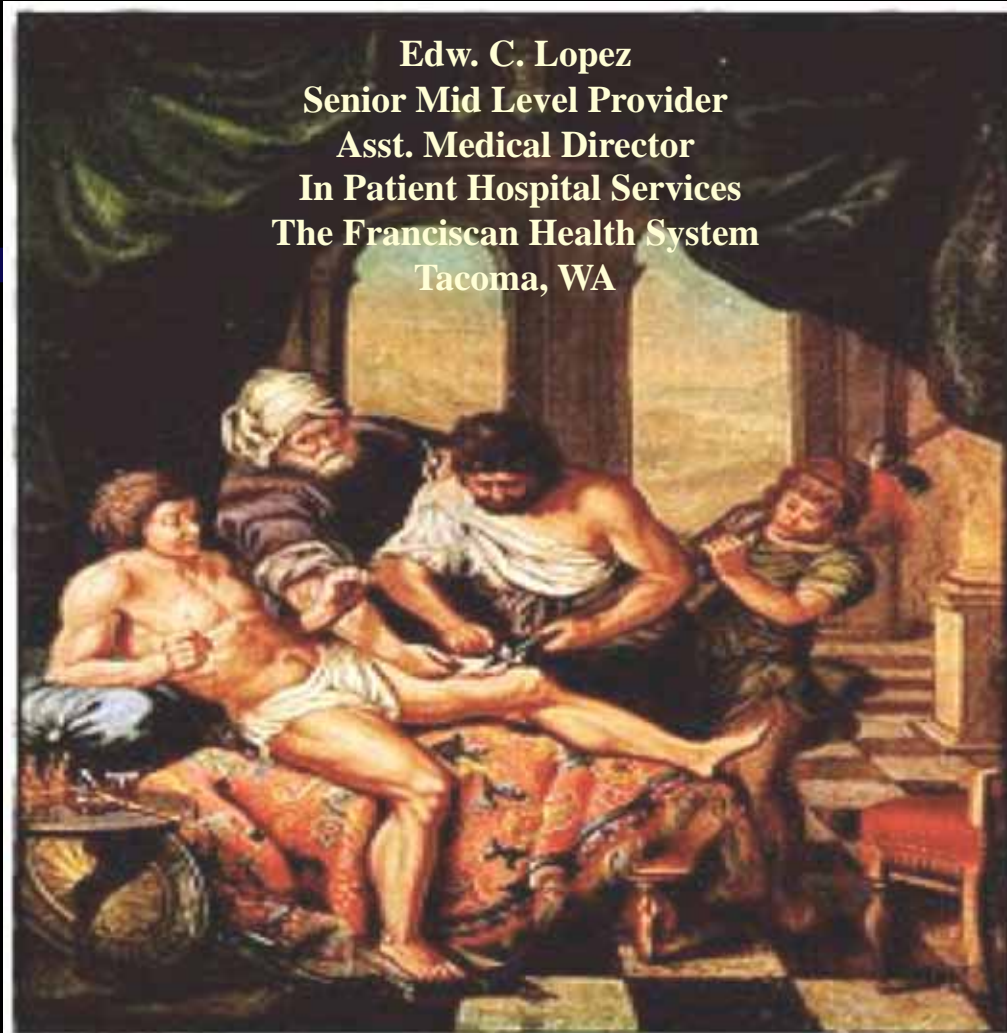


*The Endoscopic Vein Harvest Technique
Here Today Gone Tomorrow?*

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“I have NO affiliations or conflict of Interest relationships to disclose.”

In The Beginning....The 60's


- The Saphenous vein has been the preferred conduit by far as the source of restoring blood flow to viable myocardium since the beginning of coronary re-vascularization surgery in the early 1960's
- The person historically performing this procedure the most over the last 4 decades has been the cardio-vascular Physician Assistant.
- After 30 years of procedures, patients with worsening co-morbidities & the development of the intra-operative scopes this prompted the re-thinking of what could be done in using a scope to harvest saphenous veins. (Dr. Al Chin, San Francisco)

The Problem !



In The Beginning...The 90's

- In the early 1990's surgical device companies realized that the extremity wound complications from the customary surgical open technique of harvesting veins were being looked at for it's cost, increase LOS, and morbidity concerns.
- January 1995 device companies approach the Physician Assistant to help them design and perfect a device as well as a technique to help harvest a venous and ultimately arterial conduit with minimal trauma to the patient's limbs.



*The focus early on was to decrease the leg
wound complications & post operative
discomfort experienced by patients
undergoing CABG.*

The Evolution of Endoscopic Devices Starting in 1996



- J & J (Ethicon)
- Guidant
- Boston Scientific
- Maquet
- Terumo
- Etc...



EVH Results Since 1996

- Over 1 Million Endoscopic vein harvest procedures have been performed in the U.S. to date.
- Patient satisfaction of saphenous vein harvesting wound sites have markedly improved.
- Adoption and acceptance of EVH has become the standard of care for Vein conduit harvesting. (76% of all CABG procedures use EVH)
- Post-operative wound complications, including wound dehiscence and infections markedly decreased by 84%
 - (Annals of Thoracic Surgery 2003; 76; 2141-45)
- Some contend it has shortened hospital LOS thus resulting in an overall hospital cost reduction in CABG procedures

A Dramatic Change in Results



*So We Solved A Clinical Problem For
Our Patients!*



However...Did we while solving one
clinical problem, create another
perhaps bigger problem for our
Patients?

A Lingering Question Smolders ...



“What is the long term patency rate of the venous conduit today in Coronary re-vascularization when the “open” harvest technique is directly compared to the Endoscopic harvest technique over time?”



*Someone Offers To Answer That
Question!*

*Two Most Distinguished Published Studies
Available Comparing O.V.H to E.V.H.*

- Epic Trial Emory University
- Prevent IV Trial NEJM



*The New England
Journal of Medicine*

established in 1812

July 16, 2009

vol. 361 no. 3

Endoscopic versus Open Vein-Graft Harvesting
in Coronary-Artery Bypass Surgery

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M.H.S.

The Study Construct

- Analysis conducted with the use of the database from the design and main results of the PREVENT IV trial published previously.
- PREVENT IV was a phase 3, multicenter, randomized, double-blind, placebo-controlled trial of ex vivo treatment of vein grafts with the E2F transcription factor decoy, edifoligide, in patients undergoing CABG.
- Trial was conducted at 107 sites in the U.S
- More than 3000 pts. enrolled in 2002, 2003 ages 18-80 years old undergoing a first isolated CABG with at least two planned vein-graft implantations.
- First 2400 patients were in an angiographic cohort scheduled to undergo angiography 12-18 months after surgery.
- Primary outcome was the composite of death or vein-graft failure as assessed by quantitative coronary angiography post op.

Study Findings

- Patients who underwent endoscopic harvesting had higher rates of vein-graft failure at 12 to 18 months than patients who underwent open harvesting (46.7% vs. 38.0%, $P < 0.001$).
- At 3 years, endoscopic harvesting was also associated with higher rates of death, myocardial infarction, or repeat revascularization (20.2% vs. 17.4%; adjusted hazard ratio, 1.22
- Death or myocardial infarction rates (9.3% vs. 7.6%; adjusted hazard ratio, 1.38; 95% CI, 1.07 to 1.77; $P = 0.01$),
- Death alone (7.4% vs. 5.8%; adjusted hazard ratio, 1.52; 95% CI, 1.13 to 2.04; $P = 0.005$).

Study Conclusions



“...our study shows that in patients undergoing CABG, endoscopic harvesting is an independent predictor of vein-graft failure and is associated with worse clinical outcomes, including higher mortality, than is open harvesting. The mechanism behind these findings requires further investigation, and randomized clinical trials evaluating the effect of endoscopic harvesting on long term angiographic and clinical outcomes are needed.”

The Authors

Study Shortcomings To Consider

- No standardization of Vein Harvest Procedures defined either for open or Endoscopic harvest
- A Retrospective analysis rather than a pre-defined study
- This study was observational only
- More than one E.V.H. system likely used in the study
- No Identification of proceduralist (PA, MD, ARNP, RNFA, Surg. Tech?) What was their skill levels?
- No operative time of vein harvest listed for either procedure (OVH vs.EVH) was listed.

So...Do We Disregard the Study?



NO!

Study Value For ALL to Consider
“Where There’s Smoke There May Be Fire”

- A re-evaluation of SVG harvest techniques, times, processes & equipment is now underway
- A re-assessment of patients who may be at a higher risk for poor quality conduit as a result of using EVH must be considered now
- These studies have brought Surgeon and PA together to sit down and re-evaluate the how and the why of EVH
- Few if any intend to completely abandon EVH as a result of this study however we will be more thoughtful of E.V.H and it’s use.

A re-evaluation of SVG harvest techniques, times, processes & equipment is now underway

- The “No Touch” technique in EVH & OVH – New Goal
- Vein distention intra-luminal pressure is important!
- Intra & extra luminal “bathing” fluid may be clinically significant (The “He Solution?”)
- Equipment used resulting in less or NO direct contact with the vein is the new engineering goal of EVH.
- Is pre harvest heparinization a Must? (Avoidance of intra-luminal clot)
- Should there be a minimal standard of training established that determines “minimal competency vs. Mastery” in EVH? If so...who teaches, how and how many is enough?

A Proposal To Consider



Device Company's may need to establish formal centers of skill training & carefully educate each and every new user with virtual, dry lab, wet lab and ultimately apprenticeships so that skill levels are quantifiably achieved rather than just *presumed!*

Final Thoughts



Endoscopic vein harvesting has achieved it's primary goal...extraction of a conduit from a limb with little or no morbidity to that limb. And thus no one wishes to re-visit leg wound infections & pain again by abandonment of this exceptional technological advance!

A Final Thought



However...like the automobile changed all of our lives for the better, It required continued refinements and operator minimal competency standards for it to truly provide us the “tool” that it is for us today. EVH is ready for that next step!

The Success of Technology



“For a successful technology, reality must take precedence over public relations, for Nature cannot be fooled.”

Richard P. Feynman



Thank You!