**Original Article**

**The risk of harm whilst waiting for varicose veins procedure**

*Short Title:* Harm while waiting for varicose vein surgery

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**What this paper adds:**

This study looked at the effect of waiting for more than 1 year on our varicose veins patients and found significant occurrence of clinical as well as psychological harm.

**Abstract**

The risk of harm whilst waiting for varicose veins procedure

*Introduction*

Varicose veins (VV) negatively impact quality of life (QoL) and have risks of major complications including bleeding, ulceration and phlebitis. During the COVID-19 pandemic, the VSGBI (Vascular Society of Great Britain and Ireland) and GIRFT (Get It Right First Time) classified VVs as lowest priority for intervention.

*Objective*

This study aims to determine harm caused and the impact on the QoL on patients waiting for their VVs procedures for more than 1 year.

*Methods*

This was a prospective study conducted at the Norfolk and Norwich University Hospital (NNUH). Patients with VVs awaiting intervention for >1 year were included in the study. Patients with CEAP C6 disease were considered to be too high risk to be invited for treatment during the Covid-19 pandemic. Patients were sent QoL questionnaires and underwent a telephone consultation to assess harm. Both generic (EQ-VAS and EQ-5D) and disease-specific (AVVQ and CIVIQ-14) instruments were utilised. There were no control groups available for comparison.

*Results*

275 patients were identified (37.1% male) with median time on waiting list of 60 weeks (IQR 56-65). 19 patients (6.9%) came to major harm, including phlebitis (3.6%), bleeding (1.8%) and ulceration (1.8%). Fifty-two patients (18.9%) had minor harm, including worsening pain (12.7%) and swelling (6.2%). 6.9% reported psychological harm. Rising CEAP stage was also associated with worsening level of harm in patients with C5-6 disease (p<0.0001). Only 8.7% stated they would decline surgery during the pandemic.

104 QoL questionnaires were returned. Median EQ-VAS and EQ-5D was 75 (IQR: 60-85) and 0.685 (0.566-0.761), respectively. Median AVVQ score was 23.2 (14.9-31.0) and CIVIQ-14 score was 33 (21-44).

*Conclusions*

This study highlights the impact of delaying VVs surgery during a pandemic. A significant rate of both major and minor as well as psychological harm were reported. In addition, VVs had a significant detriment to quality of life.

Word Count: 302 words

Keywords: Varicose vein; Waiting list; COVID-19 pandemic; Quality of Life

**Article**

**The risk of harm whilst waiting for varicose veins procedure**

Introduction

Varicose veins are a common condition affecting approximately a third of the population1. Involving mostly the lower limb, they cause a number of symptoms ranging from achiness and swelling to more serious complications such as ulceration, bleeding and phlebitis2, 3. They have a negative impact on the quality of life (QoL) of patients, which is, in turn, improved by treatment of the condition4, 5.

In the UK, diagnosis and management of this condition are guided by the National Institute for Health and Care Excellence (NICE) guidelines6. Along with a set of referral criteria, these guidelines also include recommendations regarding treatment, with endothermal ablation methods being the ‘gold standard’ management option.

Treatment of this condition and its sequelae consume approximately 2% of the national health expenditure7. However, because of its low mortality, it is considered by many to be benign and of low priority for treatment and, therefore, often does not attract the same level of urgency compared to other vascular conditions.

This chronic situation has unfortunately been severely exacerbated by the emergence of the global coronavirus disease 19 (COVID-19) pandemic. Indeed, the pandemic led to the unprecedented cancellation of elective procedures in the United Kingdom, putting the whole National Health Service (NHS) under a tremendous amount of strain, all in a bid to protect patients from viral transmission and offer support to the wider pandemic response8. The CovidSurg Collaborative report also projected the cancellation or postponement of more than 28 million elective procedures in 20208. At the height of this pandemic, new ideas and pathways were being devised to address these issues, with tier classification of surgical procedures stratified according to their urgency increasingly being advocated9. The intended objective of these novel systems were to maintain optimal patient outcomes, preserve essential equipment and resources needed to handle the volume of critically ill patients, and uphold crucial public health guidelines for physical distancing9, 10.

To that end, in 2020, the Vascular Society of Great Britain and Ireland (VSGBI) and the Get It Right First Time (GIRFT) initiative released guidance for the resumption of vascular services with vein surgery being classified as the lowest priority (Priority 4: Surgery that can usually be delayed for more than 3 months)11, 12. This inevitably led to increased waiting times for varicose vein patients with a large number having their procedures delayed for longer than 3 months.

As such, this current study aims to investigate the effect of waiting for intervention on patients with varicose veins.

Methods

This study was conducted according to STROBE guidelines13. This was a prospective study conducted at the Norfolk and Norwich University Hospital (NNUH). All participants were managed in an outpatient setting between March and June 2021.

All patients waiting for longer than 1 year for varicose veins procedures were identified from the waiting list database and were contacted as part of clinical governance to determine if they had come to harm. These patients were included on the waiting list after being deemed to meet the criteria for treatment as per the NICE Guidelines1. After their clinic review, patients are prescribed Class II compression stockings, if there are no contra-indications, until they have their varicose vein procedures. No venotonic drugs were prescribed. Patients were also invited to participate in this study (via telephone), and complete telephone and postal questionnaires. Verbal consent and completion of questionnaires was deemed adequate informed consent. The study was registered with the local NNUH institutional audit department – to ensure all data collection was in line with local committee ethical standards and after review by local R&D department the study was deemed exempt from ethical approval owing to the minimal risk and nonidentifiable nature of the study. Patients were de-identified and analysed anonymously. Once verbal informed consent has been obtained, they were sent QoL questionnaires and had a telephone consultation. Both generic (EQ-VAS and EQ-5D) and disease-specific (AVVQ and CIVIQ-14) instruments were utilised (See Appendix 1). The telephone interview was used to assess for any clinical progression of their symptoms and the level of harm (low/major/psychological) experienced while on the waiting list. Data collection on each patient included age, gender, symptomatology, CEAP classification, delay of intervention (days), proposed planned procedure, changes in symptoms, psychological impact, and level harm. Furthermore, complications specific to bleeding, new ulceration, and phlebitis was also collected.

All patients were contacted by the same research nurse (MB) to minimise risk of bias. Study size was dependent on the number of patients on the waiting list.

*Statistical analysis:*

All data were analysed to determine distribution of data with parametric and non-parametric statistical tests carried out accordingly. The tests included calculation of means (with standard deviation), median (with interquartile range) and Pearson’s Chi-squared for examining proportions. Analysis and diagrammatic representations were undertaken using Microsoft® Excel for Mac (Version 16.53) (Redmond, Washington, USA) and Stata for Mac (College Station, Texas, USA).

Results

In total, 275 patients were identified and provided informed consent. One patient passed away while on the waiting list. One patient was waiting for foam sclerotherapy, while all the others were on the list for endovenous thermal ablation with radiofrequency (RFA) (first line treatment according to the NICE Guidelines). The mean age was 57.2 (standard deviation, SD: ±16) years and 62.9% of the sample were females. The median time on the waiting list was 60 weeks (interquartile range [IQR]: 56 to 65 weeks) and the majority of patients (91.7%) were classified as CEAP Clinical class C2-C4 (see Table 1). The C6 patients were not prioritised as they were deemed too high risk to attend during the COVID-19 pandemic.

All patients had a telephone interview while 104 patients returned their QoL questionnaires (37.8% response rate). A little over a third of patients (36.5%) felt that their symptoms had worsened since they have been added to the waiting list (Figure 1). Fifty-two patients (18.9%) suffered minor harm with worsening symptoms of pain and leg swelling, while 20 patients (7.2%) suffered what was considered to be major harm with phlebitis (3.6%), bleeding (1.8%) and ulceration (1.8%). Nineteen patients (6.9%) also experienced psychological harm as reported by the patient (Figure 2). Further analysis was undertaken to determine whether initial CEAP stage was associated with an increased risk of adverse events. Table 2 shows that with rising CEAP stage, increasing proportions of patients developed harm (3.8% of those with CEAP stage C2-4 disease compared to 60% for those with C5-6 disease; Pearson’s Chi-square, *X*2=49.0; p<0.0001).

Generic QoL was also affected with a median EQ-VAS of 75 (IQR: 58 – 81) and EQ-5D of 0.674 (IQR: 0.566 – 0.761) (Figure 3). In addition, the median disease-specific QoL scores were AVVQ 24 (IQR: 15 – 31) and CIVIQ-14 33 (IQR: 23 – 44) (Figure 3).

On direct questioning, 91.3% of patients stated that they would have been happy to attend hospital to undergo their varicose veins treatment during the Covid-19 pandemic.

Discussion

This study demonstrates the impact of delaying VVs surgery, particularly in the context of a pandemic. Along with showing worsening of patients’ symptoms, a significant number also developed major clinical and psychological harm. Predictably, worsening levels of harm were also observed with rising baseline CEAP classification, typically with patients with C5-6 disease having worse outcomes with recurrent ulceration. The implication, therefore, is that varicose veins are not a completely benign condition after all with waiting for intervention having a detrimental impact on the morbidity and QoL of patients. This state of affairs has been documented previously with Oudhoff et al. (2007) demonstrating that patients on waiting lists suffered from decreased health as well as an impaired psychological and social life14.

Progression of vein disease is a recognised phenomenon with progression of venous reflux found in nearly a third of patients following a median follow-up of 19 months15 which would fit with the observations in this study. In the long-term follow-up for the Edinburgh Vein Study, progression of venous disease was noted in 57.4% of patients after a mean follow-up period of 13 years (rate of progression: 4.3% per year) and approximately 1 in 3 of those with only varicose veins developed chronic venous insufficiency (CVI)16. In our study, we found that the progression for more advanced disease was more significant with 60% of those in stage C5-6 disease developing harm after a median waiting time of greater than 1 year.

When GIRFT and VSGBI released the recommendations regarding resumption of vascular services following the COVID-19 pandemic, the intention was not to pit different vascular conditions against each other, but rather rightly to treat the more urgent and potentially life- and limb-threatening conditions first to reduce morbidity and mortality. As the number of active COVID-19 cases were decreasing and some of the COVID-19 restrictions were being eased, more vascular procedures were being carried out. However, it became increasingly evident that some patients with venous diseases (e.g., those with bleeding/ulcerations) were being overlooked. Hence, in the VSGBI’s 4th Edition of the Provision of Vascular Surgery (2021), patients with venous bleeding or ulcerations have been elevated to the “Expedited Pathway” (time-critical outpatient pathway) for an intervention within days so as to prevent any further deterioration17. Only time will tell what effect these changes will have on the management of these venous complications, especially as the waiting list of patients on the National Health Service reached 6 million in November 202118. The reasons for the long waiting lists are often multifactorial with organisational and staffing levels often to blame. Hence, tackling these would require a combination of increases in resources available (human/infrastructure) as well as more efficient surgical pathways.

This study highlights the importance of finding effective solutions for managing patients with VVs whenever an embargo is implemented on elective procedures with low priority. Such solutions can include conducting telephone consultation follow up with patients to emphasise the importance of conservative measures including compression stockings. Such reassessments can also help identify patients who are coming to harm and prioritise them for interventions. This could include patients with more advanced clinical presentation (i.e., C5-6 disease) who have already been identified as being more likely to develop harm. During such circumstances, office-based procedures under local anaesthesia and outside operating rooms may be appropriate, such as treating incompetent truncal veins only and utilisation of foam sclerotherapy for residual veins, thus avoiding the need for stripping or multiple phlebectomies which often require general anaesthesia and the associated resources required to achieve that. Additionally undertaking multiple staged procedures such as a single leg at a time, can maintain a high proportion of procedures under local anaesthesia. Future research is required to examine these recommendations.

Despite the situation with the COVID-19 pandemic, it was rather surprising to find that more than 90% of the patients interviewed were willing to attend for their surgery should they have been on offer during that time. It could be deemed a missed opportunity to address the waiting list for this group of patients, but with an ever-evolving picture during the pandemic with unpredictable infection rates and staff/resource availability, it could be argued that this would have achieved very little, with cancellations/rescheduled procedures becoming the norm rather than the exception.

*Limitations*

One of the main weaknesses of this study is the absence of baseline QoL scores from the time the patients were reviewed in clinic and added onto the waiting list. This is especially important as it would help determine the degree and rate of deterioration while waiting for the varicose vein procedures. Unfortunately, this is not common practice and, therefore, patients were not provided with these questionnaires.

Moreover, the nature of the assessment tools used with self-completed QoL questionnaires and telephone interviews on their own poses a different type of problem. Indeed, the study would have benefitted from the addition of a clinical score (e.g., the Venous Clinical Severity Score, VCSS), which would have offered a more objective element to the evaluation done and would likely have strengthened the findings of the study. A degree of recall bias may also be present with patients having an altered recollection of the intensity and severity of their symptoms. Another limitation of the study is the modest response rate of around 38%. This could have introduced a response bias whereby patients suffering harm would be more agreeable to take part of the study. In addition, the absence of a control group prevents the comparison of our cohort to other patients waiting a long time for their procedures.

It is also likely that some of the psychological harm effects noted are secondary to the Covid-19 pandemic and its societal implications rather than purely the effect of being on the waiting list for varicose veins treatment19.

Conclusion

This study demonstrates the negative effect of waiting on patients with varicose veins and the need to identify patients most at risk of coming to harm so that any potential detriment is addressed urgently. This study has led the department to update the hospital advice leaflet with key signs of deterioration (bleeding, ulceration, phlebitis) and contact details should these occur in order to expedite treatment where required.

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**Guarantor:** Mr Wissam Al-Jundi

**Contributorship:**

* Conception and design of study: RB, MB, MMC, PWS, WAJ
* Data collection: MB
* Data analysis and interpretation: RB, MB, PWS
* Drafting and revision of manuscript: RB, MMC, PWS, WAJ
* Reading and final approval of manuscript: RB, MB, MMC, PWS, WAJ

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Table 1. Baseline patient characteristics. IQR: inter-quartile range; SD: standard deviation; (\* mean; § median)

|  |  |
| --- | --- |
|  |  |
| Males (%) | 37.1 |
|  |  |
| Age (years)\* (SD) | 57.2 (16) |
|  |  |
| Clinical CEAP Class (%) | C2S | 25.0 |
| C3 | 43.8 |
| C4 | 22.9 |
| C5 | 6.3 |
| C6 | 2.1 |
|  |  |  |
| Time on waiting list (weeks)§ (IQR) | 60 (56 to 65) |

Table 2. Development of harm with baseline CEAP classification. Higher proportion of patients develop harm with rising CEAP classification (Pearson’s Chi-square, *X*2=49.0; p<0.0001).

|  |  |  |  |
| --- | --- | --- | --- |
| CEAP Classification | Harm | No Harm | Total |
| C2S-4 | 5 | 126 | 131 |
| C5-6 | 9 | 6 | 15 |
| Total | 14 | 132 | 146 |

Figure 1. Change in patients’ symptoms since added to the waiting list

Figure 2. Harm experienced by patients since added to the waiting list

Harm

Major Harm

7.2%

(n=20)

Minor Harm

18.9%

(n=52)

Psychological Harm

6.9%

(n=19)

Phlebitis: 3.6%

Bleeding: 1.8%

Ulceration: 1.8%

Worsening Pain: 12.7%

Leg swelling: 6.2%

Figure 3. Generic quality of life of patients on the waiting list. (a) EQ-VAS (b) EQ-5D

 

(b)

(a)

Figure 4. Disease-specific quality of life for patients on the waiting list. (a) Aberdeen Varicose Veins Questionnaire (AVVQ) (b) Chronic Lower Limb Venous Insufficiency Questionnaire (CIVIQ-14)

 

(b)

(a)