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CHIVA – A prospective study of a vein sparing technique for the management of varicose vein disease

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ABSTRACT

Background: Varicose vein disease (VVD) affects approximately one third of adults. Cure Conservatrice et Hémodynamique de l'Insuffisance Veineuse en Ambulatoire (CHIVA) is a minimally invasive, vein sparing technique that is emerging as an alternative to ablative techniques for treating VVD.
Methods: This prospective study assessed the rate of recurrence of venous reflux with CHIVA. We evaluated 150 primary procedures with clinical and duplex ultrasound examinations pre and post operatively. Patients were followed at <3 months and >1-year post-op. Recurrence was defined as reflux in the diseased vessel at the saphenofemoral junction on duplex examination.
Results: There was no documented recurrence at the early follow up. To date, 58 legs have completed the late follow up and reflux was found in 5 legs resulting in a recurrence rate of 8.6%; 95% CI (2.4%, 19%).
Conclusion: Our results indicate that CHIVA appears to offer a promising alternative for the treatment of VVD.

1. Introduction

Varicose vein disease (VVD) is a chronic, gravity dependent condition, which affects approximately one third of adults[1,2] with >10% exhibiting severe venous disease.[1] VVD is characterized by the slow, progressive onset of symptoms such as visible varicosities, edema, pain or discomfort, itching, and a sensation of heaviness in the affected limb(s).[3] Primary VVD is often caused by valvular incompetence resulting in reflux of blood into the superficial system of veins and impaired antegrade venous return to the central circulation. The pooling, veno-venous shunting and venous hypertension lead to chronic venous disease (CVD) and the development of distended and tortuous leg veins.

While there is a wide range of modalities for the treatment of VVD the most common method(s) utilize a technique that completely ablates the greater saphenous vein (GSV). Varicose vein stripping has long been the standard surgical treatment modality and involves removal of the GSV disconnecting this major drainage vessel from its connection to the femoral vein and also from its superficial tributaries. The recurrence rate of vein stripping in the literature is 35–53%.[2,4–6] Newer ablative techniques have attempted to address the issues of high morbidity and recurrence rates.

Cure Conservatrice et Hémodynamique de l'Insuffisance Veineuse en Ambulatoire (CHIVA) is a novel, minimally invasive, non-ablative GSV sparing technique described for treating VVD. Portable real time duplex ultrasound technology has permitted precise identification, and mapping of the saphenofemoral anatomy as well as the location of hemodynamic incompetence along the pathway of the GSV. This procedure enables reflux points that lead to veno-venous recirculation of blood in the leg to be accurately ligated, while preserving an otherwise normal venous drainage system.

In this study, we examine our experience using CHIVA as a method for managing primary VVD.

2. Methods

This study was conducted with Vancouver Island Health Authority Health Research Ethics Board approval. Patients were accrued consecutively between October 2014 and April 2015. Each patient underwent clinical and duplex ultrasound assessment for VVD. The severity of their disease was classified using the Clinical, Etiologic, Anatomic, Pathophysiologic (CEAP) scale (Table 1).

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Table 1
Clinical CEAP classification of venous insufficiency.

Clinical	Symptoms
Class 0	No visible or palpable signs of venous disease
Class I	Telangiectasias or reticular veins
Class II	Varicose veins
Class III	Edema
Class IVa	Skin changes including pigmentation or venous eczema
Class IVb	Skin changes with lipodermatosclerosis or atrophie blanche
Class V	Healed venous ulceration
Class VI	Active venous ulceration

All eligible patients were included in the study. Patients were eligible if they had primary VVD, underwent CHIVA within the above time constraints, and the following criteria were satisfied:

Inclusion criteria: CEAP clinical classification of C2-6, confirmed evidence of saphenofemoral reflux or incompetence and one or more incompetent tributaries of the GSV, presence of at least one re-entry perforator located on the saphenous trunk, and a patent deep venous system. Exclusion criteria: previous GSV surgery, primarily or exclusive short saphenous vein (SSV) disease, history of deep venous thrombosis (DVT), deep venous insufficiency (in the common femoral vein, femoral vein and profunda femoris vein), and severe medical or surgical comorbidity (congestive heart failure, malignancy, severe autoimmune disease, coagulopathy, morbid obesity BMI >40).

CHIVA was performed under local anesthesia. Each patient underwent re-interrogation with the portable duplex ultrasound (Fujifilm Sonosite M Turbo, Toronto, ONT) in the supine position immediately prior to surgery. The skin was marked directly over the point of saphenofemoral reflux and/or over each of the incompetent perforators and tributaries along the course of the GSV. Using sterile technique, small incisions were made over each previously marked site. The GSV was doubly ligated with 2-0 silk ties 2 cm distal to the saphenofemoral junction and distal to the confluence of the superficial inferior epigastric, pudendal and circumflex veins. The anterior accessory vein to the GSV (AAGSV) was ligated concomitantly if reflux was identified. Heading inferiorly along the course of the GSV, separate incisions were made over each reflux point and incompetent tributary whereby each was isolated and doubly ligated with 2-0 silk ties. All incisions were closed with absorbable sutures and compression stockings were applied prior to discharge from the clinic.

Postoperative follow up consisted of a telephone call 48–96 h post-operatively and each patient was then re-examined clinically and by duplex ultrasound in the clinic at or before 3 months and once again after 1 year. For each patient any interval complications were documented, specifically: hospitalization, pulmonary embolus (PE), deep vein thrombosis (DVT), superficial thrombophlebitis, wound infection, persistent pain, dysesthesia, and bruising. All duplex scanning was performed from the saphenofemoral junction to the knee. Each patient was examined in the supine position and then asked to perform a Valsalva maneuver. Reflux (and thus recurrence) was defined as being present if there was reverse flow through the GSV for >1.0 s in the supine position while at rest or during Valsalva.

Data collection forms were stripped of all subject identifiers other than age, sex and a unique patient number and entered into an Excel Spreadsheet (Microsoft®Excel®2011 version 14.6.7). Tab delimited data were then exported to the statistical engine (Stata©Version 12, Statacorp, Redmond, TX) for statistical evaluation. Descriptive analysis was performed and observed proportions were determined with standard methods; confidence intervals were calculated (Stata©Version 12, Statacorp, Redmond, TX). Proportions and their differences are defined with 95% confidence intervals for non-zero values with Yates' correction for small numbers where relevant. Zero proportions are defined further through one-sided 97.5% confidence intervals.

3. Results

One hundred and eleven patients underwent 150 primary leg procedures in this study. Thirty-five (25%) were male and 106 (75%) were female. The average age was 52.2 years. The CEAP classification for our cohort can be found in Table 2.

In all 150 procedures, there were no duplex documented recurrences of reflux at the early follow up visit (0% recurrence at or before 3 months, 97.5% CI (0, 2.4%)). Of the 150 legs, 58 have completed the second follow up visit being at or beyond 12 months after surgery. The median follow up was 16.4 months (Mean 17.1 months, SD 2.9 months). Of these 58 legs, 5 demonstrated sonographic evidence of reflux; a recurrence rate of 8.6%; 95% CI (2.4%, 19%). None of these patients had recurrence of clinical symptoms. Four of the 5 cases demonstrated GSV reflux. In one case there was reflux noted in the AAGSV.

There were very few surgical complications. None of the patients experienced wound infection, persistent pain, DVT, PE or were hospitalized after surgery. The rate of superficial thrombophlebitis was 5% overall (95% CI 2.3%, 10.2%), and bruising was 3% (95% CI 1.1%, 7.6%).

4. Discussion

Normal antegrade flow of blood from the leg back to the central circulation occurs from distal to proximal and from superficial to deep venous systems through perforator veins. A series of unidirectional valves strategically positioned in these veins facilitate venous return to combat the forces of gravity.[7,8]

The majority of patients with VVD amenable to treatment have valvular incompetence,[1,3] which causes blood to flow in a retrograde fashion from deep to superficial.[6] This blood pools in the superficial system causing venous hypertension and distension distal to a competent perforator where the blood from the superficial system can return into the deep system. Due to the incompetent valves the blood re-enters the superficial system, effectively creating a veno-venous loop.[6,9] Over time, the added blood volume and increased venous pressure leads to the development of CVD of the superficial system manifested by a spectrum of sequelae including telangiectasia, varicose veins, lipodermosclerosis, and cutaneous ulcers of the skin.[1,8]

The common therapies for VVD are ablative whereby the GSV is either removed or completely destroyed.[1,10–12] High ligation of the GSV at the level of the saphenofemoral junction and stripping of this vein is the classic ablative technique, which carries a recurrence rate of 35–53%.[2,4–6] This procedure removes the diseased GSV damaged by chronic venous hypertension, but in addition all of the connecting tributary veins in the superficial system and the re-entry perforator veins within the deep system are also ablated.[10] New ablative modalities such as radiofrequency ablation (RFA) or endovenous laser ablation (EVLA) therapy all accomplish the same task with purportedly fewer complications of peripheral nerve damage and post operative pain.[10] There are however, disadvantages with ablative surgeries. These include morbidity and cost. The emergence of neovascularization in vein stripping is thought to be due to an angiogenic response to the tissue trauma of the procedure itself whereas vein sparing techniques appear to avoid promotion of angiogenesis.[11]

CHIVA is not just a technique, but a change in concept. CHIVA makes the assumption that most of the GSV and its connecting

Table 2
Patient demographics and outcomes.

	Male		Female		Total
	n = 38	25%	n = 112	75%	n = 150
Age	55	–	52	–	52.5
CEAP I	0	0%	0	0%	0 (0%)
CEAP II	14	9%	65	43%	79 (53%)
CEAP III	19	13%	21	14%	40 (27%)
CEAP IVa	9	6%	5	3%	14 (9%)
CEAP IVb	1	1%	0	0%	1 (1%)
CEAP unknown	3	2%	13	9%	16 (10%)
Outcomes at early follow up					
Recurrence	0	0%	0	0%	0 (0%)
No recurrence	38	25%	112	74%	150 (100%)
Bruising	0	0%	2	3%	2 (3%)
Superficial Thrombophlebitis	1	2%	2	3%	3 (5%)
Outcomes at late follow up					
Recurrence	1	2%	4	7%	5 (9%)
No recurrence	14	24%	39	67%	53 (91%)

veins to the deep system are not irreparably damaged, remain functional and can be spared. By selectively targeting the reflux points, the superficial drainage system remains more or less intact and circulation by way of the many perforators to the deep system will re-establish antegrade flow.[9] Studies have shown a reduction of leg edema and caliber of the GSV and deep veins following CHIVA.[13] While ablative techniques have long been the most common method to treat VVD, targeted control of the sites of venous insufficiency stops the vicious cycle of veno-venous recirculation, restores antegrade flow through the deep venous system and ameliorates CVD by decreasing venous hypertension.[9]

In our study, all patients demonstrated clinical improvement at early follow up and this was maintained at late follow up. We have considered our reflux recurrence rate of 8.6% to determine if it could be further lowered. As with all surgeries, it is conceivable that technical issues at the time of the procedure led to recurrence in some legs. As with conventional surgery, it is possible that the anatomical issues were underappreciated or not fully addressed at the time of the procedure, leading to later reflux. Additionally, having found one patient in whom the AAGSV vein later developed reflux requiring re-exploration and ligation, we have now begun to ligate the AAGSV or posterior medial (PM) veins at the time of CHIVA, regardless if there is appreciable reflux. Future study is required to determine if this technical adaptation further lowers our recurrence rate using CHIVA.

Comment should also be made on the upper bound of our confidence interval. While the sample size is not large enough to ensure a narrow confidence interval, it is important to note that the upper bound of 19% is still well below the documented recurrence rate for vein stripping. We will continue to gather follow up data, which may result in a narrowing of this interval.

For practitioners undertaking CHIVA, it is important to emphasize the role of sonography at the time of surgical assessment and follow up. Current portable duplex technology permits detailed and accurate mapping of reflux points, which is crucial for the success of this procedure. While hiring a skilled sonographer would suffice, it would be more practical and efficient if a member of the surgical team developed the necessary skills. Not only is it important for the procedure, but it is also necessary to determine follow up care and provide feedback necessary to detect and understand failed procedures.

Clearly, our study is limited as a cohort evaluation rather than a randomized controlled clinical trial. Our follow up interval to date is relatively brief and our sample size is small. While further follow up is pending, in spite of our limitations we have found that our results compare favourably with ablative treatment outcomes. Our low recurrence rates combined with anecdotal reports of a high level of patient satisfaction encourages us to continue to pursue refining our technique with CHIVA.

5. Conclusion

We found the recurrence rate using the CHIVA method compared favorably with vein ablation techniques. High patient satisfaction, low complication rate and low cost encourage us to pursue further study using this technique. This research should focus on directly comparing outcomes and cost efficiency with current ablative techniques. While there is no universal solution to varicose vein disease, CHIVA is a viable option for those with primary VVD.

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