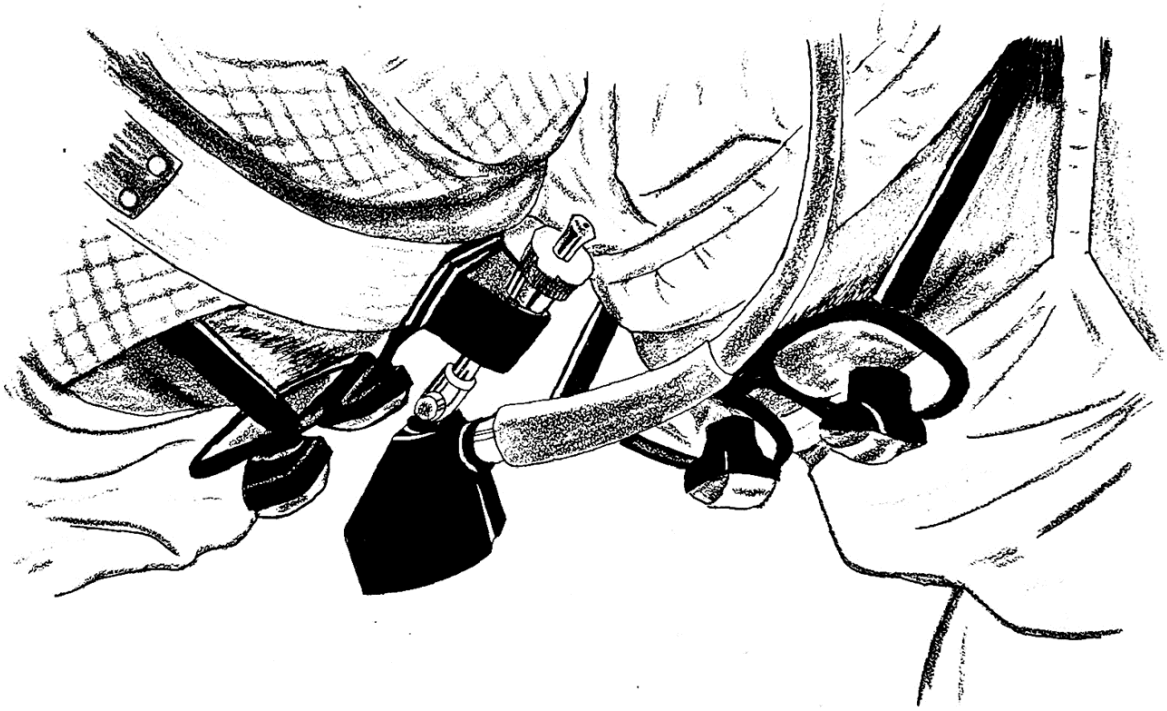
VOLUME 1 • NUMBER 1 • SPRING 2019 • www.japacvs.org

JAPACVS

Journal of The Association of PAs in Cardiothoracic and Vascular Surgery



Official Journal of The Association of Physician Assistants in Cardiothoracic and Vascular Surgery

Contents

Peer Reviewed Content

Prospective Evaluation of a Simplified System for Endoscopic Vein Harvesting.

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Abstract

Background: Simplified instrumentation has been developed to perform endoscopic vein harvesting (EVH) for coronary revascularization.

Objective: This study was performed to measure differences in conduit properties and technique parameters of simplified versus conventional EVH instrumentation.

Methods: A prospective randomized trial was conducted in 42 coronary bypass patients at NYU Winthrop University Medical Center. Consecutive patients underwent EVH using either a simplified device or conventional instrumentation. Three clinicians each performed fourteen harvests (seven with each device). Recorded parameters included: (1) number of grafts, (2) harvested vein length, (3) number of tributaries, (4) number of graft repairs, (5) presence of char on transected tributaries, (6) incision length, (7) subcutaneous bleeding, (8) drain requirement, (9) intraluminal thrombus, (10) ACT at harvest time, and (11) vein harvest time. Differences were analyzed between individual clinicians, and for overall parameters.

Results: A highly significant difference in tributary charring was observed (3 versus 18 samples, $P < 0.0001$). No significant differences were observed in vein graft repairs ($P = 1.0$), incidence of bleeding ($P = 0.66$), average harvesting time ($P \geq 0.83$), or average harvested vein length ($P = 1.0$).

Conclusion: Based on the results of this study, it appears that adoption of a simplified endoscopic vein harvesting device entails a limited learning curve, and enhanced thermal limitation may be achieved during tributary transection.

Keywords

Endoscopic vein harvest, thermal spread, C-ring, graft quality, char, bipolar energy, high density current

Introduction

Endoscopic harvesting of the greater saphenous vein (EVH) for coronary artery revascularization has been recognized as the standard of care for over a decade. In 2005, the consensus panel of the International Society of Minimally Invasive Cardiothoracic Surgery (ISMICS) stated that "EVH should be the standard of care for patients who require saphenous vein grafts for coronary revascularization".[1] Although vein quality and graft patency in endoscopically harvested conduit have been questioned in a retrospective analysis of data from the PREVENT-IV trial[2], a meta-analysis of 267,525 patients considering only data from randomized trials found no statistical difference in mortality, adverse cardiac events, vein graft stenosis or graft occlusion between EVH and OVH (open vein harvest) at a median follow-up of 2.6 years.[3]

Striving for improved conduit quality should be paramount in the mind of clinicians performing endoscopic vein harvesting for coronary artery revascularization. Simplified instrumentation has been developed to facilitate endoscopic vessel harvesting for both experienced and novice practitioners (Venapax®, Saphena Medical, Inc., West Bridgewater, MA). The instrument reduces the number of moving parts in the device to minimize graft manipulation, and it employs a cautery element that applies localized high density current to the tributary to achieve ligation with limited corresponding adjacent energy conduction. The device utilizes conventional endoscopic guided conical tip dissection under carbon dioxide gas insufflation, with bipolar cautery blades retracted into the cannula body during the dissection process (Figure 1). The blades are extended out of the cannula for tributary cautery and transection (Figure 2), following isolation of the vein from surrounding subcutaneous connective tissue. In lieu of the traditional ring retractor that rides along the adventitial surface of the vein during EVH, the device provides vein retraction with directed placement of the conical tip on the vein trunk during tributary transection. The atraumatic nature of conical tip application to the adventitial surface of the vein was demonstrated by histological and immune-histochemical studies conducted on the first nine patients undergoing tapered tip dissection in the United States.[4] Removal of the ring retractor potentially avoids inadvertent avulsion of unrecognized tributaries, and decreases the exertion of shear force on venous adventitia during axial ring movement. Tributary cautery is performed by forward extension of two elongated blades. The movable blade contains a sharp cutting edge, and it rotates with respect to the stationary anvil blade. As the pair of blades is advanced forward and rotated to close down on the tributary, bipolar cautery is applied to seal the branch vessel (Figure 3). The sharp edge of the movable blade exhibits an exceedingly small surface area of contact with the tributary. The entire energy output of the electrosurgical generator is delivered to this minute contact area, leading to conduction of high density current into tissue that causes instantaneous desiccation and sealing of the tributary. Energy delivery to the cautery blades is governed by the logic programmed into the electrosurgical generator, and energy delivery is interrupted upon a significant rise in tissue impedance. Controlled cessation of delivered bipolar energy avoids prolonged tissue heating leading to tissue charring and lateral thermal spread. Vein dissection and tributary transection are conducted within a closed insufflated tunnel. Gas insufflation is infused via a soft flexible silicone rubber port, to avoid vein compression and venous stasis.

Figure 1. Simplified Device Tip
The bipolar electrocautery blades are retracted into the cannula.

Figure 2. Cutting Blade Extension
The bipolar electrocautery blades are shown in an extended configuration.

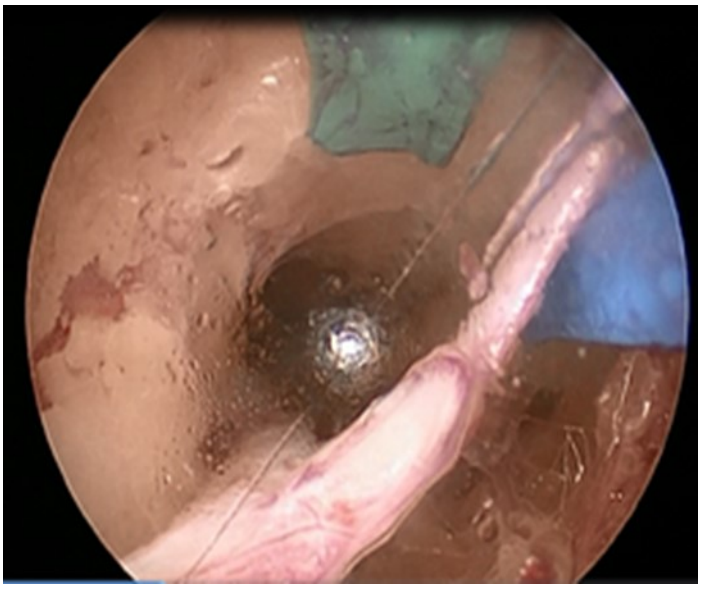

Figure 2. Cutting Blade Extension
The bipolar electrocautery blades are shown in an extended configuration.

Methods

In an attempt to determine whether endoscopic vein harvesting with simplified instrumentation results in observable differences in the harvesting process or graft properties, a prospective randomized trial was conducted in 42 patients undergoing coronary artery revascularization at Winthrop University Medical Center between May 22nd and September 1st 2017. A random number generator was utilized to rank order consecutive patients, with even numbered patients undergoing endoscopic vein harvesting using simplified instrumentation (Venapax® device, Saphena Medical, West Bridgewater, MA), and odd numbered patients undergoing endoscopic vein harvesting using conventional instrumentation (VasoView HemoPro2® device, Maquet Cardiovascular, Wayne, NJ). Three clinical vein harvesters participated in the study, with each participant performing fourteen harvests (seven with each device). Two of the harvesters were very seasoned EVH practitioners, having performed over 5,000 and 3,000 EVH procedures using the conventional device, respectively; while the remaining harvester was less experienced, with a total EVH background of 200 procedures. One experienced EVH operator had previously performed 150 harvests with the simplified instrumentation, while the other two clinicians were novice users of the simplified system, each having performed ten cases with the device prior to initiation of the study. The study was approved by the NYU Winthrop University Hospital Institutional Review Board, NYU Winthrop University Hospital Study Trial Registration Number: 1055915-2, approved May 11, 2017, and patient consent was obtained prior to the procedure. Fisher's exact tests were conducted on 2x2 contingency tables of the resultant continuous data.

Procedure

Endoscopic vein harvesting was performed in a conventional manner, via a skin incision at or slightly above the knee to isolate the greater saphenous vein. Low dose heparin was not administered prior to vein harvesting. The procedure was performed under carbon dioxide gas insufflation in a closed tunnel at approximately 10 mm Hg of insufflation pressure and a low flow rate of 6 liters per minute. The length of greater saphenous vein harvested was determined by the anticipated number of required coronary grafts. Conical tip dissection was followed by tributary sealing and transection. Following removal of the vein from the lower extremity, transected tributaries were clipped flush with the vein trunk, and needed repairs were performed with 7-0 Prolene monofilament suture upon venous distention with heparinized saline.

Data Collection

Data was collected in this study with the objective of evaluating functional characteristics of the two endoscopic vein harvesting devices, and the resultant gross morphology of the harvested conduits. The following surgical parameters were recorded during each procedure: (1) number of grafts required, (2) length of harvested vein, (3) number of tributaries encountered, (4) number of reparative graft interventions required, (5) presence of charring on transected tributaries, (6) skin incision length, (7) bleeding observed in subcutaneous tunnel, (8) requirement for a subcutaneous drain, (9) presence of intraluminal thrombus, (10) ACT (activated clotting time) at the time of harvest, and (11) vein harvest time.

Statistical Analysis

Fisher's exact tests were conducted on 2x2 contingency tables of the resultant continuous data, performed with software provided by GraphPad Software (La Jolla, CA). Potential significant difference between individual clinicians was analyzed, as well as potential significant differences in overall parameters.

Results

The results obtained in this study are summarized in Table 1. A highly significant difference in charring was observed during tributary ligation ($P < 0.0001$). No significant differences were observed in the number of interventions required to repair the vein graft between the two devices among individual harvesters, or in the overall analysis ($P = 1.0$). The incidence of bleeding associated with endoscopic vein harvesting was not significant ($P = 0.66$) between the two devices. Average harvesting time and average vein length harvested both did not exhibit significant differences, nor did skin incision lengths. No retained clot was observed in any vein endoscopically harvested with either system in this study. The ACTs measured at time of harvest were all in the normal non-anticoagulated range, between 92 – 117 seconds, with a mean ACT of 102 seconds.

Table 1. Parameters Evaluated for Traditional and Simplified EVH Devices

Variable	Traditional Cannula	Simplified Device	P
Procedures, n	21	21	
Tributary Charring	18	3	<0.0001
Number of Interventions			
Harvester 1	2	1	0.61
Harvester 2	3	1	0.64
Harvester 3	0	2	0.23
Overall	5	4	1.0
Bleeding in Tunnel	4	2	0.66
Average Harvest Times (min)			
Harvester 1	43.57	35.71	1.0
Harvester 2	18.71	17.57	0.83
Harvester 3	30.71	25.0	1.0
Average Vein Length (cm)			
Harvester 1	40.21	36.07	1.0
Harvester 2	38.4	35.0	1.0
Harvester 3	45.7	36.5	1.0

Discussion

The technique of endoscopic vein harvesting during coronary artery revascularization was initially performed with the intention of decreasing the significant morbidity associated with open extraction of the greater saphenous vein. Historically, open saphenous vein harvesting resulted in incisional wound healing complications in as high as 24% to 44% of bypass patients.[5,6] With EVH, the incidence of lower extremity wound complications has decreased dramatically, and statistically significant decreases in postoperative leg wound infection persist in more recent prospective randomized trials comparing EVH and open vessel harvesting [7,8,9]. Efforts to ameliorate saphenous vein harvest site incisional complications must be coupled with advancements in atraumatic conduit procurement, as enhanced graft longevity is the primary objective in vein graft procurement. Thermal and mechanical vein injuries that occur during the course of endoscopic harvest are postulated to be responsible elements that may reduce graft patency.[10] In this study, a highly significant decrease in charring was observed with the simplified system upon tributary sealing and transection (3 samples versus 18 samples, $P < 0.0001$). Thermal energy has been proposed to cause endothelial injury leading to intimal hyperplasia and graft stenosis. In a study comparing graft patency between EVH and open harvest for lower extremity bypass in critical limb ischemia, Eid[10] found that graft stenosis in the EVH group was more commonly seen in the body of the bypass graft, likely at the site of cauterization of large branches; whereas in the open harvest group, it was generally localized to the anastomosis. In this peripheral vascular study, the requirement for long vein graft lengths in lower extremity bypass magnified the importance of even a single compromise to the vein due to thermal conduction or mechanical error. In coronary artery bypass procedures, shorter graft length requirements may allow exclusion of an injury site in the central portion of the vein. Anatomical considerations also affect the propensity for vein graft thermal injury. Krishnamoorthy[11] observes that many side branches are cut very short in two situations – one, near the popliteal area due to superficial leg veins; and two, in patients with thin legs due to surrounding dense fibrous tissue. Short branch transection may lead to thermal injury on the vessel wall. With the simplified harvest cannula, the dot corresponding to the distal conical tip is placed on the lateral aspect of the vein during tributary sealing, ensuring an 8 mm distance between the cautery site and the vein wall. The axially confined movement of the bipolar cautery blades assists with tributary takedown in tight and superficial situations. The C-ring retractor of the traditional device deviates laterally upon extension, and an enlarged harvesting tunnel is required for proper manipulation. In confined spaces with a high number of branch vessels, such as the popliteal region, C-ring retractor use may result in inadvertent tributary avulsion.

Another important finding in this study is the absence of significant difference between the two devices in the following categories: (1) tributary avulsion rate; (2) the incidence of bleeding in the harvest tunnel; (3) the time associated with vein harvesting; and (4) the length of vein harvested. This finding is significant due to the fact that two out of three harvesters were novice users of the simplified device, with each novice user limited to a ten case prior experience with the new cannula. Tributary avulsion and shortened tributary transection sites occur more prominently during the learning curve of novice EVH practitioners.[12,13] It is estimated a one hundred case learning curve is associated with the traditional system[14]. This extended learning curve is necessitated by the large number of manipulations required to harvest a vein using the conventional cannula. With the traditional endoscopic cannula, tributary ligation and transection encompasses the following steps: (1) Extension of the C-ring retractor up and over each tributary; (2) Rotation of the C-ring to position it onto the vein trunk distal to the tributary; (3) Advancement of the heat sealing device and rotation of the jaws to place them in an orthogonal orientation to the tributary; (4) Activation of the

heating element to seal the tributary; and (5) Rotation and axial translation of the heat sealing device to transect the tributary. Not only the number of manipulations associated with each tributary takedown, but also the mandatory endoscopic hand-eye coordination required to be facile with the technique led to the protracted learning curve associated with the traditional system. The arduous process of EVH assimilation by harvesters in training has been singled out as a relevant factor in the graft quality associated with endoscopic versus open vein harvesting.[11,14,15] Removal of the C-ring retractor in the simplified harvesting device serves two purposes: One, it decreases the learning curve associated with EVH, as placement of the conventional device within the subcutaneous tunnel is complicated by the lateral deviation of the C-ring as it is extended from the cannula, effectively truncating the endoscopic working cavity. Two, it removes the component of shear force exerted on the graft adventitia as the C-ring is applied to the vein in an axial fashion during the harvesting procedure. With the simplified system, the cannula remains centered within the insufflated subcutaneous tunnel, and required control manipulation is reduced to the following three steps: (1) Extension of the paired cutting blades; (2) Rotation to close the cutting blades while simultaneously apply bipolar cautery energy; and (3) Distal translation of the closed blades to transect the cauterized tributary. Early experience with the simplified system suggests a learning curve reduction from one hundred procedures down to approximately ten procedures.

The primary impetus for a simplified EVH device is to improve graft quality and longevity, not only with harvesters undergoing the learning curve of the technique, but also with experienced clinicians. Decreasing the number of moving parts and control elements in the harvesting cannula correspondingly reduces the number of touch points on the vessel, hopefully leading to consistent, superior graft quality.

Mechanical vein graft injury may have obvious manifestations such as tributary avulsion, vein dissection or graft perforation. Less obvious injury may occur with vein traction or vein torsion sustained during the harvesting procedure. In this study, the incidence of tributary avulsion was not different between the two devices, even with the novice users of the simplified device. It is theorized that a reduction in the degree of mechanical vein manipulation that occurs with the simplified system may translate to a more physiologic conduit; and anecdotally, enhanced vein distention has been observed during graft preparation following endoscopic extraction with the simplified cannula compared with the traditional device. However, verification of this observation awaits future study with microscopic evaluation of graft endothelial morphology.

Conclusion

In summary, in a prospective, randomized study comparing the morphologic characteristics of greater saphenous vein endoscopically harvested using a simplified system versus the traditional cannula, a significant decrease in the number of thermally induced, charred tributaries was observed with the new system. We believe that this decrease in observed thermal injury translates into enhanced graft quality. The limited learning curve associated with the device will hopefully lead to increased adoption with superior clinical results in terms of conduit quality and graft patency.

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Declarations

Consent for publication: Not applicable

Data Statement: The datasets used and/or analyzed during the current study are available from JoAnn Montecalvo, MPAS, PA-C, (jmonteca@nyuwinthrop.org) on reasonable request.

Competing interests: JoAnn Montecalvo is a Surgical Advisory Board member of Saphena Medical, Inc. Dr. Chin is the Chief Innovation Officer of Saphena Medical, Inc. The other authors declare that they have no competing interests.

Funding: No sources of funding were obtained for this study.

Authors' contributions: JoAnn Montecalvo, MPAS, PA-C initiated the study design and performed the procedures. Shawn J. Sussman, PA-C and Nona Chen, PA-C performed the procedures. Albert K. Chin, M.D. was a major contributor in writing the manuscript. Scott L. Schubach, M.D, FACS, FACC directed the study design and managed the study execution. All authors read and approved the final manuscript.

Acknowledgements: Not applicable