Journal of Thrombosis and Haemostasis, **9**: 1931–1936 DOI: 10.1111/j.1538-7836.2011.04468.x

ORIGINAL ARTICLE

Long-term quality of life after pregnancy-related deep vein thrombosis and the influence of socioeconomic factors and comorbidity

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To cite this article: Wik HS, Enden TR, Jacobsen AF, Sandset PM. Long-term quality of life after pregnancy-related deep vein thrombosis and the influence of socioeconomic factors and comorbidity. *J Thromb Haemost* 2011; **9**: 1931–6.

Summary. *Background:* Little is known about the long-term impact of pregnancy-related deep vein thrombosis (DVT) of the lower limbs. *Objectives:* To evaluate the long-term consequences of pregnancy-related DVT by assessment of self-reported, disease-specific quality of life (QOL) and symptom severity using the Venous Insufficiency Epidemiological and Economic Study (VEINES)-QOL/Sym questionnaire, and to investigate the influence of socioeconomic factors and comorbidity. *Patients/Methods:* In this cross-sectional case–control study, 313 women with validated pregnancy-related DVT and 353 controls completed a comprehensive questionnaire, including the disease-specific VEINES-QOL/Sym questionnaire. After exclusion of DVT outside the lower limbs and missing scores, the study population comprised 208 patients and 347 controls. A VEINES-QOL/Sym score < the 25th percentile was defined as a clinically relevant reduced outcome compared with scores ≥ the 50th percentile. Predictors for low scores were identified in multivariate logistic regression models. *Results:* Cases reported lower mean VEINES-QOL/Sym scores than controls, 45.6/45.4 vs. 52.8/52.7, respectively ($P < 0.001$), and QOL among cases was still reduced compared with controls when adjusted for possible confounders. Low education was an independent predictor for both low VEINES-QOL and VEINES-Sym scores, and in addition being married/cohabitating predicted low VEINES-Sym scores. *Conclusions:* Long-term QOL and symptom scores as assessed with the VEINES-QOL/Sym questionnaire were lower in women with previous pregnancy-related DVT than in controls, and also when adjusted for possible confounders. By logistic regression, low education was an independent predictor for low scores. This supports the use of the VEINES-QOL/Sym questionnaire in studies on pregnancy-related DVT.

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Received 6 June 2011, accepted 8 August 2011

Keywords: deep vein thrombosis, pregnancy, health outcomes, quality of life, socioeconomic status, women's health.

Introduction

Pregnancy-related venous thrombosis (VT) affects young and otherwise healthy women in a vital phase of life. However, little or nothing is known about its long-term consequences for functioning and daily life issues in such women [1]. Patient-reported outcome measures are recognized as important in epidemiology, and a range of standardized instruments assessing health-related quality of life (QOL) have been developed for use in different populations. Five instruments designed to measure QOL in patients with chronic venous disease have been used in patients with previous VT [2,3]. The Venous Insufficiency Epidemiological and Economic Study (VEINES)-QOL/Sym questionnaire, which was originally developed '... for a practical and scientifically rigorous, patient-reported outcome measure to evaluate QOL and symptoms across the range of conditions in chronic venous disorders of the leg' [4], is most frequently used. This questionnaire was modeled on the generic QOL instrument SF-36, and has undergone psychometric testing and validation with satisfying results [3–5]. The scores have been found to correlate with the clinical classification and symptom severity of chronic venous disease [6–9], but have so far not been reported in studies on patients with pregnancy-related deep vein thrombosis (DVT).

It is known that socioeconomic factors may influence QOL scores [10]. Little investigation of the impact of such factors on VEINES-QOL/Sym scores has been reported. We have previously shown that the presence of non-venous comorbidity that caused problems in the lower limbs was associated with reduced VEINES-QOL/Sym scores in patients with a history of DVT [5]. The present study aimed to provide further insight into disease-specific QOL and symptom severity as assessed by the VEINES-QOL/Sym questionnaire. This was achieved by

using the questionnaire in a cross-sectional case–control study of women with a history of pregnancy-related DVT of the lower limb and a reference population, while simultaneously investigating the influence of socioeconomic factors and comorbidity.

Materials and methods

Study population

Women who had a validated diagnosis of VT in pregnancy or in the first three postnatal months during 1990–2003 at 18 Norwegian hospitals, were identified through the Norwegian Patient Registry and the Medical Birth Registry of Norway. The selection of case subjects has been reported in detail elsewhere [11]. Controls matched for date of delivery were selected from the birth registry, and 559 cases and 1229 controls were eligible for participation [12]. After exclusion of unreachable persons, 531 cases and 1092 controls were invited to participate [13]. A total of 313 cases and 353 controls met to complete the questionnaire and to provide a blood sample. Ninety-nine cases with VT outside the lower limbs were excluded from the present analyses, including 74 cases with isolated pulmonary embolism and two with unknown location of DVT. Finally, six cases and six controls were excluded because of incomplete responses to the VEINES-QOL/Sym. The final study population in the present report comprised 208 cases and 347 controls.

The Regional Committee for Research Ethics and the Norwegian Data Inspectorate approved the study. Written informed consent was obtained from all participants. The study was registered at ClinicalTrials.gov with the unique identifier NCT 00856076.

Variables and instruments

A comprehensive questionnaire including a validated Norwegian version of the VEINES-QOL/Sym [5] was completed when the participants presented at the hospital for participation in the study. The study questionnaire obtained information on age, marital status, parity, education, employment status, household income, social welfare, height, weight, smoking, VT, exercise and comorbidity. The variables relevant for the present analyses were categorized as follows. Education was classified into four categories: completed high school or less, or 1–2 years, 3–5 years or 6 or more years after high school. Employment status was classified into four categories: working full time, 90–100%; working part time, 50–89%; working part time, 20%–49%; not working. The latter group comprised subjects working < 20%, students, unemployed, disabled, on maternity or sick leave, or undergoing rehabilitation. Household income was classified as < 300 000, 300 000–449 000, 450 000–599 000, 600 000–749 000 or ≥ 750 000 Norwegian kroner (NOK) (100 NOK = 12.8 Euros). Body mass index (BMI) was categorized using the World Health Organization classification (i.e. underweight, < 18.5 kg m^{-2}; normal range, 18.5–24.9 kg m^{-2}; preobese, 25.0–29.9 kg m^{-2}; obese, ≥ 30.0 kg m^{-2}). Smoking was registered as 'daily', 'sometimes', 'previous' or 'never smoker'. Some of the categories were merged for the analyses to avoid small groups (Table 1 and 4). Comorbidity was assessed as a yes/no response to 14 organ-specific diseases or symptoms during the previous 12 months.

The VEINES-QOL/Sym comprises 26 items regarding problems of the lower limbs, with item contents including response scales based on those of the SF-36 [4]. The instrument measures symptoms, limitations in daily activity and psychological impact during the previous 4 weeks. Two items cover the time of day of greatest intensity and change over the past year. Responses are rated on 2- to 7-point descriptive scales, and two summary scores are computed. The VEINES-QOL summary score assesses QOL, and the VEINES-Sym score measures symptom severity; higher scores represent better QOL and/or fewer symptoms. When dividing scores into quartiles, scores < the 25th percentile were defined as representing a clinically relevant reduced outcome, and scores ≥ the 50th percentile as representing subjects without a poor outcome with regard to QOL and symptoms.

Statistical analyses

Scores for the VEINES-QOL and VEINES-Sym were computed using standard scoring algorithms obtained from the authors [4]. Bivariate comparisons of categorical data were performed with a two-sided chi-square test, but in cases with < 5 expected observations per cell a Fisher's exact test was used. When comparing continuous variables between groups, a two-sample *t*-test was used if there was no obvious deviation from a normal distribution. Data were presented as mean with standard deviation (SD). The difference between cases and controls regarding QOL and symptom burden was adjusted for possible confounders using multivariate logistic regression with VEINES-QOL and VEINES-Sym scores < the 25th percentile compared with ≥ the 50th percentile being the dependent variable and DVT the main independent variable of interest. Possible predictors of VEINES-QOL and VEINES-Sym scores < the 25th percentile compared with ≥ the 50th percentile for cases with pregnancy-related deep vein thrombosis were identified using bivariate logistic regression. Socioeconomic factors and comorbidity associated with low scores, using a liberal level of significance of $P < 0.1$, were included in two multivariate logistic regression models, and age was included even if non-significant. Variables with fewer than 10 items per category were omitted, and backward variable selection was employed to construct the final models. Data were presented as crude or adjusted odds ratios (ORs) with 95% confidence intervals (CIs). *P* values < 0.05 were considered significant. Possible interactions in the models were tested at significance level $P < 0.05$. The assumptions of the logistic regression models were checked for each analysis, and found to be adequately met. The statistical analyses were performed using the statistical package SPSS, version 18.0 (SPSS Inc, Chicago, IL, USA).

Table 1 Demographic and socioeconomic characteristics of the study population

Variables	Categories	N	Cases, *n* (%)	N	Controls, *n* (%)	*P* value*
Age (years)	22–34	208	49 (23.6)	347	66 (19.0)	0.58
	35–39		54 (26.0)		103 (29.7)	
	40–44		62 (29.8)		105 (30.3)	
	45–59		43 (20.7)		73 (21.0)	
Marital status	Married/cohabitating	202	168 (83.2)	340	304 (89.4)	0.036
	Single		34 (16.8)		36 (10.6)	
Parity	1	207	37 (17.9)	343	68 (19.8)	0.83
	2		110 (53.1)		175 (51.0)	
	3–6		60 (29.0)		100 (29.2)	
Education	≤ High school	197	53 (26.9)	340	44 (12.9)	< 0.001
	High school + 1–5 years		114 (57.9)		187 (55.0)	
	High school + > 5 years		30 (15.2)		109 (32.1)	
Employment	Full time (≥ 90%)	208	84 (40.4)	347	192 (55.3)	0.001
	Not working full time		124 (59.6)		155 (44.7)	
Household income (NOK)	Low (< 450 000)	205	64 (31.2)	342	59 (17.3)	< 0.001
	Medium (450 000–749 000)		88 (42.9)		106 (31.0)	
	High (≥ 750 000)		53 (25.9)		177 (51.8)	
Personal judgment of economic situation	Very good	208	42 (20.2)	346	104 (30.1)	0.028
	Good		154 (74.0)		219 (63.3)	
	Poor		12 (5.8)		23 (6.6)	
Difficulties paying bills	Never	207	148 (71.5)	347	262 (75.5)	0.30
	Sometimes		59 (28.5)		85 (24.5)	
BMI (kg m^{-2})	< 25.0	203	102 (50.2)	342	235 (68.7)	< 0.001
	≥ 25.0		101 (49.8)		107 (31.3)	
Smoking	Daily/sometimes	201	49 (24.4)	338	63 (18.7)	0.091
	Previous		50 (24.9)		111 (32.8)	
	Never		102 (50.7)		164 (48.5)	
Physical exercise	Once a week or less	208	65 (31.3)	346	135 (39.0)	0.10
	2–3 times per week		112 (53.8)		175 (50.6)	
	Every day		31 (14.9)		36 (10.4)	

BMI, body mass index; NOK, Norwegian kroner. *Chi-square test.

Results

Of the 208 cases with lower limb DVT, 172 were proximal and 36 were distal. Nine patients had symptomatic concurrent pulmonary embolism. In 122 patients the DVT was antenatal and in 86 postnatal. Mean follow-up was 9.5 years (SD 4.2). The distribution of sociodemographic characteristics of the study participants is presented in Table 1. Marital status, education, employment, household income, personal judgment of economic situation and BMI differed significantly between the two study groups, while difficulties in paying bills was reported by one in four in both groups ($P = 0.3$). Comorbidities that were reported by at least 10 subjects in both study groups were hypertension, allergy, kidney/urinary problems, metabolic disease, skin disease, headache/migraine, psychiatric problems, constipation and musculoskeletal disease (data not shown). Only the last two conditions occurred more often among cases than controls ($P = 0.011$ and $P = 0.005$, respectively). The less frequently occurring diseases were equally distributed between the two study groups (i.e. cardiovascular, pulmonary and gastrointestinal problems, cancer and diabetes).

The mean VEINES-QOL/Sym scores were 45.6 (SD 12.4)/45.4 (SD 12.0) for cases and 52.8 (SD 7.0)/52.7 (SD 7.4) for controls. Cases scored significantly lower than controls for both scores ($P < 0.001$). The distribution of the VEINES-QOL/Sym scores with regard to < 25th, 25–49.9th and ≥ 50th percentiles differed between cases and controls ($P < 0.001$, Table 2), with more than 40% of cases scoring < the 25th percentile and more than 60% of controls scoring ≥ the 50th percentile for both scores.

Women with a history of pregnancy-related deep vein thrombosis had significantly higher probability for having VEINES-QOL/Sym scores < the 25th percentile compared with ≥ the 50th percentile than controls, and also when adjusted for possible confounders (Table 3).

Table 2 Distribution of percentiles of VEINES-QOL/Sym scores in the study population

Variables	Percentiles	Cases ($n = 208$) *n* (%)	Controls ($n = 347$) *n* (%)	*P* value*
VEINES-QOL	< 25.0th	88 (42.3)	48 (13.8)	< 0.001
	25–49.9th	59 (28.4)	80 (23.1)	
	≥ 50th	61 (29.3)	219 (63.1)	
VEINES-Sym	< 25.0th	93 (44.7)	46 (13.3)	< 0.001
	25–49.9th	51 (24.5)	87 (25.1)	
	≥ 50.0th	64 (30.8)	214 (61.7)	

*Chi-square test.

Table 3 Odds ratios for VEINES-QOL/Sym scores < the 25th percentile vs. ≥ the 50th percentile for cases as compared with controls

	OR	95% CI	aOR*	95% CI	*P* value†
VEINES-QOL	6.6	4.2–10.3	5.0	2.8–9.1	< 0.001
VEINES-Sym	6.8	4.3–10.6	5.9	3.2–10.8	< 0.001

OR, unadjusted odds ratio; aOR, adjusted odds ratio; CI, confidence interval. *Adjusted for age, marital status, education, employment, income, personal judgment of economic situation, body mass index, musculoskeletal symptoms and constipation. †Wald test.

Predictors for low VEINES-QOL scores

To identify predictors for low VEINES-QOL scores we used logistic regression analyses with scores < the 25th percentile compared with ≥ the 50th percentile as the dependent variable. The sociodemographic variables age and education were the only variables unevenly distributed in the bivariate analyses (Table 4). Comorbidity was very low across the percentiles of VEINES-QOL scores, except for allergy and headache/migraine, which were not more frequently associated with scores < the 25th percentile ($P = 0.66$ and $P = 0.13$, respectively, data not shown). In a multivariate logistic regression model, low education was the only independent predictor for VEINES-QOL scores < the 25th percentile (Table 5).

Predictors for low VEINES-Sym scores

The sociodemographic variables education ($P = 0.042$) and marital status ($P = 0.067$) were unevenly distributed by percentiles of VEINES-Sym scores (data not shown). Correspondingly to the VEINES-QOL scores, comorbidity was very low across the percentiles of VEINES-Sym except for allergy and headache/migraine. Allergy was not associated with having VEINES-Sym scores in the lowest quartile ($P = 0.62$), but headache/migraine was unevenly distributed ($P = 0.087$). Consistent with the results in the VEINES-QOL model, low education was an independent predictor for low VEINES-Sym scores. In addition, being married/cohabitating also independently predicted low scores (Table 5). No interaction was present in this model.

Table 5 Independent predictors of VEINES-QOL/Sym scores < the 25th percentile compared with ≥ the 50th percentile

Variable		aOR	95% CI	*P* value*
VEINES-QOL	Education ≤ high school	2.6	1.2–5.7	0.020
	(ref. > high school)	1	–	–
VEINES-Sym	Married/cohabitated	4.0†	1.4–11.8	0.010
	(ref. single)	1	–	–
	Education ≤ high school	3.2‡	1.4–7.7	0.007
	(ref. > high school)	1	–	–

aOR, adjusted odds ratio; CI, confidence interval; *Wald test. †Adjusted for education. ‡Adjusted for marital status.

Discussion

In this cross-sectional case–control study we found that women with pregnancy-related DVT of the lower limbs within the previous 3–16 years had a significantly higher probability than controls of lower QOL, as assessed by self-completion of the disease-specific VEINES-QOL/Sym questionnaire, even after correction for possible confounders. Low education was an independent predictor for VEINES-QOL and VEINES-Sym

Table 4 Demographic and socioeconomic characteristics of cases by percentiles of VEINES-QOL

			Percentiles of VEINES-QOL		
Variable	Categories	N	< 25.0th	≥ 50.0th	*P* value*
Age (years)	22–39	73	38 (52.1)	35 (47.9)	0.09
	40–59	76	50 (65.8)	26 (34.2)	
Parity	1–2	102	57 (55.9)	45 (44.1)	0.19
	≥ 3	46	31 (67.4)	15 (32.6)	
Education	≤ High school	41	30 (73.2)	11 (26.8)	0.02
	> High school	99	51 (51.5)	48 (48.5)	
Employment	Full time (≥ 90%)	51	27 (52.9)	24 (47.1)	0.27
	Not working full time	98	61 (62.2)	37 (37.8)	
Household income (NOK)	Low (< 450 000)	49	25 (51.0)	24 (49.0)	0.14
	High (≥ 450 000)	99	63 (63.6)	36 (36.4)	
Difficulties paying bills	Never	105	59 (56.2)	46 (43.8)	0.21
	Sometimes	43	29 (67.4)	14 (32.6)	
BMI (kg m^{-2})	< 25.0	70	40 (57.1)	30 (42.9)	0.75
	≥ 25.0	77	46 (59.7)	31 (40.3)	
Smoking	Daily/sometimes	35	23 (65.7)	12 (34.3)	0.29
	Previous/never	108	60 (55.6)	48 (44.4)	
Physical activity	Once a week or less	46	26 (56.5)	20 (43.5)	0.67
	More than once a week	103	62 (60.2)	41 (39.8)	

BMI, body mass index; NOK, Norwegian kroner. *Wald test.

scores < the 25th percentile as compared with ≥ the 50th percentile in this population, and being married/cohabitating was an independent predictor for low VEINES-Sym scores only.

Our study indicates that pregnancy-related DVT has a significant impact on future QOL, and to our knowledge this has not been previously investigated. This indicates the robustness of the questionnaire and supports the use of this instrument also in clinical studies on pregnancy-related DVT of the lower limbs.

It has previously been shown that the long-term consequences of DVT include reduced QOL relative to population norms [14], which is consistent with our findings. Studies on the VEINES-QOL/Sym instrument have not reported possible associations between scores and socioeconomic parameters, although our group has shown that comorbidity is associated with low scores [5]. Consistent with previous publications, both VEINES-QOL and VEINES-Sym scores yielded similar mean values, and it may be argued that using both scores does not give any additional information.

A number of recognized socioeconomic variables were included in the two models [15]. However, education not more than high-school was the only parameter to independently predict low scores for both VEINES-QOL and VEINES-Sym. The association between low education and reduced VEINES-QOL/Sym scores has not previously been reported, but the association is reported in several other QOL measures [16,17]. The association between high symptom burden assessed with VEINES-Sym and marriage/cohabitation is not obvious, but the association between marriage and low QOL has been reported by others [18].

It has been suggested that, based on the 'model' questionnaire SF-36, a difference of five points in VEINES-QOL/Sym scores represents a clinically relevant difference [3]. Using this criterion, our findings show a significant impact on QOL following pregnancy-related DVT, and suggest that these women may benefit from improved health care. However, this cut-off is at least partly arbitrary and has limited documentation (i.e. the minimum important difference for the VEINES-QOL/Sym scores is not established). Hence, for the multivariate regression analyses we assumed that scores < the 25th percentile represented clinically relevant reduction compared with scores ≥ the 50th percentile. We left out women with scores ≥ the 25th but < the 50th percentiles from the analyses to make the differences between low and high QOL and symptom burden more pronounced.

All eligible women in the birth registry with a validated DVT diagnosis were invited to participate, but as a substantial number declined, the study population may not be representative. Our group has previously shown that the participating controls were slightly older and of lower parity at the time of the index pregnancy compared with the cases. However, as age was not associated with pregnancy-related VT, the selection of slightly older controls was not considered a major bias [12,13]. In this study, the mean time of follow-up since the pregnancy-related DVT was 9.5 years, and the results are therefore likely to represent a stable phase related to QOL and symptoms after VT. Considering the inherent limitations of a retrospective design, longitudinal assessment of the population would probably have added significant insight into the long-term effects of DVT in this patient group. However, the use of a healthy reference population enabled comparison with an assumed 'baseline'. Another limitation is that the present study is essentially based on information from a self-completed questionnaire, the VEINES-QOL/Sym. This questionnaire is modeled on the SF-36, which assesses generic health-related QOL, and because previous studies have used both questionnaires [4,8], the use of both in the present study may have enabled better comparisons between our results and previous reports. To our knowledge, the VEINES-QOL/Sym questionnaire has not previously been tested in healthy controls, and an SF-36 score would have added valuable information to the VEINES-QOL/Sym scores in the control group. Finally, socioeconomic status is recognized in health research as problematic to measure [15].

Future research in this patient group with pregnancy-related DVT of the lower limb would benefit from cohort studies with long-term follow-up to identify important risk factors and predictors for long-term outcomes, including recurrent DVT and subsequent pregnancies, and the important long-term sequelae of DVT such as development of post-thrombotic syndrome, as this may contribute to a reduction in QOL [6,9]. To our knowledge, this has not been investigated in pregnancy-related thrombosis.

In conclusion, long-term QOL and symptom scores assessed with the disease-specific VEINES-QOL/Sym questionnaire were lower in patients with previous pregnancy-related DVT compared with controls, and also when adjusted for possible confounders. In logistic regression models, education not more than high school was an independent predictor for low scores and marriage/cohabitation independently predicted more symptoms measured by the VEINES-Sym questionnaire. Our study supports the use of the VEINES-QOL/Sym in follow-up studies of pregnancy-related DVT, even though scores also seem to be influenced by education and marital status.

Addendum

H. S. Wik and T. R. Enden contributed equally to the work; both performed the analyses, interpreted the data and co-wrote the main draft of the manuscript. A. F. Jacobsen designed the original study, collected the data and critically reviewed the manuscript. P. M. Sandset designed the original study, interpreted the data and critically reviewed the manuscript.

Acknowledgements

Thanks to M. J. Skogstad for her excellent help in collecting the data, to A. K. Kvam for valuable scientific contributions regarding QOL, and to L. Sandvik, statistician, for important contribution to analysis and interpretation of the data. The study was financially supported by grants from the Southeastern

Health Authority Trust of Norway, the Norwegian Research Council Medicine (grant no 160805-V50), Oslo University Hospital, Ullevål, and the University of Oslo.

Disclosure of Conflict of Interests

The authors state that they have no conflict of interest.

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