Endoscopic Vein Harvesting

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Overview

Endoscopic Vein Harvesting (EVH) is a minimally-invasive procedure for harvesting the saphenous vein to use as a graft for coronary artery bypass graft (CABG) surgery.[1] The quality of graft/conduit is a key to ensuring success of surgery.[2] EVH is the preferred method over traditional open saphenous vein graft harvesting. There are significant advantages to EVH, including reduction in leg wound complications, ameliorated postoperative pain, and improved cosmetic outcomes, resulting in increased patient satisfaction.[2]

An overview of products currently available in the market offers the following information gathered from supplier websites:

- Terumo and Saphena EVH both offer a singular kit (one catalog number/kit), each supplier providing 1 kit to address vein harvesting.[3,4] Both devices use carbon dioxide (CO_2) and each is indicated for saphenous and radial harvesting. The Saphena is performed through 1 cannula and the Terumo uses 2 different cannulas.[3,4]
- Terumo (VSP550EX) is performed in 2 steps.[4] The scope and cannula are used for blunt dissection to create a tunnel, then the cannula is removed and the scope is attached to a second cannula and inserted for the actual freeing of branches. Once the length is complete the vein harvest can be completed.[4]
- The Saphena (VPX3000 & VPX400, depending on scope used) is an all- in-one device.[3] The scope and 1 cannula are inserted, blunt dissection is performed. As a branch is located, the cannula can engage an electrocautery (bipolar) device to dissect the branches. Once the length is completed the harvest can be completed.[3]
- The Getinge product is similar to the Terumo device, in that you must perform dissection first and remove the cannula, then insert the second cannula to perform the harvest.[5] Getinge offers multiple different size options, and different energy (bipolar and RF) modalities.[5]

Professional Society Statements

The Society of Thoracic Surgeons, the European Society of Cardiology, European Association for Cardio-Thoracic Surgery, American College of Cardiology Foundation, and American Heart Association professional society statements recommend use of arterial grafts over saphenous vein graft (SVG) in CABG procedures particularly for the left coronary system. Methods for harvesting SVG and radial artery grafts have limited to no discussion in professional society guidance [6,7,8]

In 2014, National Institute for Health Care Excellence (NICE) revised its position on EVH to state that the evidence supported the safety and efficacy of the procedure.[9] The 2019 release of the European Society of Cardiology (ESC) and European Association for Percutaneous Cardiovascular Interventions (EAPCI) guidelines for myocardial revascularization provided specific guidance with regard to EVH.[7] Guideline recommendations include consideration for EVH to reduce the incidence of wound complications if performed by experienced surgeons. If an open technique is utilized, the no-touch technique should be considered.[7] The recent JACC guidelines advise the use of an EVH or no–touch saphenous vein harvest in patients at risk for wound complications as a best practice.[8]

Physician Insights

A panel of Cardiovascular/Thoracic Surgeons within our HealthTrust Physician Advisor Network offered the following insights with regard to Endovascular Vein Harvesting.[10]

Endovascular vein harvesting is now standard of care in CABG. It is associated with less wound complications, shorter LOS and improved outcomes. It is important to remember that time is muscle in emergent cases and this should be considered when deciding on a conduit harvesting approach.

Key features and qualities:

- Easy set up and instrument connectivity. Well-labeled intuitive instruments and connectors that allow for operating room personnel at various levels of experience to help in the set up and tear down of the equipment during a case.
- High-definition cameras that are small. Small sub centimeter cameras with excellent high definition capabilities and high definition monitor screens. Light sources and camera conduits that are well-built and won't fracture or break with repeated use.
- Reliable energy sources for dissection. Energy sources must reliably cut and seal vessel branches, allow for easy dissection and be well insulated instruments to prevent energy spread and possible conduit tissue injury.
- Insufflation of the conduit should have safety features built in to prevent over distention of the conduits and possible injury. Suction devices must be reliable and not easily subject to obstruction.
- Instruments should be ergonomically well designed and comfortable to use. Instrument design should allow for two-hand control of all the features of the product and have little, if any, need to have the operator remove a hand in order to perform a new task in a different location.
- Patient cart transport and storage should utilize minimum space. The patient cart should be easy to move from room to room and be small for proper, efficient storage when not in use.
- Systems should be capable of being utilized for both saphenous vein and radial artery harvest during operation. This system should not require additional parts to adapt between one harvest site and the other.
- Product support and ease of training.
- Demonstrated efficacy in terms of the quality of vein conduit harvested.

The trend in current systems are "closed," in that the carbon dioxide used to distend the surrounding tissue is trapped within the created tunnel, making exposure and dissection more visible endoscopically, and therefore more easy to dissect. Manufacturers of open systems suggest that CO_2 embolization (a very rare event) and tunnel clot formation are reduced compared to closed systems.

A majority of the Physician Advisors shared that, while each system has its own unique features and nuances in usage, there were no proprietary features that would warrant premium pricing across systems. Conversion to another system is possible, but there would be a learning curve which, may lengthen surgery time. This would be a concern with regard to delay in surgical care in critical cases.

Clinical Evidence

- The quality in conduits utilizing EVH had previously come into question with early studies showing issues with statistically significant higher rates of major adverse cardiovascular events (MACE), repeat revascularizations, death, and lower rates of graph patency vs. open techniques (PREVENT-IV and ROOBY trials).[11,12] These results were thought to be related to excessive stretching and potential tears

or avulsions, which promoted structural and functional changes in the vascular endothelium and subsequent failure. Specific devices used for EVH and expertise of the vein harvesters were limitations identified in these studies.[10,11] Subsequent studies controlled for these variables and found no statistically significant difference between the two approaches.[13,14,15]

- Concerns have been raised as to the use of CO_2 insufflation and the impact on the integrity of the conduit during EVH.[16] One randomized control trial (n=301) evaluated this impact by comparing open vein harvesting (n=101) with both open and closed EVH procedures (n=100) in each group). The trial found that the different vein harvesting techniques did not increase systemic absorption of CO_2 or absorption in the pressurized endoscopic tunnel, despite differing impact on endothelial integrity. Open tunnel harvesting did see more endothelial stretching compared to the closed tunnel technique (p=0.003) and was thought to be due to the manual dissection of the vein.

  Limitations in this study include the use of heparin for closed EVH per protocol was not used in the other arms of the study. The impact of heparin on the vessel walls is not fully understood. Optical coherence tomography was not performed to assess for intraluminal clot formation in the open EVH arm of the study. The focus of this study was solely on the structural integrity of the vein and functional viability was not considered. Practitioner experience may have contributed to differences observed.[16]

- The Vein Integrity and Clinical Outcomes trial (VICO), a randomized control trial (n=300), investigated endothelial integrity and muscular damage of the harvested vein using closed tunnel EVH (n=100) open tunnel CO_2 EVH (n=100) and traditional open vein harvesting (n=100) by a single experienced harvester.[17] Secondary endpoints of the study included composite MACE up to 48 months, quality-adjusted life-year gain per patient.[17]

  The endothelial integrity in random samples for closed tunnel EVH, open tunnel EVH, and open vein harvesting were 85%, 88%, and 93% respectively (p=0.62).[17] Longitudinal hypertrophy was noted to be 1% for closed tunnel EVH, 13.5% for open tunnel EVH, and 3% for open vein harvesting (p=0.001). There were no statistically significant differences in endothelial stretching, with open and closed EVH both at 37% and open harvest at 31% (p=0.62). Despite some differences in the vein integrity, the secondary endpoints demonstrated no significant differences in composite MACE scores at 48 months and the quality-adjusted life-year gain per patient was 0.11 (p=<0.001) for closed tunnel EVH, and 0.07 (p=0.003) for open tunnel EVH compared with open vein harvesting.[17]

  Limitations of this study include the fact that 1 practitioner was used to ensure consistency in determining impact of harvesting techniques.[17] Different operators would introduce variability in surgical skills and different outcomes. Not all study participants received a routine angiogram or cardiac magnetic resonance imaging scans. The study was underpowered.[17]

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