COLUMBIA UNIVERSITY MEDICAL CENTER

DIVISION OF GENERAL MEDICINE

Senior Medicine Rotation: Evidence-Based Medicine Project

Student Name: David Tsay **Block: July 2008** **Date: 7/20//2008**

Case SIGNOUT:

VU is a 58 yo Hispanic man w h/o PSVT S/P ablation 03 who presents w an episode of syncope. The patient has not had a prior h/o syncope and was at baseline health until the morning PTA when he suddenly lost consciousness and fell to the floor while eating breakfast, hitting his head. Prior to the episode, he had felt nauseous, but otherwise no prodrome, no palpitations, no dizziness, no chest pain. Per the family, he remained on the floor for 1 min, without convulsions or incontinence. He recovered fully after one minute, EMS activated. EMS found him A&Ox3, BP100/60, P68 and an EKG showed afib @ 70 bpm. A repeat EKG 20 min later showed NSR. At the ED he had slight chest discomfort, but otherwise unremarkable, no orthostasis, EKG showed NSR w new TWI V3-V6.

He was admitted to medicine for further workup, which thus far has been largely negative. Tele has shown only SB, P40-70; TTE and carotid dopplers unremarkable. A stress test showed RCA ischemia, but diag cath revealed no lesions. EP study is pending.

Clinical Question: What is the most appropriate strategy in long-term ambulatory monitoring of patients who present with syncope of unknown etiology? (Holter, Ext loop monitor, Implantable)

Search Strategy - Database: MEDLINE/OVID

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CONTRACT

1. Krahn AD. Klein GJ. Yee R. Hoch JS. Skanes AC. Cost implications of testing strategy in patients with syncope: randomized assessment of syncope trial.[see comment]. [Clinical Trial. Comparative Study. Journal Article. Randomized Controlled Trial. Research Support, Non-U.S. Gov't] *Journal of the American College of Cardiology. 42(3):495-501, 2003 Aug 6.*
UI: 12906979

Authors Full Name
Krahn, Andrew D. Klein, George J. Yee, Raymond. Hoch, Jeffrey S. Skanes, Allan C.

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2. Sivakumaran S. Krahn AD. Klein GJ. Finan J. Yee R. Renner S. Skanes AC. A prospective randomized comparison of loop recorders versus Holter monitors in patients with syncope or presyncope.[see comment]. [Clinical Trial. Comparative Study. Journal Article. Randomized Controlled Trial. Research Support, Non-U.S. Gov't] *American Journal of Medicine. 115(1):1-5, 2003 Jul.*
UI: 12867227

Authors Full Name
Sivakumaran, Soori. Krahn, Andrew D. Klein, George J. Finan, Jane. Yee, Raymond. Renner, Suzanne. Skanes, Allan C.

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Senior Medicine Rotation: Evidence-Based Medicine Project (Cont)

Journal Article

Krahn et al. Cost Implications of Testing Strategy in Patients With Syncope. *Journal of the American College of Cardiology*. 2003 Aug 6;42(3):495-501.

Group	Criteria or definition	n
Population screened	Canadian patients referred to the Arrhythmia Service at London Health Sciences Center (Ontario, Canada)	2000+/yr
Inclusion criteria	1) recurrent unexplained syncope 2) at least one episode of syncope w injury 3) Clinical Exam, TTE, Telemetry >24 hrs	>60
Exclusion criteria	1) High clinical suspicion of other disease 2) Orthostatic BP changes 2) LV EF < 35% 3) Recorded arrhythmia 4) Unable to followup	60
Conventional Therapy	External loop recorder for 2-4 weeks followed by EP testing and Tilt-table test. Offered crossover to prolonged monitoring if all results of tests were negative.	30
Prolonged Monitoring	Implantable loop recorder (Reveal device, Medtronic) with followup at 1, 2, 3, 6, 9, 12 months or immediately after an event. Offered crossover to conventional therapy if no events.	30
Cost Determination	Based on Ontario Health Insurance Program schedule of fees	-

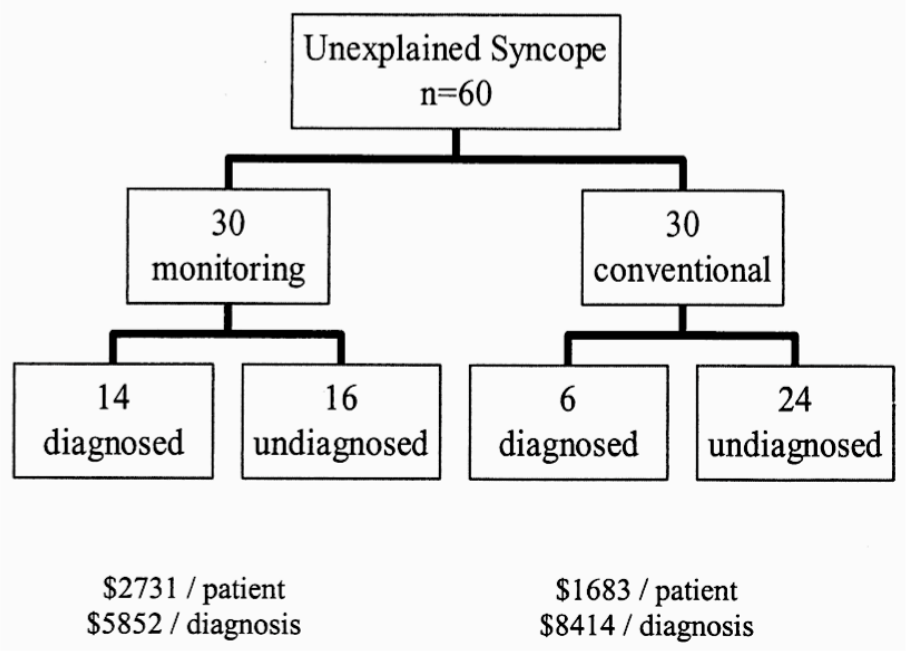
Primary Endpoint
- Confirmed diagnosis
  1) Syncopal Event with documented arrhythmia
  2) Positive EP or Tilt-test in conventional arm

Primary Guides

- Randomized? Yes. Sixty patients were randomized to each arm, and baseline characteristics were similar in each group (see Table 2).
- Blinding? No, was not practical to blind, as both conventional and prolonged monitoring groups would have to undergo sham procedures.
- Intention to treat? Yes.
- Appropriate patient sample? Yes. All patients have syncope of unknown etiology and have exhausted all the minimally invasive, low-cost tests.

Secondary Guides

- Reproducible? Mostly. The methods describes what type of devices were used, including the manufacturer of the implantable loop recorder, as well as how patients were followed. However, the authors fail to note what type of external loop recorder was used, as well as describe the details of how the EP study was done, or the parameters of the tilt table test (degree).



Test	Diagnostic Events	Non-diagnostic	Diagnostic Yield	Cost pp	Cost per diagnosis	Absolute Benefit Increase (ABI)	Relative Benefit Increase (RBI)	NNT
Conventional	6	24	20%	$1683	$8414	27%	1.35	4
Prolonged Monitoring	14	16	47%	$2731	$5852			
P value			0.029	<0.0001	<0.0001			
Conventional Crossover (21)	8 (14)	13	47%	$3683	$7891	8%	0.17	13
Prolonged Crossover (5)	2 (16)	3	53%	$2937	$5815			
P value			>0.05	0.013	0.002			

What are the results?

- Conventional vs. Prolonged Monitoring – the diagnostic yield was statistically higher in the prolonged monitoring compared to conventional therapy (47% vs 20% p = 0.029).
- Prolonged monitoring was more costly than conventional ($2731 vs. $1683; p<0.0001).
- Cost per diagnosis, however, was much lower in the prolonged monitoring arm given the higher diagnostic yield ($5852 vs. $8414, p < 0.0001).
- Overall, the diagnostic yields were similar in the crossover groups, but overall test costs were still lower the prolonged monitoring arm.

Limitations of the Study.

- No Gold Standard – primary endpoint does not account for definitive diagnosis that arrhythmia is the cause of the syncope. False positives could occur.

- Morbidity/mortality of invasive procedures – study did not report any adverse events associated with EP testing and implanting of device (infection, device migration, etc.); larger sized trial would be useful to assess differences

- Cost of EP testing and Tilt testing – could have skewed results as this was the bulk of the cost in the conventional arm. However, only 1 person out of 30 was diagnosed by the external loop recorder, and so considering a cost of loop recorder by itself is $435, the cost per diagnosis would be $435 x 30 = $13,050 much greater than prolonged strategy.

Will the results help me in caring for my patients?

- Reproducibility and interpretation satisfactory in my setting? Yes
  Both therapies are readily available in the US. Costs are likely to be relatively similar in the US in terms of device cost and procedures, which make up the bulk of the cost.

- Results applicable to my patient? Yes, although some caveats.
  The patient is similar to the study group in that he is elderly, has had at least one syncopal event with injury, has a baseline normal ECG, and has no evidence of structural heart disease or poor LVEF. However, the patients in the group tended to have syncopal episodes over a duration of 6-9 years, whereas this is my patient's first episode. The diagnostic yield may be much lower in patients without documented recurrent episodes.

- Results change my management? Yes.
  The results strongly indicate that the cost of using a long-term implantable loop recorder is outweighed by the higher diagnostic yield of the device. I would recommend a prolonged-monitor device both due to its higher yield and overall cost-effectiveness.

- Patient better off as a result of the test? Inconclusive. Although the study suggests that the costs of diagnosis would be greater, it is unclear what the potential costs of complications secondary to adverse events with the invasive procedures might entail. A larger trial with documented adverse events would be helpful in assessing this risk.

Table 2. Clinical Characteristics of Conventional and Monitored Groups

	Conventional (n = 30)	Monitored (n = 30)
Age (yrs)	64 ± 14	68 ± 14
Male gender	14 (47%)	19 (63%)
Baseline ECG normal	22 (73%)	20 (67%)
Structural heart disease	10 (33%)	13 (43%)
LVEF (%)	55 ± 6	55 ± 8
Number of syncopal episodes	5.8 ± 6.6	4.1 ± 3.3
Duration of syncope (yrs)	8.7 ± 26.6	6.6 ± 12.1

Data are presented as the mean value ± SD or number (%) of patients.
ECG = electrocardiogram; LVEF = left ventricular ejection fraction.

Table 3. Cost of Testing Before and During the Study

Cost Variable	Monitoring	Conventional	p Value	ICER
Before enrollment (n)	30	30		
Neurologic	$275 ± $357	$294 ± $299	0.83	
Cardiovascular	$606 ± $155	$578 ± $134	0.46	
Total	$1,363 ± $507	$1,290 ± $504	0.57	
Primary strategy (n)	30	30		$3,930
Cost	$2,731 ± $285	$1,683 ± $505	< 0.0001	
Cost/diagnosis	$5,852 ± $610	$8,414 ± $2,527	< 0.0001	
Crossover strategy (n)	5	21		$6,127
Cost*	$2,657	$1,548		
Cost/diagnosis*	$6,974	$7,741		
Overall (n)	30	30		
Cost	$2,937 ± $579	$3,683 ± $1,490	0.013	$−22,380
Cost/diagnosis	$5,875 ± $1,159	$7,891 ± $3,193	0.002	

*Standard deviations are not reported, because all patients in each group underwent identical testing, with identical costs.
ICER = incremental cost-effectiveness ratio.