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Early Results of Endoscopic Versus Open Saphenous Vein Harvesting in Coronary Artery Bypass Grafting: A Single Blinded Randomized Controlled Trial

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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Original Research Article

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ABSTRACT

Background: The great saphenous vein (GSV) remains the most commonly used conduit worldwide for the majority of coronary artery bypass surgery (CABG) procedures, despite concerns regarding the long-term patency of arterial revascularization. Therefore, our aim is to assess and demonstrate the impact of harvesting techniques on patient quality of life and early post-operative outcomes.

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Methods: This prospective, single-blinded randomized controlled study enrolled patients with ischemic heart disease indicated for CABG. The study was conducted at the Cardiothoracic and Vascular Surgery Center (CVSC) at Mansoura University, Mansoura, and El-Galaa Military Hospital, Cairo, involving 32 patients. Patients were categorized into two groups: Group I comprised sixteen patients where the GSV was harvested using the open vein harvesting technique (OVH), and Group II included sixteen patients where the GSV was harvested using the endoscopic vein harvesting technique (EVH).
Results: Multivariate regression analysis evaluating the effect of the endoscopic technique revealed a significant correlation with postoperative outcomes, particularly in terms of leg wound complications assessed by the ASEPSIS score ($p < 0.001$) and the prediction of postoperative NRS values for leg pain (p 0.001). Additionally, the impact on patients' quality of life across all subclinical categories was assessed using the Euro-Qol 5D ($p < 0.001$).
Conclusion: EVH presents itself as a viable minimally invasive alternative to traditional OVH techniques. It offers greater patient comfort, improved cosmetic satisfaction, a reduced incidence of postoperative leg wound complications, and lower levels of pain. Moreover, there is a statistically significant association between performing EVH techniques and enhanced quality of life, as well as a decrease in total ASEPSIS scores.

Keywords: Endoscopic vein harvesting; open vein harvesting; coronary artery bypass grafting; great saphenous vein.

1. BACKGROUND

The GSV has been considered as the most used conduit worldwide for all non-LAD coronary territories due to its superficial easy access and less bleeding risk compared to arterial conduits [1].

Traditionally, the GSV is extracted using an open technique that involves making an incision all the way down the vein to allow for branch ligation, mobilization, and clear vein visualization. This strategy does, however, come with a higher risk of wound complications, such as infection, hematoma, seroma, and longer hospital stays with higher post-operative wound care costs. In 1996, endoscopic GSV harvesting was presented as a less invasive substitute for open GSV harvesting, showing encouraging outcomes and a low rate of complications[2,3].

In this study, we compared the early post-operative outcomes, such as pain, wound healing, cosmetic satisfaction, and quality of life, between using an endoscope and a traditional open approach to harvest the GSV during CABG.

2. METHODS

2.1 Design

This is a prospective single blinded, randomized, controlled study. It mainly compares the early results of great saphenous vein harvesting by open and endoscopic techniques forpatients undergoing coronary artery bypass grafting This study was conducted at Cardiothoracic and Vascular Surgery Center (CVSC) at Mansoura University, Mansoura and El-Galaa Military Hospital, Cairo. Patients were collected within the period from September 2022 to May 2023 upon receiving authorization from the Mansoura University Faculty of Medicine's Institutional Research Board. The IRB code number for August 20, 2022, is MS.22.07.2065. CONSORT (Consolidated Standards of Reporting Trials) guidelines have been used to develop the trial design [4].

2.2 Inclusion Criteria

Patients who would undergo coronary artery bypass grafting (CABG) with potential need for 2 or 3 vessel grafts (one or two great saphenous vein conduits)

2.3 Exclusion Criteria

Single graft CABG, need for more than two venous grafts, Urgent CABG, History of GSV stripping, Redo CABG with previously GSV, Combined surgery “CABG and valve surgery in same setting.

2.4 Study Population

44 patients with preoperative potential need for 2 or 3 vesselgrafts (one or two great saphenous vein conduits) for CABGwere eligible for the study. 12 patients were excluded as they needed extra two vein grafts intra operatively. The remaining 32 patients were randomized to either open or endoscopic vein harvesting in a 1:1 ratio. Group I: Sixteen patients, the great

saphenous vein was harvested by open vein harvesting technique (OVH). Group II: Sixteen patients, the great saphenous vein was harvested by endoscopic vein harvesting technique (EVH).

2.5 Preparation

2.5.1 Pre-operative assessment

Regarding age, sex, chronic illnesses, and other details, a comprehensive and complete history was obtained. a thorough physical examination that covers the patient's overall health, vital signs, a full cardiovascular evaluation, a local lower limb vascular assessment, etc. routine examinations. Hemoglobin A1c, coagulation profiles, CRP, liver and kidney function tests, complete blood counts (CBC), and other laboratory testing. radiological testing, including CT scanning, Doppler studies, and chest x-rays for GSV mapping.

2.5.2 Surgical technique

2.5.2.1 OVH group

The number of vein segments needed determined the length of a longitudinal skin incision that was made over the anticipated anatomical path of the GSV. Participants in this study who needed three or more vein segments were not included. The vein side branches were ligated on both sides by using titanium clips or 3-0 silk ties.

2.5.2.2 EVH group

The Maquet Vasoview Hemopro2 vein harvesting equipment was employed in our investigation. A cut around 5 cm below the knee was performed for each patient. The vein was visible, hanging from the vascular loop. Through the incision in the skin, a 30-mm, 0° endoscope was introduced. Its tip included a clear and sharp dissecting cone. To seal the incision port, the balloon was inflated following 3 cm of anterior dissection. The pressure of the CO2 insufflator was adjusted to 10–15 mm Hg. To prevent intraluminal clot formation, the patients were administered 5000 U of heparin [5]. The vein was separated by ligaSure from the surrounding tissues in both the anterior and posterior directions, ultimately arriving at the groin femoral junction. Following retrieval, the vein side branches were tied up on the proximal sides using titanium clips or 3-0 silk ties (Fig. 1).

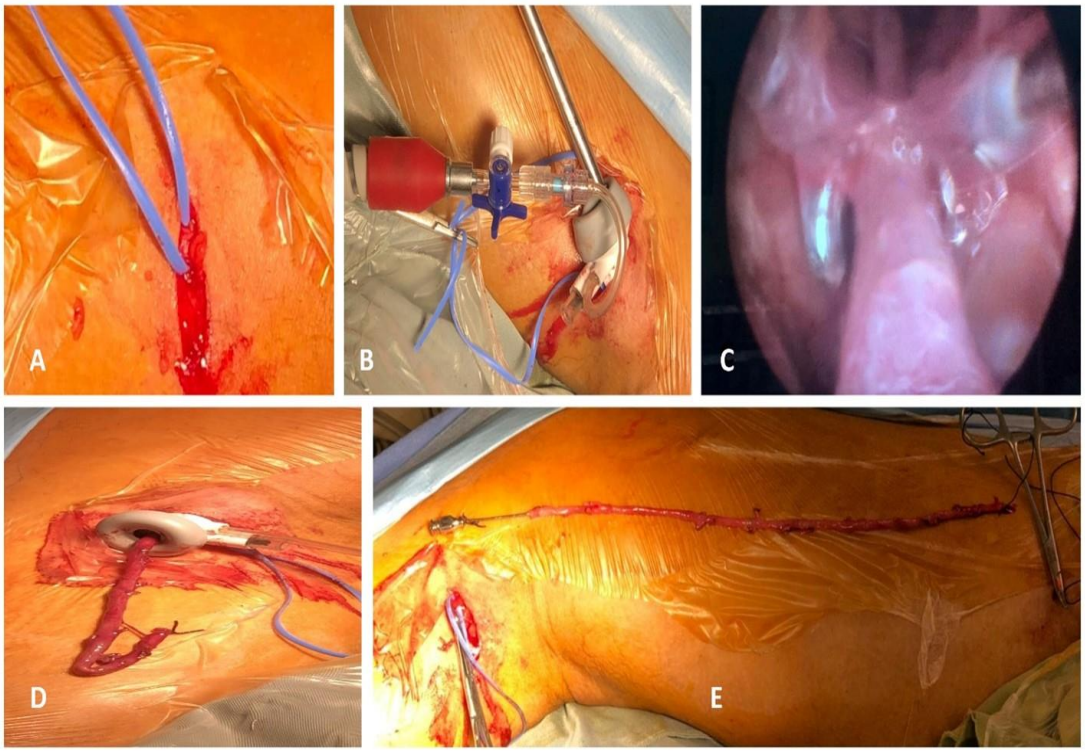

Fig. 1. Steps of EVH: A- dissection on the vein and hanged by vessel loop. B-insertion of telescope and balloon connected with insufflator. C- Dissection of the vein. D- Release of the vein through the port. E- the harvested vein with proximal and distal stumps are clamped

2.6 Postoperative Assessment

We assessed the following criteria during the post-operative 30 days:1- ASEPSIS scores are calculated by allocating points for deep tissue separation, erythema, serous exudate, and purulent exudate. Additional points are awarded for more interventional techniques. [6].2- The Numerical Rating Scale (NRS) was used to measure pain. Mild pain was scored 0 None 1-3, moderate pain scored 4-6, and severe pain scored 7 or 10 [7]. 3-Assessment of the quality of life by Euro-Qol Questionnaire [8]. 4-Major post-operative complication as Ischemic ECG changes and Mortality. 5-Others: Lower limb edema, cosmetic satisfaction and prolonged hospital stay for more than 2 weeks.

2.7 Sample Size Calculation

Sample size calculation was based on incidence of complications between cases with endoscopic vs open saphenous vein harvesting for CABG retrieved from previous research [5]. Using G*power version 3.0.10 to calculate sample size based on difference of =37%, 2-tailed test, α error =0.05 and power = 80.0% Then total sample size will be 16 in each group at least.

2.8 Statistical Analysis

Version 22 of the statistical package for social sciences (SPSS) was used to examine the data. Quantitative data were reported as mean and standard deviation for normally distributed data and median and range for non-normally distributed data after being evaluated for normality using the Kolmogorov-Smirnov test. Qualitative data were expressed as numbers and percentages. The student t test, Mann Whitney U test, and Chi-Square test are the recommended tests that will be used to choose the right statistical test based on the type of data. A P-value of less than 0.05 was deemed statistically significant.

3. RESULTS

Out of 44 initially assessed for eligibility, 32 patients were randomized, with 16 each allocated to the open and endoscopic groups for vein harvesting. All patients underwent the intended interventions without any exclusions, resulting in a complete analysis of 16 patients in each group Fig. 2.

Regarding preoperative demographic information and clinical features, no statistically significant differences were observed between the two groups. However, the endoscopic group exhibited a higher prevalence of diabetes (62.5%) Table 1.

The assessment of leg wounds in the open group, as determined by the ASEPSIS score and NRS score, was statistically higher compared to the endoscopic group Table 2.

Notably, leg edema in the endoscopic group was significantly less severe than in the open group. Additionally, there was a statistically significant difference in cosmetic satisfaction between the endoscopic and open groups. Table 3

Patients in the endoscopic group exhibited notably higher quality of life across the five domains assessed in the quality-of-life questionnaire, as well as reflected in the overall Euro-Qol score, compared to the open group Table 4.

Multivariate regression analysis highlighted a significant relationship between the use of the endoscopic technique and the ASEPSIS score, NRS score, and EuroQol Score Table 5.

Postoperatively, neither ischemic ECG changes nor hospital mortality were reported in either group.

4. DISCUSSION

Coronary artery bypass grafting (CABG) stands as a widely utilized surgical intervention for coronary artery disease (CAD). A range of autogenous arteries and veins serve as options for coronary artery grafting. While arterial grafts exhibit superior long-term patency rates compared to veins and can significantly enhance patient prognosis, their length often restricts their applicability in clinical settings, particularly for individuals with multivessel CAD requiring multiple vein grafts. Given the GSV's ease of harvesting, widespread availability, and adaptability, it continues to stand as the most frequently employed conduit [9].

Traditionally, the great saphenous vein (GSV) has been obtained through an open approach involving a lengthy skin incision, a method associated with considerable morbidity rates and wound complications. Minimally invasive techniques like endoscopic vein harvesting

(EVH) have emerged to mitigate post-CABG leg wound complications [10]. EVH, in contrast to the open technique, has demonstrated reduced rates of post-surgical complications, positioning it as the preferred procedure in numerous facilities today. Although concerns about long-term graft patency after EVH persist, cohort studies have shown the procedure to be both safe and effective. This study aimed to ascertain whether utilizing an endoscope or an open technique for GSV harvesting would yield superior early post-operative outcomes, evaluating parameters such as pain, wound healing, cosmetic satisfaction, quality of life, and potential co-morbidities.

Preoperative demographic and clinical data exhibited no statistically significant differences between the two groups, diminishing the potential for bias in the patient selection process. The inclusion criteria focused on patients requiring no more than two venous grafts, aiming to minimize substantial differences in tissue injury between groups in cases involving open harvesting of three or more venous grafts. However, this perspective might limit the generalizability of our results to all patients requiring multiple coronary venous grafts. Nevertheless, our research aimed to investigate differences between the two harvesting approaches within this specific population.

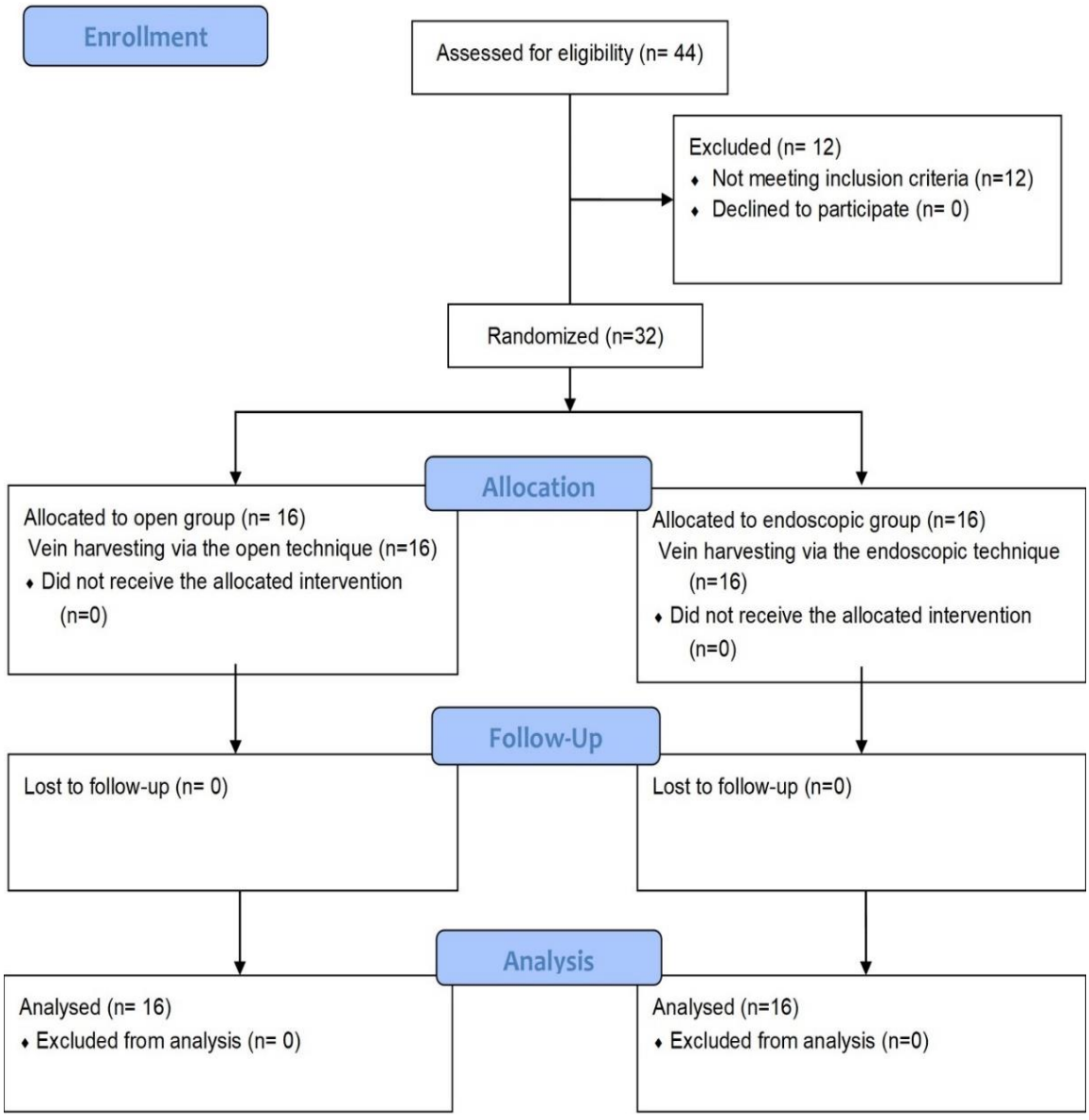

Fig. 2. Consort flowchart of the studied patiens

Table 1. Base line characteristics including demographic data, comorbidities, and number of vein segments to be harvested

Parameters		Open group (n= 16)	Endoscopic group (n= 16)	P-value
Age (years)		58.19 ± 5.540	58.44 ± 5.253	0.897
Gender	Male	13 (81.3%)	14 (87.5%)	0.626
	Female	3 (18.8%)	2 (12.5%)	
Body weight (kg)		86.44 ± 6.011	84.63 ± 3.862	0.318
Diabetes		6 (37.5%)	10 (62.5%)	0.157
Hypertension		13 (81.3%)	14 (87.5%)	0.626
Chronic kidney disease		1 (6.3%)	0 (0.0%)	0.310
Smoker		12 (75.0%)	9 (56.3%)	0.264
Vein segments to be harvested				
1		2 (12.5%)	4 (25.0%)	0.362
2		14 (87.5%)	12 (75%)	

Table 2. Leg wound complications and assessment using ASEPSIS score

	Open group (n= 16)	Endoscopic group (n= 16)	P
Additional treatment			
None	9 (56.3%)	15 (93.8%)	0.044
Antibiotics	5 (31.3%)	1 (6.3%)	
Debridement	1 (6.3%)	0 (0.0%)	
Drainage	1 (6.3%)	0 (0.0%)	
Serous Discharge	10 (62.5%)	3 (18.8%)	0.012
Erythema	12 (75.0%)	2 (12.5%)	< 0.001
Purulent exudates	2 (12.5%)	0 (0.0%)	0.144
Separation of deep tissues	1 (6.3%)	0 (0.0%)	0.310
Isolation of Bacteria	1 (6.3%)	0 (0.0%)	0.310
Stay in hospital prolonged for more than 14 days due to leg wound	2 (12.5%)	0 (0.0%)	0.144
ASEPSIS Score	13.75 ± 12.715	2.19 ± 3.637	0.001
Level of pain from leg wound. (Based on the NRS)	4.81 ± 1.377	1.75 ± 1.390	< 0.001
Marked Wound Complication. e.g., wound maceration, gangrene.	1 (6.3%)	0 (0.0%)	0.310
Re- Admission for Wound infection	1 (6.3%)	0 (0.0%)	0.310

Table 3. Degree of lower limb edema and cosmetic satisfaction in the studied groups

	Open group (n= 16)	Endoscopic group (n= 16)	P
Lower Limb Edema Grading			
None	1 (6.3%)	8 (50.0%)	**0.026**
Grade I	7 (43.8%)	7 (43.8%)	
Grade II	6 (37.5%)	1 (6.3%)	
Grade III	1 (6.3%)	0 (0.0%)	
Grade IV	1 (6.3%)	0 (0.0%)	
Cosmetic satisfaction			
Not Satisfied	1 (6.3%)	0 (0.0%)	**< 0.001**
Moderately satisfied	13 (81.3%)	0 (0.0%)	
Extremely satisfied	2 (12.5%)	16 (100.0%)	

Table 4. Results of the quality-of-life assessment in the 5 domains and the total Euro-QOL for the studied group

	Open group (n= 16)	Endoscopic group (n= 16)	P
Mobility			
No problems	3 (18.8%)	12 (75.0%)	0.019
Slight problems	8 (50.0%)	4 (25.0%)	
Moderate problems	3 (18.8%)	0 (0.0%)	
Severe problems	1 (6.3%)	0 (0.0%)	
Inability	1 (6.3%)	0 (0.0%)	
Self-care			
No problems	1 (6.3%)	11 (68.8%)	0.001
Slight problems	7 (43.8%)	5 (31.3%)	
Moderate problems	6 (37.5%)	0 (0.0%)	
Severe problems	2 (12.5%)	0 (0.0%)	
Inability	0 (0.0%)	0 (0.0%)	
Usual activity			
No problems	0 (0.0%)	6 (37.5%)	0.003
Slight problems	8 (50.0%)	10 (62.5%)	
Moderate problems	6 (37.5%)	0 (0.0%)	
Severe problems	2 (12.5%)	0 (0.0%)	
Inability	0 (0.0%)	0 (0.0%)	
Pain/ Discomfort			
No pain	1 (6.3%)	8 (50.0%)	< 0.001
Slight pain	4 (25.0%)	8 (50.0%)	
Moderate pain	8 (50.0%)	0 (0.0%)	
Severe pain	3 (18.8%)	0 (0.0%)	
Extreme pain	0 (0.0%)	0 (0.0%)	
Anxiety / depression			
Not anxious	2 (12.5%)	14 (87.5%)	0.001
Slightly anxious	6 (37.5%)	2 (12.5%)	
Moderately anxious	6 (37.5%)	0 (0.0%)	
Severely anxious	1 (6.3%)	0 (0.0%)	
Extremely anxious	1 (6.3%)	0 (0.0%)	
Total EuroQol Score	12.88 ± 3.324	6.81 ± 1.109	< 0.001

Table 5. Multivariate regression analysis and correlation between ASEPSIS Score, Level of pain from leg wound, EuroQol Score and the endoscopic technique

Endoscopic group	Correlation coefficient	B	Std. Error	Beta	95% CI	P
ASEPSIS Score	-0.538	-11.562	3.306	- 0.538	-18.31, -4.81	0.001
Level of pain from leg wound	-0.753	-3.063	0.489	- 0.753	-4.06, -2.06	< 0.001
EuroQol Score	-0.784	-6.062	0.876	- 0.784	-7.85, -4.27	< 0.001

In our study, the ASEPSIS Score was notably lower in the EVH group. The open technique exhibited significantly higher rates of erythema and serous discharge compared to the endoscopic technique. Multivariate regression analysis highlighted a statistically significant association between the endoscopic technique and the ASEPSIS Score. This could potentially be explained by greater disruption to blood supply and fascial perforators in the lower limb skin and subcutaneous tissue during the long continuous incision of the open technique, leading to inferior healing compared to EVH. Moreover, the conventional technique's long, continuous skin incisions increased the risk of hematoma, ecchymosis, edema, and other wound complications. These findings align with the trial conducted by Elbassioni and colleagues [11].

Research by Black et al. demonstrated significantly lower ASEPSIS scores on post-operative day 4 in patients undergoing minimally invasive vein harvesting surgery, indicating reduced indicators for wound inflammation [12]. Šimek and Němec reported that minimally invasive vein harvest techniques significantly reduced wound-healing disturbances, including hematoma formation, leg edema, skin necrosis, wound dehiscence, and wound infection [13]. Additionally, Rosati et al. revealed a lower incidence of leg wound complications with the EVH technique, consistent with findings from Zenati's randomized trial [14,15].

Enhancing exercise tolerance and improving overall quality of life represent primary objectives that prompt patients to opt for CABG surgery. However, complications arising from lower limb harvesting wounds can impede patients' recovery despite successful coronary revascularization. Postoperative lower limb edema, pain, and inadequate leg wound healing may restrict patients' mobility and activity levels.

In this study, quality of life, as assessed by Euro-QOL, exhibited significantly better outcomes in the EVH group compared to the OVH group. Patients undergoing EVH encountered fewer issues related to mobility, usual activities, and self-care for their wounds. Moreover, they reported significantly lower pain scores, with an NRS assessment of 1.75 ± 1.390, compared to patients in the OVH group with scores of 4.81 ± 1.377. Our findings align with those of Amouzeshi et al., who similarly concluded that individuals undergoing endoscopic vein harvesting experienced less discomfort and significantly lower pain scores during the 6-week follow-up compared to those undergoing open vein harvesting [16].

Khan et al. conducted a study where leg pain significantly decreased among patients undergoing minimally invasive harvesting, with all pain scores reaching 0 in both groups after six weeks [17]. Similarly, Omer Aziz et al. found that the method of harvesting impacted post-operative discomfort, sensory disturbances, and mobility, all of which were lessened in minimally invasive approaches [18].

Patients in the EVH group expressed significantly higher satisfaction with the cosmetic appearance of leg wounds compared to those in the OVH group. The smaller endoscopic wounds were aesthetically superior to the long continuous open incisions. These findings align with Marty et al., who highlighted excellent cosmetic results following endoscopic harvesting as a notable difference between the two approaches [19]. Ferdinand et al. also noted substantially higher satisfaction with cosmetic outcomes in EVH patients compared to OVH patients [20].

The endoscopic technique, in contrast to OVH, eliminates the necessity for a long incision, reduces pain, and importantly, lowers the rate of serious wound infections. This reduction in complications potentially leads to shorter hospital stays and decreased need for multiple readmissions [21]. However, in our study, we found no significant differences between the two groups regarding prolonged hospital stays or readmissions due to leg wound infection. Group I had one patient (6.3%) requiring readmission for prolonged parenteral antibiotics and frequent VAC assisted device dressing for 45 days, while Group II had no such readmissions. Additionally, two patients (12.5%) from Group I had prolonged stays exceeding 14 days due to leg wound complications, whereas Group II had no instances of prolonged hospitalization. Studies by Rosati et al., Crouch et al., and Ozgur et al. demonstrated reduced hospital stays, infection rates, and dressing times in the EVH group compared to the OVH group [14,22,23]. The lack of significant differences in our results may be attributed to the mild nature of wound problems in the OVH group, such as serous discharge in 10 patients (62.5%) and erythema in 12 patients (75%), which did not necessitate prolonged admission compared to potential deeper wound infections.

Furthermore, our study revealed no instances of ischemic ECG changes or hospital mortality in either group. This is consistent with Vuong et al., who found no statistically significant differences between harvesting methods in terms of efficacy outcomes, such as myocardial infarction, vein graft patency, and mortality [24].

These findings emphasize the need for further standardization of the endoscopic harvesting process to ensure the longevity and durability of vein transplants. Subsequent research is necessary to conclusively assess the safety and efficacy of endoscopic vein harvesting.

Our study acknowledges certain limitations, notably the relatively small sample size. However, it is important to note that this sample size was statistically validated and is considered

adequate within the scope of our national research in this specific domain. Additionally, it's essential to address criticism concerning the inclusion criteria, specifically limiting patients to those requiring no more than 2 venous grafts. Therefore, future multicenter or larger randomized trials encompassing a more diverse population are strongly recommended.

Another limitation worth considering is the short-term follow-up period and the reliance on local wound conditions as the primary outcome measure. Consequently, we advocate for further extensive, long-term studies that can elucidate the extended impact on quality of life, graft patency, and cardiac functions.

5. CONCLUSION

EVH is a feasible minimally invasive alternative for the traditional OVH techniques. It is more comfortable for patients as it has better cosmetic satisfaction, less incidence of post operative leg wound complications and less pain. Furthermore, there is a statistically significant relationship between performing EVH techniques and improved quality of life as well as a lower total ASEPSISs score.

CONSENT

As per international standards or university standards, patient(s) written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

As per international standards or university standards written ethical approval has been collected and preserved by the author(s).

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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