Original Research Article

Accuracy of Handheld Continuous - Wave Doppler Ultrasound in the Assessment of Varicose Veins.

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Abstract

The incidence of varicose veins and the need for treatment has shown a tremendous increase over the years. Debilitating venous ulcers and dragging edemas of the lower limb with overall improvement in cosmetic results and availability of endovenous procedures has brought many patients forward for treatment. Continuous-wave handheld Doppler usage is limited by its diagnostic capabilities, thus the need to determine its real effectiveness. Benefits of using hand-held dopplers lies in its rapidity in assessment of patients, it's low running cost and short learning curve. This is important as duplex ultrasounds are not readily available in district hospitals. This study aims to determine the clinical effectiveness of hand-held continuous wave dopplers in the local setting especially in primary uncomplicated varicose articles veins. All electively referred patients with primary uncomplicated varicose veins who were referred to the Varicose Vein Clinic were evaluated with continuous-wave handheld Doppler (CWD) and duplex ultrasound (DUS) examination. The study duration was from the 1st of July to 31st of August 2013 (2 months). All patients in the study were independently evaluated with CWD and DUS in the clinic on the same day after adequate rest time. DUS was taken as the gold standard for evaluation of CWD specificity and sensitivity. The Chi-square and T-test was used to test for statistical significance. A total of 41 patients were evaluated in this study. The specificity of CWD when compared to DUS for diagnosing Sapheno-femoral junction (SFJ) was 100% and at the Sapheno-popliteal junction (SPJ) was 87%. Meanwhile sensitivity of CWD for SFJ was 75% and SPJ was 60%. The examination time with CWD was significantly faster than when compared with DUS examination with significant faster tracing times that can be achieved with CWD. CWD also significantly shorter reflux times when compared to DUS. Continuous-wave handheld doppler proves to be an indispensable clinical tool in the evaluation of SFJ and SPJ reflux in varicose veins. CWD assessment in this study was shown to be equal if not better for evaluating reflux when compared to DUS assessment for SFJ reflux. Main advantages for CWD also lie in its low running cost, rapidity in assessment and short learning curve when compared to duplex ultrasound examinations.

Keywords: Varicose veins, continous-wave doppler, duplex

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Introduction

Varicose vein and its management have undergone tremendous change over the past 30 years. The disease itself has seen a rise in incidence as more patients come forward with various presenting symptoms owing to an increase in awareness. The symptoms of the disease such as cramping of the lower limbs, stasis eczema, the

long course of venous ulcers can be debilitating to the patient. Progression to chronic venous insufficiency can be avoided if the varicosities are detected and treated early with proper clinical tools. The improvement in less invasive techniques for treatment has also contributed to this increment of patients who are willing to come forward with their ailments. Earlier epidemiological studies when compared to the landmark study "The Edinburgh Vein Study" does show an increased prevalence of varicose veins from 17.4% in males to 39.7% and 31.6% in females to 32.2% (1,2). The disease has consistently shown to affect females more than males and in some studies; the prevalence in females is twice of that in males.

Several risk factors have been established that contribute to the development of varicose veins. These risk factors include obesity, occupation with longstanding hours, high parity in females, family history and advancing age (2). Varicose veins as a disease entity can be divided into primary, secondary and congenital. Primary varicose veins occur when there is inherent weakness in the venous wall architecture where as secondary varicose veins has an identifiable obvious cause such as previous history of trauma or deep vein thrombosis. The resulting weakness in the architecture leads to incompetency of the valves in the veins causing reflux of blood into the superficial venous system (3). This reflux may occur at the junctions between the superficial and deep venous system, which is at the sapheno-femoral junction or/and at the sapheno-popliteal junction or in the perforator veins of the lower limbs (4).

Current trends of varicose vein surgery have strategically evolved itself towards minimally invasive endovenous procedures with the aim of better cosmesis and reduction in recurrence as well. This changing trend owes itself to the advancement of medical technology such as thermal (laser or radio-frequency) ablation taking over most procedures where previously ligation surgery might have been done (5). The improvement in outcomes has also been attributed to the perfection of older surgical techniques and diagnostic imaging such as the use of duplex ultrasound in the preoperative assessment of varicose veins. Classical surgical techniques for varicose vein surgery include, high saphenous vein ligation, sapheno-popliteal ligation with or without multiple stab avulsion of visible varicosities. Due to the relatively simpler nature of surgery and the wide unavailability of vascular surgery services, in many countries, the bulk of varicose vein surgery is still done by the general surgeon (6). This scenario holds true in our country as well. The wider coverage of general surgery as compared to vascular surgery services lands the management of varicose veins in the hands of the generalist. Until the services and fraternity grows further, general surgeons will continue to contribute to the treatment of varicose veins, either in the state or district hospitals.

Although the nature of varicose vein surgery is relatively simpler when compared to other surgeries that can be executed by the general surgeon, improper assessment of the pathological anatomy prior to surgery can have disastrous recurrence issues. As much as 20% of varicose vein surgery are for the treatment recurrence, which is 65% at 5 years follow-up (7). The recurrence happens in the majority of cases due to inadequate first surgery. Assessment of varicose veins prior to surgery itself has undergone major shifts in terms of modalities and rapidity of assessment. Currently, duplex ultrasound is the method of choice for varicose vein assessment. Duplex ultrasound confers the surgeon with a wide-range of information that aids in surgery such as exact haemodynamics of the venous system, assessment of valve morphology, complete venous system anatomical mapping and visualization of reflux (retrograde flow) with the ability to quantify them objectively (7,8). Literature findings note that duplex ultrasound has a specificity of 100% with a sensitivity of 79.2% in diagnosing varicose veins in the lower limbs (9). Although duplex has proved to be indispensible in varicose vein management, it has shortcomings with regards to its expensive initial cost, limited availability due to the need for specialized training of radiologists and vascular surgeons to interpret the findings adequately and it is not practical to incorporate directly during clinical examination (10). Moreover, in most public hospitals, there is a paucity of sonographers, and as such, ultrasounds are done by physicians, both from radiology and vascular surgery. Therefore, it is not necessary that duplex ultrasound be ordered for every patient concerned but only when findings are inconclusive or termed 'suspicious' during clinical assessment by hand-held continuous-wave Doppler findings (11,12).

On the other hand, hand-held Doppler ultrasound technology has also proven to be an indispensible tool in the management of varicose veins. First introduced in 1970s, hand-held dopplers itself has undergone some specific changes with regards to introduction of new probes (5MHz and 8MHz vascular probe) specific for vascular assessment and more objective assessment with tracing recording (via Liquid-Crystal-Display screen or onboard printers). Due to its simplicity of use and extreme portability, hand-held dopplers have proved to be the most practical tool in the clinic during clinical consultations. In many instances, the hand-held Doppler capabilities extend beyond just screening purposes (12), but play a role in decision for surgical

management in patients. This capability of hand-held dopplers has a wide range of opinion in previous literatures. The current accepted performance of continuous-wave Doppler sensitivity and specificity in diagnosing varicose vein reflux are 52% and 97% respectively (13). Continuous-wave Doppler ultrasound have been found to be less effective in diagnosing reflux in the sapheno-popliteal junction, low-velocity saphenous vein reflux and confusion with the Giacomini Vein presence (14-17). Although so, in many instances, hand-held dopplers avoided the need for duplex ultrasound imaging hence saving time and valuable resources for the hospital. In addition to that, with proper selection of patients, duplex imaging can be avoided in more than 50% of cases further adding savings to equipment costs, personnel and waiting times (13,14).

Currently, in most hospitals patients are subjected to surgery based on clinical grounds only as duplex ultrasounds can be a 'luxury' in some hospitals. As such, the use of CWD as an adjunct to clinical examination can improve evaluation and final clinical decisions. Considering the Malaysian setting and our available resources, the role of hand-held dopplers with corresponding justification for the need of duplex imaging needs to be established. Vascular surgery services are expanding, but its reach is not sufficient enough to manage every case of varicose veins in the country. In this scenario, the significant load of varicose vein surgery will be managed by the general surgeons and with limited resources, the role of hand-held Doppler needs to be justified clearly and its weakness (if any) be identified. This justification and identification is where this study will attempt to achieve for the improvement of preoperative assessment of varicose vein surgery services in Malaysia.

The Torniquet-Test

This test is currently the standard for physical examination assessment of patients with visible varicosities. The sequential application and removal of the applied torniquets allows the examiner to determine the level of valvular/perforator incompetence that is suspected to cause the varicosities. However, the test itself is cumbersome with maneuvers that the patient might not be able to cooperate with the attending examiner.

Continuous-Wave Hand Held Doppler (CWD)

Wherever available, the supplement of CWD to physical examination has increased the overall accuracy for clinical assessment of varicose veins. Several studies which used CWD in combination with the tourniquet-test yielded an accuracy up to 62% (16). Therefore, the availability of CWD should be advocated especially to centers which definitely do not have duplex facilities but have active running surgical clinics where patients most often present first. As the advances in technology improve, in current practice, the devices that provide Doppler assessment have become small enough to be portable or hand-held which is used in this study.

Colour Duplex Ultrasonography (DUS)

Before the advent and feasibility of duplex technology, the gold standard for varicose vein assessment prior to surgery was with venography. The 1980s saw the introduction then increased usage of duplex for real-time assessment of varicose veins. As the technology improves with better probes and image resolution, duplex became the new gold standard. Duplex is also 'less invasive' when compared to venography and avoids the patient the risk of allergy to contrast injections and radiation exposure. However, its images are also subjected to the skills of the operator and in our country, the availability is limited with significantly higher cost to purchase the machines.

The advantages of CWD devices and its usage cannot be over emphasized. The recognized potential and advantage of Doppler usage in the assessment of varicose veins are:

i) Easy portability with hand-held units with very low dependence on power source
ii) Significantly lower cost as compared to the next available device which is duplex
iii) Short and easy learning curve for the operator
iv) Reproducible results
v) Non-invasive to patients
vi) Provides a more objective assessment for reflux when equipped or paired to a recording device
vii) Rapid assessment for patients especially in the busy clinic
viii) Much easier and immediate result availability
ix) When supplemented to physical examination findings, increases sensitivity in picking up refluxing veins.

The main objective of the present study was to compare continuous-wave hand held doppler (CWD) with that of duplex ultrasound (DUS) in the pre-operative assessment of patients with varicose veins. We also aimed to assess the accuracy, specificity and sensitivity of hand-held doppler assessment and ascertain specific limitations of hand held doppler assessment for better understanding among clinicians.

Materials and Methods

This was a prospective and observational study which was carried out between 1st August 2013 to 30th October 2013 on patients with confirmed diagnosis of uncomplicated varicose veins that are managed in the varicose vein clinic in Hospital Kuala Lumpur. The clinic is managed by the vascular surgery team, which receives referrals both from within and outside the hospital. Each affected limb was considered as one study sample. The inclusion criteria for this study were (CEAP Classification Standards); a) Patients with confirmed diagnosis of varicose veins; b) Have not undergone varicose vein related surgery; c) Age between 18-75 years; d) Consented for this study. Patients with the following criteria were excluded from this study; a) Patients with underlying malignancy especially abdominal, pelvic and lower limb malignancies; b) Previous history of varicose vein surgery or proven recurrence disease c) Varicose veins that have active or healed venous ulcers d) Unable to stand for imaging procedure e) Patients with gross lower limb deformities (congenital or acquired).

History was taken form the patient and entered into a standard proforma. All necessary measurements and examinations were done during the same day in the Vascular Lab, Hospital Kuala Lumpur. At least 2 minutes of rest (sitting) was provided for patients before each assessment to allow adequate blood pooling in the lower limbs (1). Room temperature in the Vascular Lab was recorded at the start and the end of each assessment. All patients in this study underwent assessment with CWD and DUS with the following protocol/technique:

Clinical Assessment

Patients with varicose veins were classified according to the CEAP (Clinical, Etiological, Anatomical and Pathophysiology) Classification (18) for severity of varicose vein. The CEAP classification is the gold standard and internationally accepted classification tool for varicose vein assessment. The anatomical distribution of visible varicosities were also documented according to the proforma of this study. This assessment was done strictly by the primary investigator/author.

Continuous-wave Doppler Ultrasound Assessment (CWD)

CWD assessment was done using Nicolet ImexDop CT+™ hand-held continuous wave doppler unit. The examination will be done with the examination limb in non-weight bearing position. Patient was supported by the bed-side examination bed frame. A 2-minutes rest time was given to each patient before the test for adequate pooling of blood in the lower limb veins (1). CWD assessments were carried out by the investigator and results from CWD will be blinded from the vascular surgeon conducting DUS assessment to eliminate bias. The Doppler audio-signal will be channeled directly to an Apple Macbook Pro with built in audio-signal processor (with time scale measurement of signal) for interpretation of reflux. The 'calf squeeze test', which is a routine clinical test, were conducted to augment reflux signals during both CWD and DUS assessment of varicose vein reflux. A reflux signal of more than 0.5s upon releasing the calf will be regarded as 'positive reflux'.

Localisation of Sapheno-femoral Junction (SFJ) and Long Saphenous Vein (LSV)

a. Examination conducted from patients' front.
b. Patient supported by the bed side frame and examination limb in non-weight bearing position and externally rotated to provide adequate access for probe.
c. Isolation of the SFJ and LSV at the groin (20)
    i. Femoral artery palpated and isonated first
    ii. Probe is then moved medially to locate femoral vein
    iii. By performing calf squeeze-test simultaneously moving the probe further infero-medially to locate SFJ and isolation of LSV from thereon.
d. The LSV were examined in groin, mid-thigh, above calf and below calf
    i. Examination in the mid thigh to be done 10cm above the knee to avoid mid-thigh perforators
    ii. Probe is advanced from posterior to anterior simultaneously performing calf-squeeze test to isolate LSV

Localisation of the Sapheno-popliteal Junction (SPJ) and Short Saphenous Vein (SSV)

a. Done with the patient facing away from investigator
b. Examination at the popliteal fossa
    i. Location of the popliteal artery is determined by identifying its pulsation signal.
    ii. Probe is then advanced medially with the calf-squeeze test performed to locate the popliteal vein and SSV.
    iii. Documentation of signals is then performed once isolation is confirmed and reflux augmented. Results from the CWD assessment tracings were recorded according to the anatomical diagram as stated in the proforma following the specified 4 anatomical regions.

Duplex Ultrasound Assessment (DUS)

Two vascular surgeons who have adequate experience of performing duplex mapping of lower limb veins will perform DUS assessment. These surgeons have at least 2 years experience performing duplex examinations for varicose veins and are proficient in ultrasound machine usage. A Phillips HD 11XE Ultrasound Machine will be used together with a 12-3 Linear Probe. The examination position will be the same as in the CWD method of assessment for similarity in position for comparison and easier patient understanding of instructions. The calf squeeze test will be employed again for augmentation of reflux signal during the assessment. Retrograde flow on colour mode with corresponding pulse doppler recording (>0.5s) will be regarded as positive for reflux (8,13,17). Duplex mapping of the affected lower limb will also be done during the same sitting with emphasis on the SFJ, SPJ, perforators above and below knee for later identification of anatomical issues, which could affect Doppler results. Results from the DUS assessment were recorded according to the anatomical diagram as stated in the proforma following the specified 4 anatomical regions.

Endpoints of the Study

The main end points of this study were accuracy, specificity and sensitivity of continuous-wave hand held Doppler when compared to duplex ultrasound for predicting reflux in varicose veins especially in the SFJ and SPJ. The positive-predictive value and negative-predictive value were also reviewed to determine the performance of CWD.

Statistics

The data was tabulated and analyzed using the SPSS software version 17. The continuous variables like age, body mass index (BMI) and parity were presented in bar charts while categorical variables were presented in tables or pie charts.

The results from both Doppler and duplex assessments were tabulated in a 2x2 table and their specific sensitivity, specificity with related predictive values were calculated. Chi-square tests were used for each anatomical areas of the examination limb to test for associations. A p-value of less than 0.05 was deemed as significant.

The respective examination time for each type of assessment were compared and tested with the T-test. This was to assess for significant differences in the mean examination time(s) between the two methods. The results from CWD and DUS measurements were also tested with the T-test to identify significant differences in the recording time between the two examination methods (19). A p-value of less that 0.05 was considered statistically significant for both tests.

Results

A total of 41 patients who met all the inclusion criteria were included in this study. The age of the patient ranged between 31-66 years with a median age of 55 years (Fig. 1). There were a total of 28 females and 13 males in this study sample. When expressed in percentages, females represented 68.3% while males made up 31.7%. The majority of patients were females (Fig. 2). In this study sample, there were 12 Malays, 13 Chinese and 16 Indians (Fig. 3). Weight and height of patients recorded in the proforma were further calculated to yield BMI and tabulated in excel sheets up to one decimal point. They were further grouped into standardized categories for data layout and easier identification of subjects who are above normal BMI range. No patients were underweight (Fig. 4).

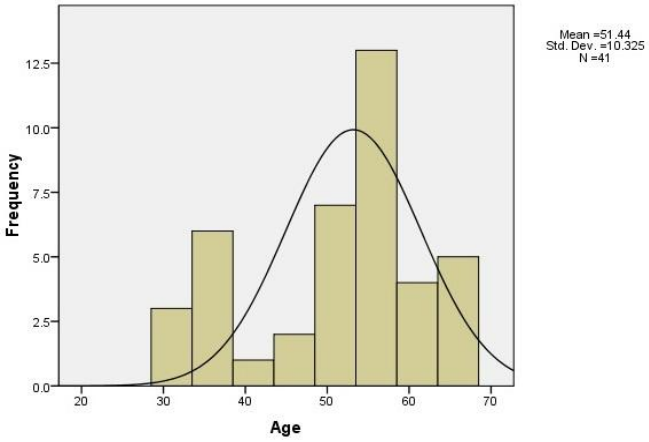

Figure 1: Histogram showing the distribution of ages of patients.

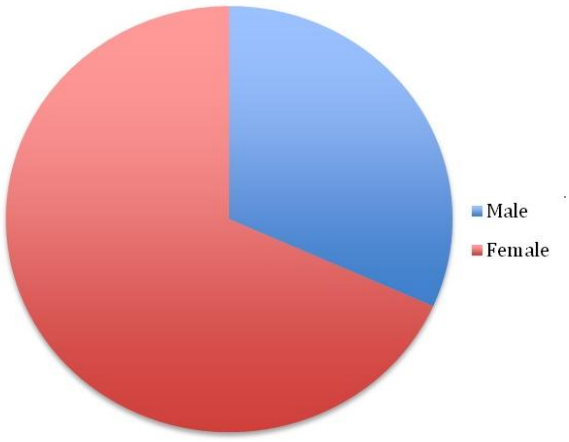

Figure 2: Pie Chart showing the gender of patients.

On the whole, majority of patients had no underlying co-morbid disease. Only one patient had ischaemic heart disease, but clinically this patient did not have any other signs or symptoms of cardiac failure (Table 1). Only one female patient had no previous pregnancy. Only pregnancies that were brought up to term or live births were included in this study (Fig. 5). There were almost equal numbers of patients who were affected by varicose veins in either limb. This holds true for bilaterally affected limbs as well. However, their symptoms usually predominate in either limb that brings them forward for treatment (Table 2).

Majority of patients in this study presented within the first 2 years of onset of clinically visible disease. A very minority of patients presented very late due to the onset of symptoms was at a later course in the disease. The mean time for presentation to the clinic was 42 months (Fig. 6). A greater proportion of patients in this study fall within C4 category of the CEAP classification. As those with ulcers or healed ulcers were excluded, C5 and C6 category of the CEAP charting are of zero value. There were 12 patients with C2 disease, 5 patients with C3 disease and 24 patients with C4 disease (Fig. 7).

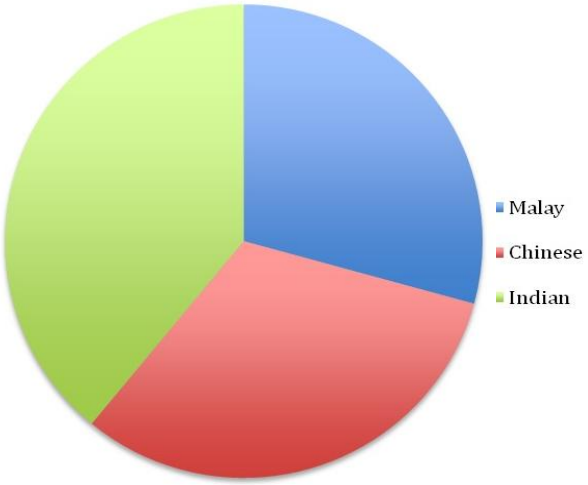

Figure 3: Pie Chart showing racial distribution of patients.

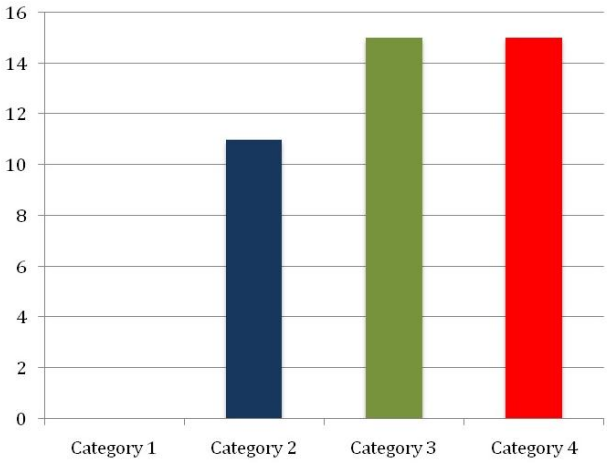

Figure 4: Bar-Graph depicting BMI category of patients.

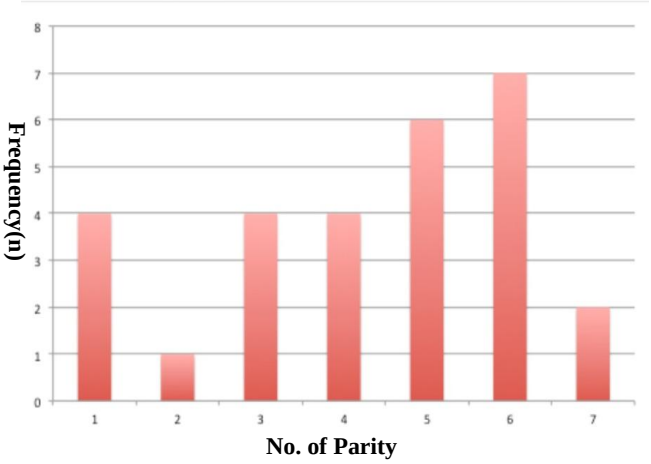

Figure 5: Bar-Graph showing frequency of females with their corresponding parities.

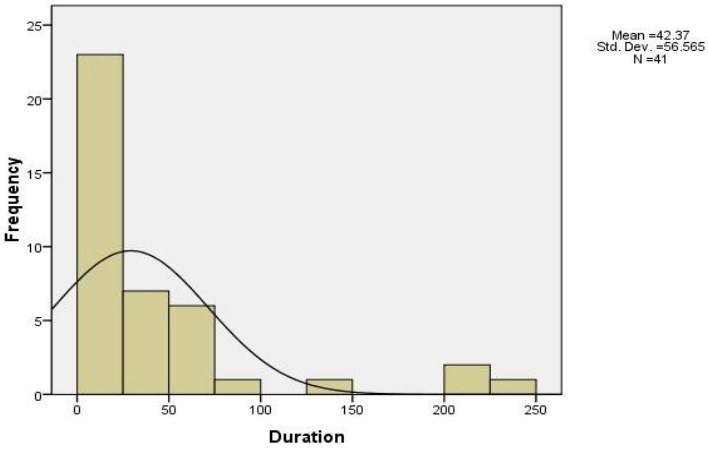

Figure 6: Histogram depicting the duration of illness of patients.

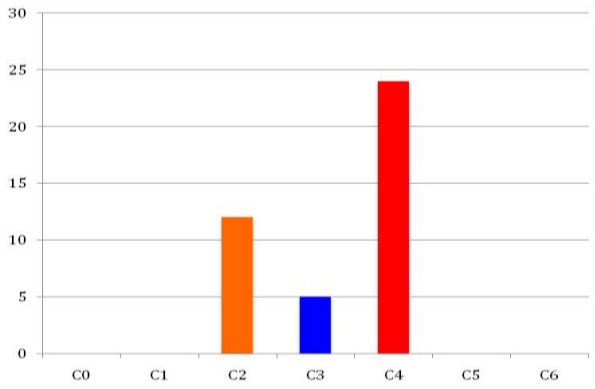

Figure 7: Bar-graph showing the clinical severity score based on CEAP classification of patients.

The waiting time for patients was measured in weeks. This time was taken from the date of the clinical encounter to the actual duplex date. This data was then rounded to the nearest week. Two patients had a maximum waiting time of 6 weeks. This was due to the rescheduling requested by the patients due to the logistical reasons (Table 3).

There were notable differences in the time taken to perform a doppler examination when compared to the time consumed to complete a duplex examination on the same patient. These differences were tested using the t-test to see if the differences observed were statistically significant (Table 4). The calculated p-value was <0.001 hence showed that the shorter time to conduct a Doppler examination was statistically significant when compared to duplex examination time.

There were observable differences in the reflux time measurements between CWD and DUS that were noted during the study. In order to test whether these differences were significant, a Chi-square test was used (Table 5). The statistically significant difference in tracing times between CWD and DUS were consistent throughout the different anatomical assessment areas. Part 4 is valued zero due to no observed reflux between the two methods during assessment.

A 2 x 2 table was constructed for each anatomical areas examined by CWD and DUS for calculation of the sensitivity (Sn) and specificity (Sp). DUS was taken as the gold standard measurement in this study (Table 6,7,8,9).

Table 1: Table showing distribution of co-morbid disease of patients.

Co-Morbid	Frequency(n)	Percentage(%)
Diabetes Mellitus	8	20
Hypertension	12	29
Ischaemic Heart Disease	1	2
Hyperlipidaemia	4	9
Disease Free	22	54

Table 2: Table showing distribution of co-morbid disease of patients.

Laterality of Limb(s)	Frequency (n)	Percentage (%)
Right	13	32
Left	14	34
Bilateral	14	34

Table 3: Table showing mean duplex waiting time for patients.

Mean Duplex Waiting Time	3 weeks

Table 4: Table showing mean of duration times for CWD and DUS of patients.

	N	Mean (mins)	P-value	Std. Deviation
Doppler Time	41	5.54	<0.001	0.505
Duplex Time	41	12.37		2.426

Table 5: Table showing the chi-square values and its corresponding p-values for CWD and DUS reflux tracing times

Anatomical part	p-value	Chi-square (time to detect reflux in seconds) CWD vs DUS
Part 1 (SFJ)	<0.001	15.530
Part 2	0.003	8.667
Part 3 (SPJ)	0.003	9.094
Part 4	0	0

Table 6: 2x2 Cross Tabulation for Area 1(SFJ) for CWD and DUS

Area 1 (SFJ)		Duplex	
		Yes	**No**
Doppler	Yes	25	0
	No	8	8
Sp	100%	NPV	50%
Sn	75%		

Table 7: 2x2 Cross Tabulation for Area 2 for CWD and DUS

Area 2		Duplex	
		Yes	**No**
Doppler	Yes	12	5
	No	6	18
Sp	78%		
Sn	67%		

Table 8: 2x2 Cross Tabulation for Area 3(SPJ) for CWD and DUS

Area 3 (SPJ)		Duplex	
		Yes	**No**
Doppler	Yes	6	4
	No	4	27
Sp	87%	NPV	87%
Sn	60%		

Table 9: 2x2 Cross Tabulation for Area 4 for CWD and DUS

Area 3 (SPJ)		Duplex	
		Yes	**No**
Doppler	Yes	0	4
	No	0	37
Sp	90%		
Sn	NIL		

Discussion

Traditionally, the treatment of varicose veins has always been with open surgery with high saphenous vein ligation and stripping with multiple stab avulsions. As technology advances and with the advent of more endovenous tools such as radio-frequency ablation devices, the treatment for varicose veins has become less invasive (21). This provides excellent cosmetic result which attracts patients alike to come forward for treatment. The increasing awareness amongst patients has led to a higher proportion of clinic patients seen for management of varicose veins. Together with these advances, the introduction of Doppler and Duplex imaging systems has significantly improved the detection, management and treatment of this illness.

Main implications for usage of Doppler and Duplex in medical facilities fall on two major concerns. Cost and with it the adequate provision of services to units managing varicose veins. As the cost for purchasing and maintaining duplex machines together with training the related sonographers are high, alternative imaging or assessment methods needs to be considered to keep cost in perspective especially with the patient load on the rise. This situation would lead to better and earlier detection and subsequently those who undergo surgical intervention (22), whether endovenous or classical open surgery.

Varicose vein surgery has most often been a disease of the west, where cosmesis is a major contributing factor for seeking treatment. Epidemiological studies such as the landmark Edinburgh Study (1) from the west has previously quoted the prevalence to be higher in men than women (39.7% vs 32.2%). This data differs from our finding where in our sample, there were more women than men (68.3% vs 31.7%). More recent data are more consistent with this study which shows the disease predilection for females. In fact, their data[2] is almost similar where the prevalence is twice in females than in males. Another difference in the distribution of patients is that our sample had a mean age of 51 years old whereas in other studies their mean age of disease were much lower at 44.8 years old (1,2). This difference in mean age of presentation could be attributed to several factors including the higher disease awareness in developed nations and accessibility to medical resources which in our country where varicose vein rarely causes mortality does not trigger the patient to present earlier. Our study mean age does however co-insight with Murliet et al. (23) whereby their mean age of patients receiving treatment was 51 years of age. The ethnic composition in this study shows an equal distribution among the main races in our country. It does not reflect the overall ethnic composition in our

country where the majority are malaybumiputras at 67.4% (24). This finding also does not concur with Murliet et al. (23) where his majority of patients were Chinese (47.5%) and Malays were a minority (12.5%). The discrepancy may be due to the urban composition of Kuala Lumpur city which is almost even across all races. Referrals to the unit also come mainly from the state of Selangor where urbanization is taking place rapidly.

Patients in this study tend to be overweight and obese (BMI category 3 & 4). This group of patients when combined made up 73% of the study subjects. This data reflects the higher morbidity and mortality for surgery when compared to normal patients who have to undergo surgery. In a follow-up to the Edinburgh Study, Amanda et al. (25) had similar findings where a BMI of more than 30kg/m^2 was associated with a higher risk of developing varicose veins. A higher proportion of our study subjects which were females and with higher than normal BMIs further concurs with Lindsay et al. (26) and Iannuzzi et al. (27) which showed significant relationship between higher BMI patients with varicose veins and increased their risk of developing chronic venous ulceration. This alarmingly high percentage of patients having higher BMI values reinforces the need for better clinical evaluation prior to the decision for surgery.

Majority of patients had no underlying co-morbid disease. This finding however does not reflect the higher BMI values which was detected in our subjects. Patients were screened only via history for established diagnosis of medical diseases or if were stated in their referral letters. A more thorough investigation is needed to further delineate this issue since the discrepancy exist as diseases such as hypertension, diabetes mellitus and hyperlipidaemia are definitely more prevalent in overweight or even obese individuals as a matter of fact. This relationship was well established by the Framingham Heart Study (28). The investigation for underlying co-morbid illness could be done either prior to receiving the referral by the respective primary care practitioner or screened especially if the patient would be undergoing surgery. On the discussion regarding contribution of previous parity among women to be as a risk factor for acquiring varicose veins, our data showed no obvious tendencies for high parity women to have significantly worst disease or risk for varicose veins. This is in alignment with the findings by Lee et al. (29). Perhaps other obstetrical factors can be investigated in the future to see significant associations between parity and the development of varicosities in the lower limb. Laterality for development of varicose vein showed no preference in either limb. Further analysis of the data showed no obvious increase in frequency in our patients when bilateral or unilateral limbs were concerned. The findings from previous studies also validates this finding (1-3).

Patients with varicose veins have a multitude of symptoms. These range from mild aching to debilitating ulcers of the lower limb. On the whole, symptoms tend to start very mild and run a very gradual course as the disease progresses. A significant portion of patients also sought treatment due to the unsightly nature of the varicosities. Our group of patients mostly presented during the first 24 months from the onset of clinically visible varicosities. The number of patients presenting later gradually decreased with increasing time with symptoms. This pattern of patient distribution is most probably due to symptoms being mild as pointed out by Simon et al. (30) and in his set of patients, a large proportion presented by 30 months prior to the onset of symptoms. Another explanation for decreasing frequencies with prolonged duration with disease is probably due to patients developing coping mechanisms with the disease such as lifestyle modifications.

The CEAP Classification since its inception by the American Venous Forum in 1988 has been regarded as the gold standard in classifying varcicose vein disease. Following the revision of CEAP in 2004, there have been newer studies that attempt to correlate CEAP scores with patient symptoms. As per our findings, CEAP classification did not show obvious relationship to the duration of presentation for patients nor did it predicted severity of duplex scan findings. This concurs with findings from Howlader et al. (31). In addition to that, the ‘C’(clinical) subset of CEAP has been shown to have significant inter-observer variability as demonstrated by Helen et al. (32). We eliminated this issue in our series with allowing only the author to document CEAP findings and this was blinded to the vascular surgeon conducting the duplex examination. In our subjects, there were C5 and C6 classes as these patients were excluded from the study to maintain study criteria for uncomplicated varicose veins. Active or healed ulcers presents as a separate entity with regards to complexity of pathophysiology, anatomy and management. It is perhaps due to the perception of patients in our society that varicose veins only affect them after the varicosities are grossly visible (C2 stage). This also partially explains the later presentation to the clinic for treatment with a mean of 42 months.

In our unit, the mean time for duplex mapping of the venous system has a mean waiting time of 3 weeks. Majority of patients actually have their duplex at around this time with the data skewing due to some patients actually requested to have their scans later for logistical reasons. These patients were not excluded from the data

analysis to maintain data integrity with intention to treat analysis. The reason for the relatively fast date for getting a duplex done is that the unit is equipped with its own vascular lab with multiple ultrasound machines to conduct a duplex examination. The availability of vascular surgeons for interpretation of their duplex findings is also abundant hence no reliance on the radiologist or other sonographers. We would expect, in other centers where facilities like these are not available, the waiting time for duplex would be much longer if not at least double. In a non-vascular unit, the same ultrasound machine would have to be used for other purposes and machine-time would also be dependent on the availability of the radiologist. Hence, it is impractical to subject most subjects in a periphery center for a duplex scan for varicose veins where in terms of severity when compared to other dire emergencies, it ranks lower on the list. Services may also hamper duplex waiting time in other centers should there be machine breakdown or undergo routine maintenance. This further supports the point to advocate usage of Doppler hand-held units, which are cheaper and offer clinical assistance in improving diagnosis.

CWD and DUS both are devices that use ultrasounds and the Doppler effect as their core technology. An obvious obstacle that comes with duplex examinations is the time taken to perform it. When compared to hand-held dopplers we found that the duration to perform a duplex examination for assessment of varicosities to be significantly longer, mean time 5.54mins vs 12.37mins with $p<0.001$ using T-test method. The mean times for DUS examination are twice as long as CWD. We considered this an important aspect for advocating CWD usage in varicose assessment as the rapidity of the examination matters most with units running high volume of patients and are pressed for time in the clinics. This rapidity in assessment has been also acknowledged by Campbell et al. (10,11) and more recently by Galeandro et al. (33), however no exact data for comparison was published. CWD offers the rapidity for diagnosis due to the fact that it relies on anatomical knowledge and careful tracing of the LSV and SSV from its junctions at the SFJ and SPJ, respectively. The isolation by isonation of the respective veins is confirmed instantly by the calf-squeeze test. Similar methods via valsalva maneuver are as reliable in causing venous distension for establishing a reflux diagnosis with CWD and DUS (34,35).The significantly longer duration for DUS examination is probably due to the meticulous tracing of the SFJ, SPJ, LSV and SSV that requires a longer learning curve and dexterity of the sonographer since the manipulation of the probe is guided via the image on screen. In our observation, it is quite common that the vascular surgeon has to reposition the ultrasound probe on the vein or junction that is under examination for a proper pulse Doppler signal to be visualized. Cumbersome and time consuming; however the advantage is that the adjustment is done directly under image guidance on the screen. It is this elimination of the screen or image guided placement of probe is what gives CWD its main advantage.

Hand-held dopplers have evolved significantly since their introduction in the 1980s. Nowadays, dopplers are equipped with their own printer or screens for that record tracing times for interpretation of reflux patterns. In our study unit, which was the Nicolet dop CT+, the trace recordings were significantly shorter when compared with the duplex tracings on the Phillips HD 11XE. This difference was consistent throughout the whole length of the lower limb and statistically significant ($p<0.005$). The difference was most pronounced over the SFJ area where p-value was less than 0.001. Whether this would have altered the overall sensitivity and specificity for our CWD results is highly unlikely since CWD consistently displayed shorter tracing times. If the situation was reversed then CWD could have displayed falsely positive results that may have been less than 0.5s (reflux cut-off value) on DUS (gold-standard). Another variable that may have to be considered to cause the difference in the tracing times is the sensitivity of the respective probes for CWD and DUS. The specification for both devices only shows the frequencies and not decibel (dB) ranges. With respect to the calf-squeeze test that may have affected the compression time and recoil of the veins, in our opinion this is negligible. The reason is that, the vascular surgeon conducting the DUS examination is blinded to CWD examination findings. The DUS examination was conducted entirely independent from the investigator and was only given the results at the end of the examination. This discrepancy can be further investigated should follow-up studies be conducted to further validate CWD. An alternative method to eliminate calf-squeeze test variations (if any) is to employ the test suggested by M. De Maeseneer et al. (36), where by a standardized valsalva maneuver by blowing in a standardized tube to achieve 30mmHg flow pressure or a inflatable-deflatable cuff device could be used. This is however in our rationale, impractical in the clinics where everyday practice occurs and is not available in our facility. Area 4 in our results was invalid due to no reflux was detected during clinical, CWD and DUS examinations. Although the final part of the LSV and SSV is not surgically important in terms of intervention, it was still included in our data analysis to maintain data integrity.

As part of our step to advocate CWD use in other general surgical units, we wanted to evaluate our center

with respect to the sensitivity and specificity of CWD to determine its performance. Previous studies including The Ediburgh Vein Study (1) quote their CWD sensitivity (Sn) to be between 40-65%, specificity (Sp) 80-97% (12-16,44,45) at the SFJ for diagnosing reflux and this performance drops to a specificity of 23-55% and sensitivity 80-96% (1,13,17,37-40). In our study, we have found that, for SFJ assessment, the sensitivity is 75% with specificity of 100%. Meanwhile, the specificity at the SPJ decreased as expected to 87% and 60% sensitivity, respectively. This trend follows other previous literatures as well (1,13,16). Negative predictive value (NPV) for SFJ was 50% while SPJ was 87%. This figure is relatively higher than previous reported literature (38,41,43). There were 8 false negatives noted using CWD at the SFJ and 4 false negatives at the SPJ area. These false negatives are of concern since it changes the clinical decision where if duplex examination was not done, this group of patients would not have been offered surgery (42).

The limitations of this study lies on the part of its small number of patients. Main reason for the smaller sample of patients is the inclusion criteria that only patients with uncomplicated varicose veins were selected. A sizable portion of at least 20% of patients actually have recurrent disease or active/previous venous ulcers that if included may give a better size. Due to the complexity of this group of patients and wide variations in patterns of reflux and anatomy, they were excluded to keep the study objective in perspective. The smaller sample population affects the outcome for sensitivity and specificity calculations to a larger degree for every small change in the result findings. This may mask possible better results that is achievable with CWD during its testing. The examination protocol in this study was adopted from The Edinburgh Study and that from the Bassle Study, which was conceived in 1995. The standardized rest time before examination was set to be at 2 minutes which was strictly adhered to but there may be better results if the examination was conducted at an entirely different time with the patient allowed more complete rest time for venous filling. The calf-squeeze test although conducted independently between CWD and DUS examinations, it was still not fully standardized. Perhaps the application of more mechanized and uniformly reproducible valsalva pressures could be employed with acquisition of relevant tools. Such tools include the automated inflatable-deflatable cuff device, which delivers more consistent calf pressures during examination. Another weakness that was noted was that variations in intra- and inter-observer variability were not measured to completely assess accuracy for DUS and CWD. This could be overcome in future studies with a larger population set with the examination both for CWD and DUS repeated at least twice and the suitable statistical analysis employed. Lastly, to completely assess the full performance of both CWD and DUS, the findings could be compared with operative findings for true positives and negatives.

Conclusion

CWD examination has shown itself to be an indispensible tool to aid in the diagnosis of SFJ and SPJ reflux in varicose vein patients. In this study, SFJ assessment with CWD was shown to be as good or even beter than DUS examination. DUS examination may be reserved for patients who are keen for surgical intervention to aid in the planning for surgery. CWD examination should be advocated in the management of varicose veins given its rapidity in assessment time and ease of use in the clinical setting when compared to DUS examination.

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