (clinical and periprocedural exclusion criteria).
  - All patients accounted for at end? Yes, follow up was completed in 99.5% of cases.
  - Intention to treat? Yes.
  - Blinding? No.
  - Equal treatment of groups? No, 10% (50/498) of patients assigned to exercise stress test group *DID NOT* undergo exercise stress testing.
  - Did randomization work? Yes, both groups well matched for baseline and procedural characteristics.

- Are the Results of the Trial important?
  - How large was the treatment effect? There was no risk differences between the treatment or no treatment group in the primary or secondary endpoint.

Endpoint	Result	Significance	ARR	NNT
Primary end point of clinical stent thrombosis at 14 days	1% of pts with stress test (5/496) vs. 1% of pts without stress test (5/499)	Not significant (p=1)		
Secondary end point of vascular access site complication	4% of pts with stress test (20/496) vs. 5.2% of pts without stress test (26/496)	Not significant (p=0.37)		

- Can I apply these results to my patient?
  - **Comparison of my patient to trial patients?** My patient would be included in this trial based on his clinical demographics. However, the incidence of CAD risk factors such as hypertension, diabetes and hypercholesterolemia was not indicated. Moreover, the type of cardiac stent was not stated, though it is likely that bare-metal stents were used during the trial period between September 1997 till June 2001.
  - **Were all important clinical outcomes considered?** Clinical primary end-points of death, MI or need for urgent TVR were used to detect angiographic documentation of stent thrombosis. However, follow up was only to 14 days. Although the vast majority of stent thrombosis occurs early, there have been reports of late stent thrombosis up to 12 months.
  - **Is the likely treatment worth the benefit?** Yes, this study addresses the safety of early physical exertion after coronary stenting. However, in patients with unstable angina and suboptimal procedural results (i.e the presence of residual stenosis >50%, non-flow limiting dissections, or side branch compromise in the absence of flow impairment) had a statistical significant increase incidence of stent occlusion. Secondly, the treatment group had supervised symptom limited exercise testing, though patients with symptoms during exercise testing (i.e. syncope at maximum workload in the absence of rhythm disturbances and transient ST-segment deviation) remained free of cardiac events during the follow-up. Therefore, we cannot generalize this trial to the safety of *non-supervised* early vigorous exercise post coronary stenting.