

Quality of life after pulmonary embolism: the development of the PEmb-QoL questionnaire

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We are currently developing a disease-specific questionnaire to measure quality of life after pulmonary embolism (PE). The aim of this letter is to invite colleagues to cooperate on the validation of our questionnaire.

PE is a rather common disease, with an annual incidence of approximately 0.5 per 1000 persons in Western countries [1]. As PE shares many features with deep vein thrombosis (DVT), both diseases are considered to be different manifestations of the same entity: venous thromboembolism (VTE) [2]. PE and DVT share the same risk factors, such as thrombophilia, pregnancy, cancer, surgery, immobilization, and oral contraceptive use. Furthermore, both manifestations occur in venous blood and coincide frequently [3–5]. Accordingly, treatment recommendations are similar [2].

PE is a leading cause of mortality and morbidity: death occurs in about 15% of cases within 6 months of its presentation [6]. In addition, VTE often can be considered a chronic disorder: recurrence is common, with an incidence of approximately 30% within 10 years [7,8]. Moreover, residual complaints (known as post-thrombotic syndrome) are reported in 30% of patients with DVT within 2 years after the initial event, despite the use of compression stockings [9]. The most important long-term complication of PE is chronic pulmonary hypertension (which may manifest as fatigue, limited exercise tolerance or shortness of breath), which was shown to affect 3.8% of PE patients within 2 years following the initial event in one study [10].

Quality of life is conceptualized increasingly as the central outcome of health care. 'Perceived health, health-related quality of life, and health-state utilities bring health assessment progressively closer to the patient's perspective', is a conclusion in a paper by Sullivan on taking the patient's point of view regarding health care and health into account [11]. To illustrate the gained interest in quality of life, we performed a broad-brush search in Medline with the MeSH term 'quality of life'.

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This yielded 7143 articles published in 2007, compared with 4923 in 2002. Surprisingly, a more sophisticated search without any restriction yielded not a single publication on quality of life after PE (neither by a disease generic questionnaire, nor by a disease specific questionnaire). In contrast, quality of life following DVT has been the subject of investigation and several DVT-specific questionnaires have been developed over the past decade [12–16].

We aimed to develop a disease-specific questionnaire to assess quality of life after PE using the principles of grounded theory. We performed qualitative, semi-structured interviews in 10 outpatients (4 males/6 females) whom we selected for the gravity of their complaints following PE. These patients did not have other cardiopulmonary diseases that might have resembled PE-related complaints. Two investigators (LB and EN) visited the subjects at their homes and structured the interviews into social functioning, physical complaints and emotional disturbances. The interviews were tape-recorded with consent and transcribed later. Characteristics of the interviewed patients are listed in Table 1. The most remarkable complaints were shortness of breath/difficulty in breathing, fatigue, fear of recurrence after discontinuing anticoagulant treatment, more readily emotionally disturbed (which bothered a subgroup of the patients) and more social isolation than prior to the PE. The authors (of whom two are experienced clinicians with a specific interest in patients with VTE) remodeled the outcomes of the interviews into the draft questionnaire.

The original version was developed in Dutch. For the creation of the English version, the Dutch version was independently translated by two native English speakers and subsequently back-translated by a third native English speaker. The structure of the questionnaire, which we named PEmb-QoL (Pulmonary Embolism Quality of Life), was modeled in line with the existing generic SF-36 (short form 36) questionnaire and the disease-specific VEINES-QOL/Sym questionnaire, which has been developed for DVT. The PEmb-QoL currently contains 10 questions (40 items) covering six dimensions: frequency of complaints (eight items), activities of daily living (ADL) limitations (13 items), work-related problems (four items), social limitations (one item), intensity of complaints (two items) and emotional complaints (10 items). Two questions provide descriptive information. The PEmb-QoL is a self-administered questionnaire, in line with the SF-36 and Veines-QOL/Sym questionnaires.

Table 1 Characteristics of interviewed patients

	Gender, age (years), marital status	PE event	Main functional complaints	Main psychological complaints	Main social limitations
1	Female, 37, married	7 months prior to interview. Massive PE, resuscitated	Fatigue, muscle weakness	Anxiety; more readily emotional; fear of recurrent PE; worried about stopping anticoagulant treatment	Afraid of being a burden for relatives and friends, afraid of being alone
2	Male, 31, unknown	6 years prior to interview first PE; two recurrences (22 months and 7 months respectively)	Pain behind the shoulder blades, pain in the chest, tiredness, difficulty in breathing	Fear of recurrent PE, more readily emotional (experienced as annoying), depressed	Not able to work, limited in social contacts
3	Female, 84, widow	1 year ago PE	Fatigue, not able to exert herself	Depressed (at times)	Becomes easily weary after having a visit from friends /relatives
4	Female, 43, married	PE at 13 months and 5 months prior to the interview	Pain in the back and fatigue	Fear of recurrence, depressed feeling, more readily emotional	Avoids visits to friends and shopping in the center of the city, which is too exhausting
5	Female, 73, widow	PE 4 years prior to the interview	Breathlessness, sensation of pressure, fatigue	Fear of recurrence	More socially isolated, limited in taking a trip
6	Female, 32, single	PE 14 months prior to PE	Difficulty in breathing, pain at the back and between shoulder blades	Anxious about recurrence, worried about stopping anticoagulant treatment	No complaints
7	Male, 34, married	PE 4 months prior to interview	Difficulty in breathing, fatigue, shortness of breath, pain behind shoulder blades, chest pain	Fear of recurrence, more readily emotional (which bothers the patient)	Feeling of lack of attention to his children, not able to work, not able to have visitors too often (too exhausting)
8	Male, 63, married	PE 13 months prior to interview	Shortness of breath, tired, difficulty in breathing	Much more emotionally disturbed	Not able to perform as much as he intends
9	Female, 79, widow	First PE 7 years prior to interview, recurrent PE 6 years	Difficulty in climbing stairs and fatigue, shortness of breath	No typical complaints	No typical complaints
10	Male, 55, married	PE 18 months prior to interview	More easily tired, difficulty in breathing following exercise, chest pain	Afraid of a recurrent PE, worried about stopping anticoagulant treatment	Prefers staying at home

Our future aims are to further validate this questionnaire. We are currently distributing the PEmb-QoL questionnaire amongst patients with a recent PE to assess construct validity. The PEmb-QoL questionnaire will be distributed together with the disease generic SF-36 questionnaire to measure its responsiveness. A subgroup of patients with PE will receive the PEmb-QoL a second time for analysis of the test-retest reliability.

At present, it is too early to consider this questionnaire a useful measure. However, to avoid duplication of efforts, we would like to offer the current version of the PEmb-QoL questionnaire to colleagues who are working in this field, in order that it might be further validated.

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Disclosure of Conflict of Interests

The authors state that they have no conflict of interest.

References

- Naess IA, Christiansen SC, Romundstad P, Cannegieter SC, Rosendaal FR, Hammerstrom J. Incidence and mortality of venous thrombosis: a population-based study. *J Thromb Haemost* 2007; **5**: 692–9.
- Büller HR, Agnelli G, Hull RD, Hyers TM, Prins MH, Raskob GE. Antithrombotic therapy for venous thromboembolic disease: the Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy. *Chest* 2004; **126**: 401S–28S.
- Hull RD, Raskob GE, Ginsberg JS, Panju AA, Brill-Edwards P, Coates G, Pineo GF. A noninvasive strategy for the treatment of patients with suspected pulmonary embolism. *Arch Intern Med* 1994; **154**: 289–97.
- Moser KM, Fedullo PF, Litlejohn JK, Crawford R. Frequent asymptomatic pulmonary embolism in patients with deep venous thrombosis. *JAMA* 1994; **271**: 223–5.
- Nielsen HK, Husted SE, Krusell LR, Fasting H, Charles P, Hansen HH. Silent pulmonary embolism in patients with deep venous thrombosis. Incidence and fate in a randomized, controlled trial of anticoagulation versus no anticoagulation. *J Intern Med* 1994; **235**: 457–61.
- Murin S, Romano PS, White RH. Comparison of outcomes after hospitalization for deep venous thrombosis or pulmonary embolism. *Thromb Haemost* 2002; **88**: 407–14.
- Prandoni P, Lensing AW, Cogo A, Cuppini S, Villalta S, Carta M, Cattelan AM, Polistena P, Bernardi E, Prins MH. The long-term clinical course of acute deep venous thrombosis. *Ann Intern Med* 1996; **125**: 1–7.
- Heit JA, Mohr DN, Silverstein MD, Petterson TM, O'Fallon WM, Melton LJ III. Predictors of recurrence after deep vein thrombosis and pulmonary embolism: a population-based cohort study. *Arch Intern Med* 2000; **160**: 761–8.
- Brandjes DP, Büller HR, Heijboer H, Huisman MV, De Rijk M, Jagt H, ten Cate JW. Randomised trial of effect of compression stockings in patients with symptomatic proximal-vein thrombosis. *Lancet* 1997; **349**: 759–62.
- Pengo V, Lensing AW, Prins MH, Marchiori A, Davidson BL, Tiozzo F, Albanese P, Biasiolo A, Pegoraro C, Iliceto S, Prandoni P. Incidence of chronic thromboembolic pulmonary hypertension after pulmonary embolism. *N Engl J Med* 2004; **350**: 2257–64.
- Sullivan M. The new subjective medicine: taking the patient's point of view on health care and health. *Soc Sci Med* 2003; **56**: 1595–604.
- Lamping DL, Schroter S, Kurz X, Kahn SR, Abenhaim L. Evaluation of outcomes in chronic venous disorders of the leg: development of a scientifically rigorous, patient-reported measure of symptoms and quality of life. *J Vasc Surg* 2003; **37**: 410–9.
- Kahn SR, M'LAN CE, Lamping DL, Kurz X, Berard A, Abenhaim L. The influence of venous thromboembolism on quality of life and severity of chronic venous disease. *J Thromb Haemost* 2004; **2**: 2146–51.
- Korlaar van I, Vossen CY, Rosendaal FR, Bovill EG, Cushman M, Naud S, Kaptein AA. The impact of venous thrombosis on quality of life. *Thromb Res* 2004; **114**: 11–8.
- Kahn SR, Lamping DL, Ducruet T, Arsenault L, Miron MJ, Roussin A, Desmarais S, Joyal F, Kassir J, Solymoss S, Desjardins L, Johri M, Shrier I. VEINES-QOL/Sym questionnaire was a reliable and valid disease-specific quality of life measure for deep venous thrombosis. *J Clin Epidemiol* 2006; **59**: 1049–56.
- Hedner E, Carlsson J, Kulich KR, Stigendal L, Ingelgard A, Wiklund I. An instrument for measuring health-related quality of life in patients with Deep Venous Thrombosis (DVT): development and validation of Deep Venous Thrombosis Quality of Life (DVTQOL) questionnaire. *Health Qual Life Outcomes* 2004; **2**: 30.