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Reducing the risk of venous thromboembolism following superficial endovenous treatment: a UK and Republic of Ireland consensus study

Short title

Managing venous thromboembolism risk following superficial endovenous treatment

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Key words

Deep vein thrombosis, Varicose veins, Venous thromboembolism, VTE management

Abstract

Objectives

Venous thromboembolism (VTE) is a potentially fatal complication of superficial endovenous treatment. Proper risk assessment and thromboprophylaxis could mitigate this hazard, however there are currently no evidence-based or consensus guidelines. This study surveyed UK and Republic of Ireland vascular consultants to determine areas of consensus.

Methods

A 32-item survey was sent to vascular consultants via the Vascular and Endovascular Research Network (VERN) (phase-1). These results generated 10 consensus statements which were redistributed (phase-2). ‘Good’ and ‘very good’ consensus were defined as endorsement/rejection of statements by >67% and >85% of respondents, respectively.

Results

Forty-two consultants completed phase-1. This generated 7 statements regarding risk factors mandating peri-procedural pharmacoprophylaxis and 3 statements regarding specific pharmacoprophylaxis regimes. Forty-seven consultants completed phase-2. Regarding VTE risk factors mandating pharmacoprophylaxis, ‘good’ and 'very good' consensus was achieved for 5/7 and 2/7 statements respectively. Regarding specific regimens, ‘very good’ consensus was achieved for 3/3 statements.

Conclusions

The main findings from this study were that there was ‘good’ or 'very good' consensus that patients with any of the 7 surveyed risk factors should be given pharmacoprophylaxis with low-molecular-weight-heparin. High-risk patients should receive 1-2 weeks of pharmacoprophylaxis rather than a single-dose.

Introduction

Endovenous thermal ablative procedures are first line for the management of superficial venous incompetence (SVI) of the lower limb. Supported by The National Institute for Health and Care Excellence Guideline (NICE CG167) recommendations (1), endothermal techniques have become the most common method for treating truncal SVI (2). There is general consensus that endovenous procedures confer a significant peri-procedural benefit when compared with open surgical treatment in terms of reduced morbidity and enhanced recovery (3–5).

Like all varicose vein treatments, endovenous interventions for SVI are not without complications, one of the most important being the development of venous thromboembolism (VTE). VTE after superficial endovenous treatment most commonly occurs as a deep venous thrombosis (DVT) however, rarely VTE can manifest as a pulmonary embolism (PE), which may prove fatal. Such cases have attracted media coverage (6) and may have significant medico-legal implications for clinicians (7). Rates of DVT following endothermal ablation have been reported to be as high as 16% (8), however the 2 largest studies in this area suggest the true incidence lies between 0.5% and 3.2% (9,10). VTE risk assessment and targeted administration of pharmacoprophylaxis could mitigate this complication when patients have additional risk factors for VTE. At present there is an absence of evidence-based or consensus guidelines to inform clinicians in this area. The purpose of this study was to survey United Kingdom (UK) and Republic of Ireland (ROI) vascular surgeons about their practices regarding VTE risk stratification and subsequent pharmacoprophylaxis preferences during SVI interventions, with the aim of obtaining their consensus view.

Methods

A 2-phase survey was performed of UK and ROI consultant vascular surgeons between February 2017 and May 2019 via the Vascular and Endovascular Research Network (VERN), which is a vascular research collaborative consisting of vascular surgery trainees, vascular nurse specialists, vascular scientists and some vascular surgery consultants (11) with a proven track record for delivering multicentre research

(12–15). A modified Delphi consensus methodology was utilised (16). Surveys were created using the Google™ Forms platform and links to surveys were circulated to VERN members by email. Three follow-up emails per survey were sent as reminders. VERN members were asked to survey consultant vascular surgeons working in their own units, however consultants who were also VERN members were eligible to answer regarding their own practices. If multiple VERN members had surveyed the same consultant, only the first submitted response was used for that round of the survey. In situations where the surveyed consultant wished to remain anonymous, only the unit name was recorded. Responses relating to consultants from outside the UK and ROI were excluded from analysis. Collaborative authorship was offered to individuals completing the survey in accordance with ICMJE authorship guidelines (17).

The 1st phase consisted of a 32-item survey (see supplementary material) asking consultants about the relative significance (Likert scale) of various possible VTE risk factors when considering a patient for endovenous treatment, and which risk factors would prompt them to prescribe VTE pharmacoprophylaxis (‘yes/no’ response). Risk factors chosen for inclusion in the 1st phase represented some risk factors from established VTE risk assessment tools such as the Caprini risk assessment model (18), but were largely based on risk factors felt to be most important, by the authors of the study, to patients undergoing superficial endovenous treatment. A 10-point Likert scale was used to grade the significance of each risk factor. There were further questions in phase 1 relating to which specific thromboprophylaxis regimes were preferred when indicated (multiple choice responses).

The responses from the 1st phase questions were displayed graphically using histogram analysis and any questions with a significant skewness in the responses were taken forward to phase 2 to create consensus statements.

The 2nd phase consisted of 10 statements (see Figure 3) where each statement could only be answered by a ‘yes’ or ‘no’ response. The responses to these 10 statements were then analysed to find areas of consensus. ‘Good’ and ‘very good’ consensus were defined *a priori* as acceptance or rejection by >67% and >85% of the respondents, respectively. A >67% acceptance or rejection rate was chosen to

represent a ‘good’ consensus based on a previous similar survey relating to deep venous interventions (19). A further classification of ‘very good’ consensus (>85%) was defined in this study to identify areas of particularly high agreement amongst consultants.

All data analyses were performed using SPSS (version 22, IBM®) and Excel (version 2011, Microsoft®).

Results

Phase 1

The 1st phase received a total of 45 consultant responses. After removal of duplicate (n=3) responses (where multiple VERN members had surveyed the same consultant or where the consultant had additionally responded to the survey themself) there were 42 unique and valid consultant responses available for analysis. For phase 1, each VERN member surveyed a median of 1 consultant (range 1 to 5 consultants).

Consultants perceived a personal history of VTE, an inherited thrombophilia and reduced mobility / impaired calf muscle pump function as the 3 most significant risk factors for VTE when performing superficial endovenous treatment (Table 1).

Similarly, the three most common risk factors prompting consultants to prescribe pharmacoprophylaxis during superficial endovenous treatment were a personal history of VTE, an inherited thrombophilia and reduced mobility / impaired calf muscle pump function (Table 2).

The preferred thromboprophylaxis regimens amongst consultants were a single peri-operative dose of low molecular weight heparin (LMWH) when treating patients deemed to be at ‘moderate’ risk for VTE development (Figure 1), and 5 to 7 days of LMWH when treating patients deemed to at ‘high’ risk for VTE development (Figure 2).

Phase 2

Following histogram analysis of the responses from the first phase of the survey, ten 'yes/no' statements were created with the aim of establishing consensus on when and how best to administer pharmacoprophylaxis for patients undergoing superficial endovenous treatment. Seven of these statements related to specific risk factors for VTE and 3 of these statements related to specific pharmacoprophylaxis regimens (Figure 3).

The 2nd phase received a total of 58 responses. After removal of duplicate responses (n=8) and responses from non-UK or Ireland consultants (n=3), there were 47 unique and valid consultant responses available for analysis. For phase 2, each VERN member surveyed a median of 1 consultant (range 1 to 5 consultants).

The consultant responses to each of the 10 consensus statements are shown in Figure 4. 'Good' consensus (>67% consensus amongst consultants) was achieved for 5 statements relating to VTE risk factors. 'Very good' consensus (>85% consensus amongst consultants) was achieved for the remaining 2 out 7 statements (statements 5 and 7) relating to VTE risk factors and for all 3 statements relating to pharmacoprophylaxis regimens (statements 8 to 10).

Discussion

VTE following superficial endovenous treatment is relatively rare and these therapies, usually performed as a day case procedure, are considered to be low risk. As a result, clinicians may face significant scrutiny in the unfortunate circumstance that a VTE event does occur, particularly if VTE risk assessment was not performed, if the patient had not been adequately counseled and consented in relation to VTE, if appropriate thromboprophylaxis was not given and/or if the VTE was associated with significant morbidity or mortality. Most patients in the UK and ROI routinely receive compression garments following SVI intervention (20), with variable duration (21), as part of a treatment package to enhance treatment success and patient reported outcome measures (22). Pharmacological VTE prophylaxis here would be additional to any benefit conferred by the compression hosiery.

The decision about whether patients undergoing superficial endovenous treatment should receive pharmacoprophylaxis against VTE is frequently based on individual clinician opinion due to an absence of evidence-based or consensus guidelines (7,23). The aim of this study was to investigate these opinions by surveying UK and ROI consultant vascular surgeons and to determine areas of consensus practice. The main findings from this study were that there was 'good' or 'very good' consensus that patients with any of the 7 risk factors surveyed (BMI >30 kg/m^2, impaired mobility / reduced calf muscle pump function, on HRT / hormonal contraception, a personal / family history of VTE or an inherited thrombophilia) should be given pharmacoprophylaxis. For 2 of the risk factors (a personal history of VTE or an inherited thrombophilia) there was nearly universal agreement that these patients should receive pharmacoprophylaxis when undergoing superficial endovenous treatment. When asked about how pharmacoprophylaxis should be delivered, there was 'very good' consensus amongst consultants that LMWH should be used. In addition, most consultants (>85%) felt that a single-dose of LMWH was sufficient for patients deemed to be at moderate risk of VTE, however patients deemed to be at 'high-risk' should receive a longer course (between 1 - 2 weeks of LMWH).

The issue of how to stratify patients undergoing superficial endovenous treatment who might be at increased risk for VTE has long been a problem. Traditional risk assessment tools such as those developed by Caprini (18) or the UK Department of Health (24) are potentially less appropriate for patients undergoing ambulatory endovenous procedures since most of the risk factors in these models are only applicable to patients undergoing major surgical intervention. Further research is needed to develop specific risk prediction tools for patients undergoing ambulatory endovenous procedures, however such studies will require large numbers of patients given the relatively low absolute incidence of VTE in this patient cohort. The responses from this study (both phases taken together) indicate agreement, at least amongst the UK and ROI surgeons studied, that a personal history of VTE, an inherited thrombophilia (and probably also reduced mobility / impaired calf muscle pump function) are regarded as the risk factors putting patients at the highest risk. Whether such factors could or should be used to stratify the duration of pharmacoprophylaxis treatment in this patient population clearly requires further

investigation since the current study only tested strength of agreement amongst surveyed consultants.

The consensus regarding VTE pharmacoprophylaxis shown in this study provides clinicians with a steer as to what a body of UK and ROI consultant colleagues consider to be reasonable practice. However this study was not a trial of different methods of assessment nor did it study the effectiveness of one regime of pharmacological thromboprophylaxis over another.

It is expected that clinicians inform patients of any serious risks related to a procedure, of guidelines on treatment choices and if a recommended treatment differs from what is specified in guidelines then clinicians must explain their rationale for not following the guideline (25). Practicing in accordance with consensus opinion used to afford clinicians a certain level of medico-legal protection should complications occur (26). However, since the landmark UK Supreme Court ruling in the case of Montogomery versus Lanarkshire Health Board the medico-legal position has shifted (27). It is no longer acceptable for clinicians to unilaterally decide what risks would be relevant to an individual patient. Instead it is now the duty of clinicians to inform patients undergoing a treatment of all relevant material risks attached to that treatment (25,27).

There are a number of limitations to this study. Firstly, by surveying only the consultant grade there was a reasonable assumption that all respondents were competent and experienced at performing superficial endovenous treatments. However it is unreasonable to assume that these same clinicians also represent experts in the time-course, pathophysiology and effective management of VTE. This limitation may account for the finding in phase 1 that the preferred pharmacoprophylaxis regime amongst responding consultants was a single peri-operative dose of LMWH when treating patients deemed to be at ‘moderate’ risk for VTE. The median time-course for VTE presentation is 11 days post-operatively (9), with the majority occurring within 30 days post-operatively (28). A single peri-operative LMWH dose therefore represents ineffective prophylaxis and cannot be justified. The practice probably reflects learned historic vascular practice that was originally promoted as a medico-legal defensive aid rather than providing any benefit

for the patient in terms of VTE prophylaxis. Secondly, we only surveyed consultant vascular surgeons and did not survey the few consultants from other specialties who also perform these procedures such as consultant interventional radiologists. Thirdly, it is important to state that strength of agreement reported in this study does not relate to degree of VTE risk and, furthermore, this survey asked respondents regarding the relevance of individual risk factors and not risk factors in combination. Fourthly, this study only examined the risk factors felt to be most relevant (by the authors) to patients undergoing superficial endovenous surgery. Various other risk factors for VTE exist, such as a history of inflammatory bowel disease, congestive cardiac failure, chronic obstructive pulmonary disease or recent stroke, which were not examined in this study but may be important in a small minority of patients undergoing these procedures. Clinicians performing these procedures should be vigilant about taking a thorough medical history during the initial consultation aiming to elicit any and all such risk factors for VTE so as to best gauge the individual patient's VTE risk. Finally, we used members of the VERN research collaborative to approach consultants working in their units. Since most VERN members were trainee vascular surgeons, it was not possible to ensure the same consultants were surveyed during each phase of the study since trainees tended to move from one unit to another as they progressed through their training. In addition consultants performing superficial venous treatments exclusively in non-teaching hospitals or the private sector (where VERN members are unlikely to be based) were unlikely to be represented in this study.

Despite these limitations, endovenous treatments for SVI are increasing (29,30) and therefore the results from this study, which surveyed consultants from across the UK and ROI (see acknowledgements for geographical locations), remain important since they inform on the current state of pharmacological thromboprophylaxis practices for superficial endovenous treatments in the UK and ROI.

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Tables & Figures

Table 1. Consultant perceptions on the relative significance of various risk factors for VTE during superficial endovenous surgery. Data shown as median value and interquartile range (IQR), where 1 represents 'very low risk' and 10 represents 'very high risk'. BMI, body mass index; HRT, hormone replacement therapy; VTE, venous thromboembolism.

Risk factor	Median (IQR) perceived significance value
Age >75 years	6 (3.25 - 7)
Age 61 - 74 years	5 (3 - 6)
BMI >30 kg/m^2	7 (5 - 8)
Procedure duration >1hour	6 (5 - 7)
Reduced mobility / impaired calf muscle pump function	8 (6 - 9)
Current smoking	6 (4 - 7)
Use of HRT	7 (5.25 - 8)
Use of hormonal contraception	7 (6 - 8)
Personal history of VTE	9 (8 - 10)
Family history of VTE	7 (6 - 8)
Long haul flight (>3 hours) within 4 weeks of procedure	6 (3.25 - 7)
Past history of malignancy	7 (6 - 8)
Inherited thrombophilia	9 (7.25 - 10)
Moderate / Major surgery within last 12 weeks	7 (5 - 8)

Table 2. Consultant opinions on which risk factors for VTE would prompt pharmacoprophylaxis prescribing during superficial endovenous surgery. BMI, body mass index; HRT, hormone replacement therapy, VTE, venous thromboembolism.

Risk factor	Number (%) of consultants stating risk factor would prompt VTE pharmacoprophylaxis prescribing
Age >75 years	21 (50.0)
Age 61 - 74 years	19 (45.2)
BMI >30 kg/m^2	27 (64.3)
Procedure duration >1hour	24 (57.1)
Reduced mobility / impaired calf muscle pump function	35 (83.3)
Current smoking	17 (40.5)
Use of HRT	31 (73.8)
Use of hormonal contraception	33 (78.6)
Personal history of VTE	42 (100)
Family history of VTE	28 (66.7)
Long haul flight (>3 hours) within 4 weeks of procedure	26 (61.9)
Past history of malignancy	26 (61.9)
Inherited thrombophilia	37 (88.1)
Moderate / Major surgery within last 12 weeks	26 (61.9)

Figure 1. Preferred thromboprophylaxis regimens amongst consultants when performing superficial endovenous surgery on a patient deemed to be at 'moderate' risk of VTE. LMWH, low molecular weight heparin.

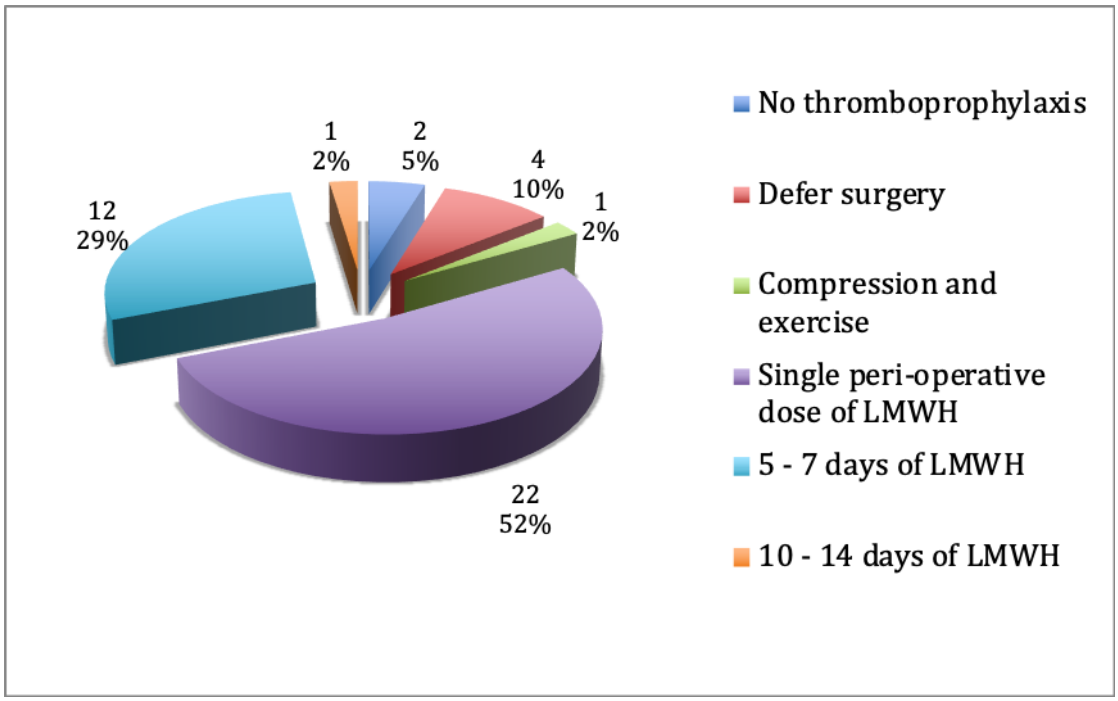

Figure 2. Preferred thromboprophylaxis regimens amongst consultants when performing superficial endovenous surgery on a patient deemed to be at 'high' risk of VTE. DOAC, direct oral anticoagulant; LMWH, low molecular weight heparin.

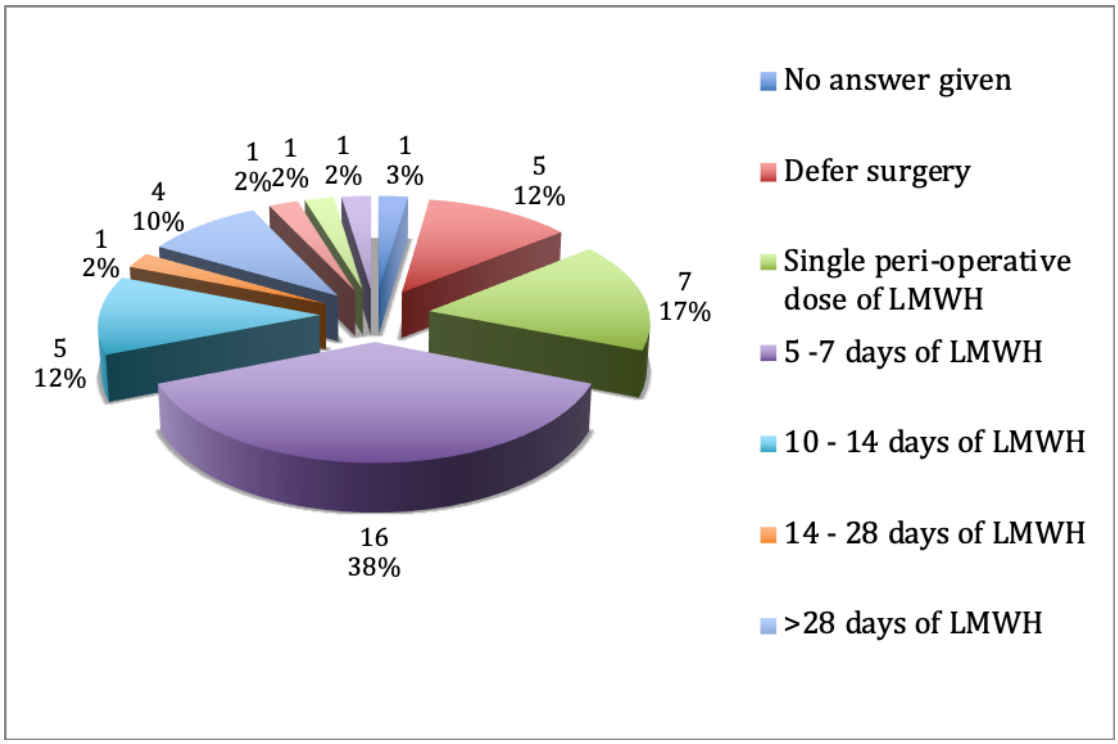

Figure 3. Ten consensus statements used for phase 2. LMWH, low molecular weight heparin; VTE, venous thromboembolism.

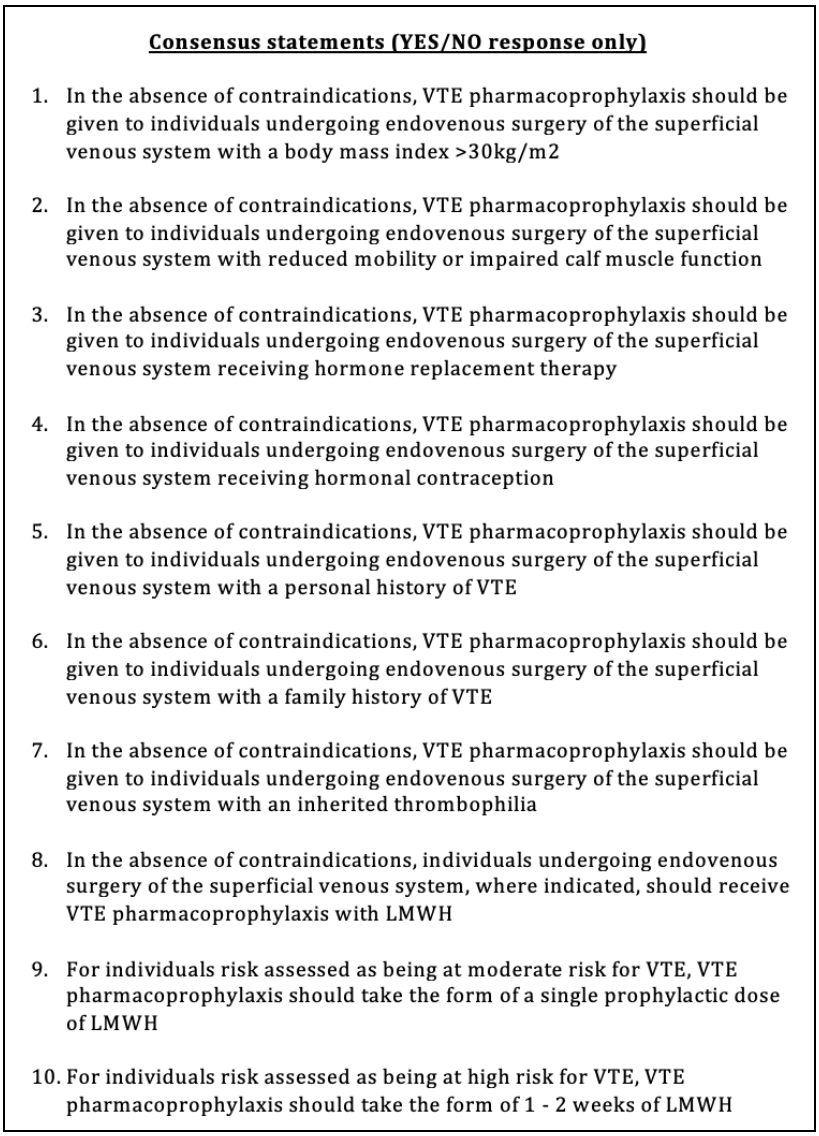

Figure 4. Consultant 'yes/no' responses to 10 consensus statements defined in Figure 3.