

Treatment Outcomes and Lessons Learned From Transilluminated Powered Phlebectomy for Varicose Veins in 1034 Patients

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Abstract

Introduction: Transilluminated powered phlebectomy (TIPP) is a minimally invasive technique of varicose vein removal, which combines irrigated illumination with tumescent anesthesia for ablation of superficial varicosities and endoscopic-powered venous resection. The objective of this study was to analyze treatment outcomes of this treatment modality. **Methods:** A retrospective evaluation of prospectively collected data from all patients undergoing TIPP procedure for symptomatic varicose veins during a recent 12-year period was performed. Pertinent patient demographics, disease classification, perioperative complications, quality of life, and treatment outcomes were collected and analyzed. **Results:** A total of 1167 limbs in 1034 patients (mean age, 52.4 years) were treated during the study period. The mean procedure time was 18.4 ± 8.9 minutes (range, 6.0-82.0 minutes). The mean number of incisions for TIPP procedure was 6.3 ± 3.6 . All TIPP procedures were technically successful, and no patient required conversion to hook stab phlebectomy. Fifteen (1.5%) patients developed residual or recurrent varicosities, which were treated with sclerotherapy during the follow-up period. Postoperative complications included hematoma at 2 weeks (5.8%), ecchymosis at 2 weeks (32.9%), saphenous neuropathy (0.3%), cellulitis (1.0%), and skin pigmentation (1.9%). There was no postoperative deep vein thrombosis or mortality. **Conclusions:** Transilluminated powered phlebectomy is an effective method for varicose vein removal and is associated with high clinical success and excellent cosmetic results. Meticulous technical steps are critical in achieving successful outcomes while minimizing complications. Technical considerations and lessons learned from our experiences are discussed in this report.

Keywords

stab phlebectomy, varicose vein, transilluminated powered phlebectomy

Introduction

Varicose veins can result in debilitating symptoms including swelling, pain, and venous stasis ulcer secondary to chronic venous insufficiency. This condition is largely due to incompetence of the great or small saphenous vein.¹ Published reports showed that the prevalence of chronic venous insufficiency can occur up to 40% in women and 17% in men, and the prevalence of varicose veins varies from 1% to 73% in women and 2% to 56% in men.¹ The traditional treatment of symptomatic varicose veins is ambulatory phlebectomy, which entails techniques such as excisional phlebectomy, stab avulsion phlebectomy, hook phlebectomy, and micropuncture phlebectomy.^{2,3} These procedures are generally performed in an outpatient setting and have been associated with low complications, high patient satisfaction, and good cosmetic results.^{4,5} Critics of these traditional vein removal techniques frequently noted that this treatment can be time consuming and frequently

require multiple stab incisions.^{4,5} As stab phlebectomy is often done in a blind fashion, many varicosities may be missed and complete varicosity removal may be challenging.

Transilluminated powered phlebectomy (TIPP) using the TriVex system (LeMaitre Vascular, Burlington, Massachusetts) was first developed by Dr Spitz in 1999 and approved

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for clinical application by the Food and Drug Administration in 2000.⁶ This is a minimally invasive varicosity removal therapeutic strategy, which potentially may replace multiple phlebectomies. Transilluminated powered phlebectomy incorporates 3 technologies: (1) hydrodissection of the varicosities, (2) transillumination facilitating direct visualization of the varicosities, and (3) varicosity removal using a powered endoscopic tissue resector.^{2,3,6-8} Numerous physicians have reported their experience with TIPP and found that this technique is safe, quick, and highly satisfactory to patients.^{4,9-16} The aim of this study is to present our institutional experience over the course of 12 years using TIPP in patients with varicose veins. Lessons which we learned to improve treatment success and minimize procedure-related complications are also discussed.

Patients and Methods

This is a retrospective review from a prospectively maintained database for all patients undergoing TIPP procedure from January 1, 2003, to June 30, 2015, at a tertiary university-affiliated medical center. Patients undergoing concomitant endovenous saphenous ablation or saphenous vein stripping were also included in the study. Indications for varicose vein removal procedure included leg pain, superficial phlebitis, swelling, heaviness, itching, and bleeding. Conservative treatment was initiated in all patients, which included a 3-month or 6-month period of compression stocking, depending on the individual insurance requirement. All patients underwent preoperative venous duplex ultrasound examination to determine venous reflux and to rule out deep vein thrombosis. Saphenous vein reflux was defined as reversal of flow greater than 0.5 seconds, or the venous diameter was greater than 8 mm. Varicosities were graded using the Clinical, Etiologic, Anatomic, Pathophysiologic (CEAP) clinical classification.¹⁷ Patients with class 2 through 5 disease were candidates for TIPP procedure. Concomitant great saphenous vein reflux was routinely treated with TIPP at the same setting.

All patients were followed at postoperative day 3, 2 weeks, 3 months, 6 months, and 1 year following TIPP procedure. Quality-of-life assessment using Medical Outcomes Study Short Form 36 (SF-36; QualityMetric, Lincoln, Rhode Island) was completed by patients and recorded in the most recent 132 patients in our series. The SF-36 is a generic quality-of-life instrument, which consists of 8 domains: vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning, and mental health. Each domain is scored from 0 (worst) to 100 (best).¹⁸

Operative Techniques

Prior to the TIPP procedure, venous clusters are marked using an indelible ink marker with the patient in a standing position in the preoperative holding area. All operations were performed in an operating room setting under either general or regional anesthesia. For patients who underwent concomitant saphenous

vein ablation and TIPP procedures, the endovenous procedure was performed first. Briefly, the ablation treatment consists of segmental heating of the great saphenous vein using a catheter with a 7-cm heating element (VNUS Medical Technologies, Covidien, Mansfield, Massachusetts). The catheter is advanced under ultrasound guidance to 2 cm below the saphenofemoral junction before the start of ablation. The temperature is maintained at 120°C for 20 seconds per segment using a thermocouple on the heating element, which provides a feedback loop to the generator during withdrawal. Once the radiofrequency ablation is completed, TIPP procedure is performed next. All TIPP procedures are performed utilizing the TriVex system (LeMaitre Vascular, Burlington, Massachusetts) with techniques described previously.¹⁹ The TriVex system is an endoscopic instrument that consists of a combined irrigation illuminator device, a powered vein resector, a 300-W xenon light source, and a pressure infusion system. Multiple small incisions are made around the vein cluster to allow device insertions. Endoscopic instrumentation could be switched through stab incisions to reduce the number of incisions. The irrigation illuminator device consists of 2 channels. One is used to deliver tumescent anesthetic fluid, and the second channel provides light to transilluminate vein clusters under the skin. The tumescent solution creates a hydrodissection effect around the tissue surrounding the vein as it also increases the transillumination of the veins. The first stage of the TIPP procedure involves subcutaneous instillation of tumescent anesthetic fluid via the tumescent illuminator. The tumescent anesthetic fluid consists of 50 mL of 1% Xylocaine and 2 mL of 1:1000 epinephrine diluted in 1000 mL 0.9% normal saline. The first-generation TriVex system required a separate irrigation pump. However, with the second-generation system, the irrigation pump is incorporated into the TriVex transillumination handheld device. Adjustment can be made in the intensity of pump pressure generated, but higher settings are more commonly used. The irrigated tumescent solution facilitates in defining the operative plane via hydrodissection, provides local anesthetic effect, and expedites hemostatic process. A second handheld device of the TriVex system is the powered resector, which is inserted through another incision just around the previously outlined varicose veins. A resector blade size of either 4.5 or 5.5 mm is chosen based on the size of clustered veins. The resector blade will rotate in an oscillating fashion based on an adjustable rotational speed determined by the physician. The powered resector is inserted into the subcutaneous space via a second incision opposite to the tumescent illuminator. The tip of the resector is visualized and then placed in the subcutaneous space under and lateral to the target vein while tumescent anesthesia is administered simultaneously. By suction, the vein is drawn into the working tip opening, and through this opening, the vein is suctioned in, morcellated, and removed. The resector slowly follows the line of the vein and aspirates its fragments. The resector is activated in a pulsed fashion to allow sufficient time for proper aspiration. Once the varicosities were fully resected, second-stage tumescent anesthesia is infiltrated along the paths of the excised veins to minimize hematoma formation and postoperative pain.

At the completion of the procedure, the incisions are covered with multiple layers of compression dressing including ABD pads, Kerlix dressing, Coban self-adhering wrap dressing (3M Health Care Ltd, St. Paul, Minnesota), and ACE self-adhering elastic bandages (3M Health Care Ltd). These absorbent dressings are placed from base of toes to high up on the thigh. The dressings are left in place for 48 hours. The patient is encouraged to ambulate as much as tolerated. The patient is instructed to return to clinic on postoperative day 3 for dressing change. The patient is then transitioned to graduated compression stockings, which were continued for 6 months. Subsequent follow-up visits are also made at 2 weeks, 3 months, and yearly if necessary.

Statistical Analysis

Continuous variables were expressed as mean with standard deviation or median with range, and categorical variables as counts and percentages. Differences between groups were analyzed by Student *t* test or Mann-Whitney *U* test for continuous data and by Fisher exact test. A *P* value of less than .05 was considered to be statistically significant. All analyses were performed using SPSS software for Windows (SPSS Inc, Chicago, Illinois).

Results

During the study period, a total of 1034 patients underwent 1167 TIPP procedures. Among them, 658 (63.6%) patients underwent solely TIPP procedure and 376 (36.3%) patients underwent concomitant superficial venous radiofrequency ablation and TIPP procedures. In these patient cohorts of 1034 patients, 745 (72.1%) patients underwent TIPP procedure in one limb only, 249 (24.1%) patients had TIPP procedures in bilateral legs, and 60 (5.8%) patients underwent multiple TIPP procedures on the same or both legs. Pertinent patient characteristics and demographic data are shown in Table 1. Our patients comprised 631 females (61%) and 403 males (39%), with a mean age of 52.4 years (range: 18.0-82.0 years). Operative variables are included in Table 2. Briefly, the mean operative time for the TIPP procedure was 18.4 ± 8.9 minutes (range, 6.0-82.0 minutes), whereas the mean operative time for concomitant venous ablation and TIPP was 31.5 ± 13.5 minutes (range: 15.0-94.0 minutes). The mean number of incisions for TIPP procedure was 6.3 ± 3.6 (range: 3-18, median: 5.3). All TIPP procedures were technically successful and no patient required conversion to hook stab phlebectomy. Postoperative complications are also summarized in Table 2. Although these complications varied widely, there was no incidence of hematoma, lymphocele, or infection that required surgical evacuation or debridement. There was no postoperative deep vein thrombosis or procedure-related mortality. Quality-of-life assessment based on SF-36 questionnaires is summarized in Table 3. Significant improvements in physical functioning, physical role functioning, emotional role functioning, mental health, vitality, and pain were noted at 3 months.

Table 1. Patient Demographic Data and Clinical Symptoms.

Variable	Value
Demographic data	
No. of patients	1034
No. of limbs treated	1167
Sex ratio (female vs male)	61% vs 39%
Age, years	52.4 ± 6.2
Duration of symptoms, years	3.8 ± 2.6
Pertinent risk factors	
Hereditary	586 (56.6%)
Pregnancy	625 (60.4%)
Obesity	358 (34.4%)
Clinical classification	
C2: varicose veins	551 (47.2%)
C3: edema	286 (24.5%)
C4: skin changes	168 (14.4%)
C5: healed ulcer	15 (1.3%)
C6: active ulcer	14 (1.2%)
Etiology classification	
Primary disease (p)	158 (13.5%)
Anatomical classification	
Left side	574 (49.1%)
Great saphenous vein (As)	1085 (93.0%)
Perforating veins (Ap)	214 (18.3%)
Pathophysiological classification	
Reflux (r)	1125 (96.4%)
Clinical symptoms	
Pain	1008 (86.4%)
Heaviness	861 (73.8%)
Cramping	612 (52.4%)
Swelling	486 (41.6%)
Itching	186 (15.9%)
Bleeding	58 (5.0%)

Table 2. Perioperative Variables and Postoperative Complications.

Variable	Value
General anesthesia	1011 (97.8%)
Regional anesthesia	23 (2.2%)
No. of patients who underwent TIPP only	658 (63.6%)
Procedural duration (TIPP only)	18.4 ± 8.9 mins
No. of patients who underwent TIPP and saphenous ablation	376 (36.3%)
Procedural duration (TIPP and saphenous ablation)	31.5 ± 13.5 mins
No. of phlebectomy incisions	6.3 ± 3.6
Complications	
Hematoma at 2 weeks	68 (5.8%)
Ecchymosis at 2 weeks	384 (32.9%)
Saphenous neuropathy at 6 weeks	4 (0.3%)
Residual veins	65 (5.6%)
Cellulitis	12 (1.0%)
Skin pigmentation	22 (1.9%)
Skin perforation	13 (1.1%)
Deep vein thrombosis	0
Postoperative mortality	0

Abbreviations: TIPP, transilluminated powered phlebectomy.

Table 3. Quality-of-Life Assessment (SF-36) at 2 Weeks and 3 Months.

Quality-of-Life Variables	2 Weeks (Mean)	3 Months (Mean)	P Value
Physical functioning	81.3 ± 6.2	87.5 ± 9.2	.03
Social role functioning	83.6 ± 7.4	86.1 ± 8.2	NS
Physical role functioning	87.6 ± 7.3	94.3 ± 6.9	.03
Emotional role functioning	81.1 ± 8.4	88.2 ± 6.7	.04
Mental health	84.5 ± 7.1	94.2 ± 5.7	.02
Vitality	78.6 ± 11.5	84.3 ± 9.1	.05
Bodily pain	79.2 ± 11.9	85.3 ± 8.3	.04
General health perceptions	83.5 ± 12.5	86.4 ± 7.9	NS

Abbreviation: NS, not significant.

With regard to patient follow-up, 158 (15.2%) patients were lost to follow-up and the remaining 876 (84.7%) patients formed the basis of outcome analysis who had a mean follow-up period of 22.3 ± 5.7 months (range: 1-43 months). In all, 65 (5.6%) patients developed residual veins during the follow-up period. Among them, 15 (1.4%) patients were treated with sclerotherapy using sodium Sotradecol solution during the follow-up period. None of these patients underwent repeat TIPP procedure.

Discussion

Since the Food and Drug Administration first approved TIPP for varicose vein removal in 1999, this technique has been widely described by physicians with remarkable outcomes.^{4,9-16} Despite the perceived benefits of less incisions compared to the traditional stab phlebectomy technique, many vein specialists remained intimidated in adopting this technology due to the necessary equipment setup and various technical steps needed to master this surgical technology. Our report is notable as it encompasses the largest clinical series of TIPP procedure to date with long-term follow-up as well as demonstrable improvement in the patient's quality of life. Additionally, this report shared various lessons learned to reduce procedure-related complications based on this large clinical experience.

Although the safety and efficacy of TIPP has been reported previously,^{11,12,20} the findings of our study in terms of procedural success and postoperative hematoma and ecchymosis were comparable to those previously reported in the literature.^{7,20-22} The number of incisions in our patients treated with TIPP ranged between 4 and 7, which was similar to those reported previously.^{6,7,12,20} The postoperative cellulitis in our series was 1%, which was consistent with those reported in the literature of 0.2% to 3.5%.^{6,7,12,20} In a prospective randomized study of 29 patients and 33 patients who were treated with the TIPP procedure and stab phlebectomy procedure, respectively, Chetter and associates noted that the TIPP procedure incurred less complications, fewer incisions, shorter procedure times, decreased discomfort, and greater patient satisfaction compared to the traditional stab phlebectomy procedure.²³ The authors noted that there was considerably less incidence of

varicosity recurrence when treated with TIPP procedure. Several researchers noted that up to 73% of redo ambulatory phlebectomy procedures were due to inadequate vein excision from an initial stab phlebectomy procedure.^{15,24} With the TIPP procedure, these researchers postulated that transillumination should provide better visualization, which can result in fewer missed veins and reduced incidence for redo phlebectomy.^{11,25} This was an observation with which we concurred based on our experience, as it is underscored by the fact that the conventional stab phlebectomy procedure is often time consuming and often performed blindly via multiple stab incisions without any capability to confirm the total removal of the vein cluster.^{1,5,24} Taken altogether, the findings of these studies including our report demonstrated many clinical benefits of the TIPP procedure in varicose vein removal. Additionally, our study was notably significant as it demonstrated a substantial quality-of-life improvement following the TIPP procedure.

Procedure-related complications, while infrequent, can occur with any minimally invasive procedure including TIPP. By far the most commonly described complication associated with TIPP is hematoma formation or leg bruising, with a reported incidence ranging widely from 0% to 95%.^{4,11,14,15,20,26,27} This wide disparity in the reported incidence of hematoma may be due in part to diverging definitions used by various authors, with terminologies such as ecchymosis, bruising, skin discoloration, or hematoma have been used to characterize a similar phenomenon. We defined hematoma as a localized collection of blood within the subcutaneous space, whereas ecchymosis or bruising as skin discoloration due to blood spreading under the skin. Although hematoma and ecchymosis are common following TIPP procedure, we considered these events as complications when they remained present at 2 weeks following the procedure. The overall incidence of hematoma and ecchymosis was 5.8% and 32.9%, respectively, at 2 weeks following the TIPP procedure in our series. However, similar incidence dropped considerably to 2.1% to 21.3%, respectively, at 2 weeks since 2011 or in the most recent 620 patients in our series. We attribute this to modification of our techniques. We believe techniques utilized in the TIPP procedure can directly influence hematoma formation, a finding that has been echoed by other authors.^{12,25,28} As we gained clinical experience over the years along with device refinement of the TIPP instruments, we have invariably modified our treatment technique in an effort to reduce these procedure-related complications. The following 10 technical considerations represent the lessons we learned over the course of 12 years to maximize treatment success while reducing hematoma or ecchymosis formation:

1. Outline the region of varicosities with the patient standing up before TIPP, which maximizes vein dilation.
2. Position the patient's leg to optimize the device entry site of the TriVex system. This is to ensure the incision sites are in the anterior or superior plane to the varicosities so the TriVex devices have free mobility without hitting the operating room table.

3. Incorporate epinephrine in the tumescent solution, which will promote vasoconstriction and reduce blood extravasation. This may reduce hematoma and ecchymosis formation. However, be mindful that prolonged idling time between tumescent solution infusion to TriVex resection of varicosities may obscure adequate varicosities due to venous vasospasm.
4. Infuse a copious amount of primary and secondary tumescent solution during the TIPP procedure. The goal of primary tumescence is to expand the subcutaneous space and elevate the varicosities toward the skin surface, which enables better visualization with transillumination. The purpose of secondary tumescence is to fill the subcutaneous space to prevent blood extravasation following vein resection.
5. Avoid dissection using the TriVex resector adjacent or parallel to the varicosities. Also avoid lateral movement of the resector and minimize creation of dead space as this will promote blood accumulation resulting in subsequent hematoma formation. Similarly, we avoid dissection using the TriVex resector along the anteromedial aspect of the tibial region as this may result in cutaneous nerve injury. If extensive varicosities are encountered in this region, we routinely perform stab phlebectomy using a Crochet hook.
6. Set the oscillation frequency of the TriVex resector to a lower range. High oscillation range (>500 rpm) may result in overly aggressive vein resection and incur soft tissue trauma, which may result in hematoma or ecchymosis formation. In our practice, we preferentially set the oscillation frequency at 300 rpm.
7. Use a “pulsed technique” with the TriVex resector, which enables sufficient time for proper aspiration. This technique entails frequent stopping and starting the resection with an interval of 2 to 3 seconds to allow for proper suction. This interval pulsed resection also allows for copious rinsing with tumescent fluid to fully evacuate blood trapped in the resector, which facilitates smooth blade rotation for vein resection.
8. Use multilayer circumferential dressings following TIPP to ensure complete fluid absorption during the immediate postoperative period. For our preferred postoperative dressing, we routinely use 10 to 15 absorbent abdominal (ABD) pads in every TIPP procedure, which are placed directly over the leg incision sites. This is followed by 2 to 3 Kerlix gauze bandage rolls, two 6-inch Coban self-adhering wrap dressing, and lastly two 6-inch ACE self-adhering elastic bandages. Inadequate dressing placement can lead to soaking of the dressing with serosanguineous fluid containing both residual tumescent fluid and blood. The patient may misinterpret this as active bleeding following the procedure, which may result in undue anxiety and patient dissatisfaction.
9. Educate patients so that they are aware that mild ecchymosis or transient skin bruising is expected following TIPP procedure. This ensures appropriate patients’ expectations that can reduce potential postoperative anxiety or dissatisfaction.
10. We recommend our patients to wear knee high-compression stocking after the initial postoperative dressing is removed and continue with daily compression stocking for an additional 6 months thereafter. We also recommend our patients to engage in aerobic exercise 30 minutes daily such as walking as we believe this will reduce the risk of postoperative deep vein thrombosis and facilitate the recovery process.

It is noteworthy that the aforementioned technical lessons were accumulated and modified as a result of 12 years of learning evolution. As we adapted these technical principles, we have witnessed improved treatment outcomes and encountered greater patient satisfaction. Several authors have similarly reported various technical considerations using the TriVex system based on their experience, and many have noted a definite learning curve associated with the TIPP procedure with which we fully concur.^{14,19,29} As each practitioner gains experiences with the TriVex system, procedural steps used in TIPP may vary and differ from our experience described herein. It is certain that one can overcome the learning curve, achieve procedural efficiency, and improve treatment success with experience as reported by many authors.^{11,14,15,25,26,30}

There are certainly several weaknesses in our study. The lack of randomization or a control group in this report precludes a fair comparison to determine the true efficacy of the TIPP procedure. As the majority of the procedures analyzed in this study were performed by the lead author, this may have resulted in patient selection bias as the treatment philosophy and strategy was largely based on one physician’s experience. Similarly, various technical considerations discussed in this report to minimize procedure-related complications were derived from the clinical experience of one physician, rather than a collection of many expert operators. However, one should understand that these lessons were outlined with primary objectives of reducing complications and enhancing treatment success, and these objectives can be achieved in a variety of manners by different operators even though the same surgical technology is being used. Another weakness of this study is the heterogeneous patient population, which included patients undergoing concomitant saphenous ablation and the TIPP procedure as well as those treated with TIPP procedure alone. Consequently, the inclusion of patients undergoing adjunctive venous ablation procedure may result in longer procedural time as well as complications that might not be entirely attributable to TIPP procedure alone.

In conclusion, our study demonstrated that TIPP is a highly effective methodology in removing varicose veins with high patient satisfactory rates and remarkable long-term success. As with any surgical procedure, there is a learning curve that can be easily overcome with experience as well as meticulous techniques. Awareness of potential complications and experiences in performing the procedure will enable a physician to achieve excellent outcomes with minimal incisions for both

transillumination and vein excision. This is a highly beneficial armamentarium for physicians with clinical interests in varicose vein management.

Declaration of Conflicting Interests

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