Discrepancies between Patient-Reported Outcomes and Clinician-Reported Outcomes in Chronic Venous Disease, Irritable Bowel Syndrome, and Peripheral Arterial Occlusive Disease

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ABSTRACT .

Objective: To explore the degree of agreement between patient- and clinician-reported outcomes (PROs and CROs, respectively) in three chronic diseases.

Methods: Respectively, 120, 131, and 61 French general practitioners (GPs) included 291, 307, and 90 patients with chronic venous disease (CVD), irritable bowel syndrome (IBS), and peripheral arterial occlusive disease (PAOD), in a cross-sectional survey. Patients completed a specific Health-Related Quality of Life (QoL) questionnaire (Chronic Venous Insufficiency Questionnaire [CIVIQ], Functional Digestive Disorders Quality of Life [FDDQL], and Claudication Scale [CLAU-S], respectively) and scored their pain (visual analog scale, pain-free walking distance). GPs were concomitantly asked to estimate patients' pain and QoL.

Results: Although correlated (CVD and IBS: Kw = 0.27 and Kw = 0.31, respectively; PAOD: r = 0.64, P < 0.01), pain intensity estimated by GPs was lower than as estimated by patients with CVD and IBS (e.g., 39.0 ± 24.9 vs. 30.4 ± 21.0 for IBS), and pain-free walking distance was greater as esti-

mated by GPs than by patients with PAOD. Pain estimated by patients only partially reflected their QoL (r between 0.30 and 0.78; P between 0.02 and <0.01). Global QoL scores estimated by patients and GPs were moderately correlated (Kw between 0.17 and 0.28). GPs underestimated QoL impairment in CVD (global score: 72 ± 19 vs. 61 ± 20) and in most dimensions of the IBS questionnaire (in six of eight dimensions), and overestimated QoL impairment in PAOD (54 ± 21 vs. 66 ± 23).

Conclusions: Although correlated, PROs and CROs differed. In addition, their relationship was not consistent across diseases. PROs are therefore essential to take account of all the aspects of diseases.

Keywords: chronic venous disease, Chronic Venous Insufficiency Questionnaire, Claudication Scale, Functional Digestive Disorders Quality of Life, Health-Related Quality of Life, irritable bowel syndrome, peripheral arterial occlusive disease.

Introduction

It is nowadays generally agreed [1] that health consists in "a state of complete physical, mental and social well-being, not merely the absence of disease and infirmity" [2]. Physicians, researchers, and regulators therefore need to procure the information needed for them to be in a position to assess the impact of a disease on the patient's daily life and its mode of management, that is, what Schipper et al. [3] defined as quality of life related to state of health.

Information generally passes or ally from patient to doctor during consultation. For more than 20 years

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now, however, advances in psychometrics and decision analysis have enabled the development of scientific tools measuring the impact of a disease and its management as perceived by the patient. Such so-called health-related quality of life (QoL) scales or questionnaires may be generic or disease-specific. The generic instruments can be used in a wide range of situations and are especially useful for comparing the differential QoL impact of pathologies [4]. Specific instruments can only be used for one given pathology, but they are more change-sensitive than generic instruments and more relevant to the assessment of treatment effects [4]. Nevertheless, all of these kinds of instruments are still little used, and the impact of many chronic pathologies on patients' QoL is often underestimated or hardly, if at all, taken into account in assessing drug effectiveness [5].

It thus seemed worth measuring the degree of agreement between QoL as perceived by patients and meas-

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ured on QoL scales and that estimated by their general practitioner (GP) on consultation. Three disabling chronic pathologies, frequently encountered in general practice and each belonging to a different medical field, were selected: chronic venous disease (CVD) [6], irritable bowel syndrome (IBS) [7,8], and peripheral arterial occlusive disease (PAOD) at the intermittent claudication stage [9]. A French-version QoL questionnaire existed for each of these at the time of the study [10–14].

Patients and Methods

Study Design and Patients

This cross-sectional study, which collected data on QoL and pain, was carried out in France between October 2002 and July 2003, with the participation of urban GPs. All GPs included were members of the Thalès Medical Observation Center [15,16] and routinely used the Doc'Ware software package (2002, Version 5.1d, BKL Consultant, France) to which an extra question page could be added to detail certain points regarding patient management.

Spontaneously consulting adult patients known by their regular GPs to present with chronic venous or veno-lymphatic disease [17], IBS [18], or lower limb arterial disease at the intermittent claudication (stage II according to Fontaine and Leriche's classification) [19] were included in the study if: 1) they gave their consent; 2) they were able to fill in a self-administered questionnaire; or 3) they did not receive for at least a month a medical treatment for their disease. Patients presenting with current serious diseases (e.g., progressive cancer, severe cardiac insufficiency) were excluded.

At the end of each consultation with an included patient, the GP filled out an extra question page especially designed for the study, and then handed the patient the QoL questionnaire matching the diagnosis. The patients filled out the questionnaire themselves at home and posted it to the Thalès Medical Observation Center.

Patient Questionnaires

The Chronic Venous Insufficiency Questionnaire (CIVIQ) is a CVD-specific QoL questionnaire developed and validated in France [10]. It comprises 20 items along four dimensions: physical (four items), pain (four items), social (three items), and psychological (nine items). On each item, five responses are proposed (5-point Likert scale). Scores were calculated as per the user manual, except insofar as the global score and the scores on the four dimensions were subjected to a linear transformation to give response values lying between 0 (bad QoL) and 100 (good QoL), to make the results easier to grasp.

The Functional Digestive Disorders Quality of Life scale (FDDQL) is a specific questionnaire for IBS and

dyspepsia developed and validated in French, English, and German [11,12]. It comprises 43 items along eight dimensions: daily activities (eight items), anxiety (five items), diet (six items), sleep (three items), discomfort (nine items), coping with disease (six items), control of disease (three items), and stress (three items). Patients choose one of five responses per item (5-point Likert scale). Scores were calculated as per the user manual, by adding up the item scores so as to give global and dimension scores from 0 (bad QoL) to 100 (good QoL).

The Claudication Scale (CLAU-S) is a dedicated intermittent claudication questionnaire developed and validated in German, then translated into French, and revalidated as such [13,14]. It comprises 47 items along five dimensions: daily living (9 items), pain (10 items), social life (4 items), disease-specific anxiety (13 items), and mood (11 items). Patients choose one of four or five responses per item (4- or 5-point Likert scale) except for one question which rates pain intensity on a visual analog scale (VAS) graduated from 0 to 10. After readjustment as per the user manual, global and dimension scores ranged from 0 (bad QoL) to 100 (good QoL).

The CVD and IBS patients were also required to answer a question about the intensity of pain experienced over the previous two weeks, on a VAS going from 0 (no pain) to 10 (severe pain). VAS values were then subjected to a transformation to give values lying between 0 and 100. PAOD patients had to specify the distance (in meters) at which pain started when walking.

Computerized Extra Question Page (Filled out by GPs)

Depending on whether the patient was suffering from CVD, IBS, or PAOD, the extra question page comprised four, eight, or five questions corresponding to the label of the four, eight, or five dimensions of the CIVIQ, FDDQL, and CLAU-S questionnaires, respectively. Responses ranged from 0 to 10 for CVD, and 0 to 5 for IBS and PAOD. Linear transformation produced scores lying between 0 (bad QoL) and 100 (good QoL) per question. A global score (average of each dimension score) was then calculated, lying between 0 (bad QoL) and 100 (good QoL). The GPs also estimated patients' pain, on a VAS from 0 (no pain) to 10 (severe pain) for CVD and IBS, and in terms of painfree walking distance (in meters) for PAOD.

Statistical Analysis

The Thalès Medical Observation Center performed the statistical analyses, using the SAS software package, Version 8.2 (1999–2001, SAS Institute, Cary, NC, USA). For each pathology, pain intensity according to patients and to GPs, pain intensity and QoL scores according to patients, and QoL scores according to patients and GP estimates of patient QoL, respectively, were compared by regression, analysis of variance

(ANOVA), or using weighted Kappa (Kw) correlation coefficients. For regression and ANOVA, the significance threshold was set at 0.05. Missing QoL questionnaire data were replaced as per the user manual.

Ethical Considerations

The study did not alter patient management and therefore was not declared or submitted to ethical committee approval, in line with current French legislation. Patients who agreed to take part, on the other hand, were informed of their rights under the *Informatique et Libertés* law on protection of information.

Results

Patients

In all, 291 CVD, 307 IBS, and 90 PAOD patients were recruited by 120, 131, and 61 GPs, respectively. The CVD patients were overwhelmingly female (80.8%), with a mean age (\pm SD) of 60.3 \pm 15.6 years. The IBS patients were also mainly female (64.3%), with a mean age of 57.5 \pm 16.1 years. The PAOD patients, on the other hand, were generally male (70.0%), aged 72.0 \pm 10.9 years. Many patients presented with comorbidity—notably high blood pressure (32.6%, 24.1%, and 51.1% of CVD, IBS, and PAOD cases, respectively) or hyperlipidemia (29.9%, 26.1%, and 55.6%, respectively). Twenty-one percent of the PAOD patients were diabetic, and 30% suffered from angina or had a history of myocardial infarction.

Questionnaire Response Rate and Quality

The response rate for the QoL questionnaires was good: 240 of the 291 patients suffering from CVD (82.5%), 239 of the 307 patients suffering from IBS (77.9%), and 68 of the 90 patients suffering from PAOD (75.6%) filled out the questionnaires. The response quality for the QoL questionnaires was very good: 216 of the 240 (90.0%), 229 of the 239 (95.8%), and 60 of the 68 (88.2%) CIVIQ, FDDQL, and CLAU-S questionnaires, respectively, had less than four missing items, and 169 (70.4%), 211 (88.3%), and 38 (55.9%) were complete. GP responses to the extra question page were equally satisfactory, being complete for 276 (94.8%), 211 (68.7%), and 81 (90%) CVD, IBS, and PAOD patients, respectively.

Pain Intensity According to Patients and GPs

Overall, pain was rated as more intense by patients than by their GPs in case of CVD and IBS (Table 1). In CVD, patient- and GP-rated pain correlated moderately (Kw = 0.27): the greater the pain according to the patient, the greater the pain according to his or her GP. GPs, however, underestimated pain, in particular in those patients they deemed less affected (i.e., with the lowest GP pain ratings) (Fig. 1). IBS results were similar (Table 1). PAOD patients claimed to experience

Table 1 Pain intensity assessed by patients and general practitioners. Relationship between patients' and general practitioners' pain scores

Disease	Patients	General practitioners	Relationship between the two assessments*			
Chronic venous dise	ase (CVD)†					
Number of data	233	291	233 [‡]			
Mean \pm SD	42.2 ± 24.9	29.7 ± 19.2	Kw = 0.27			
Irritable bowel syndrome (IBS)†						
Number of data	232	307	232 [‡]			
$Mean \pm SD$	39.0 ± 24.9	$\textbf{30.4} \pm \textbf{21.0}$	Kw = 0.3 I			
Peripheral arterial o	cclusive disease	(PAOD)§				
Number of data	68	90	68 [‡]			
Mean ± SD	431 ± 711	880 ± 1734	$r = 0.64 \ (P < 0.01)$			

^{*}The relationship between patients' and GPs' scores was analyzed using weighted Kappa coefficient (CVD, IBS) or a regression (PAOD).

pain as of 431 ± 711 m, compared with 880 ± 1734 m according to their GPs. This result indicated that, although their responses were greatly variable, the GPs overestimated the pain-free walking distance and therefore underestimated the pain perceived by the patients. There was a significant correlation between the GP-estimated pain-free walking distance and that stated by the patients (r = 0.64, P < 0.01): the shorter the pain-free walking distance according to the patient, the shorter that estimated by the GP.

QoL Score and Patient-Estimated Pain Intensity

In CVD and IBS, global QoL scores correlated significantly with patient-assessed pain intensity (r = 0.78 and r = 0.71, respectively; P < 0.01) (Table 2): global QoL score fell (indicating reduced QoL) as pain intensity rose. In IBS, QoL scores varied by as much as 60 on a scale of 100 for a given pain intensity (Fig. 2), suggesting that pain intensity only partially reflected

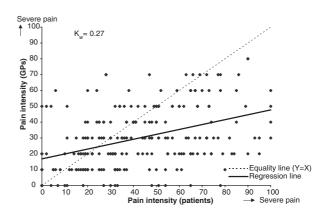


Figure 1 General practitioners (GPs) underestimated pain in patients suffering from chronic venous disease (CVD). All values under the equality line indicate GP underestimation of pain.

 $^{^\}dagger Pain$ intensity was assessed using a visual analog scale, ranging from 0 (no pain) to 100 (severe pain).

[‡]Number of (paired patient + GP) data.

[§]Pain intensity was assessed by means of the pain-free walking distance (m).

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Table 2 Quality of life (QoL) global scores and pain intensity according to patients. Relationship between the two parameters

Disease	QoL global score*	Pain intensity [†]	Relationship between the two parameters [‡]
Chronic venous disc	ease (CVD)		
Number of data	240	233	233 [§]
Mean ± SD	60.9 ± 20.3	42.2 ± 24.9	$r = 0.78 \ (P < 0.01)$
Irritable bowel disea	ise (IBS)		
Number of data	239	232	232 [§]
$Mean \pm SD$	57.4 ± 15.4	39.0 ± 24.9	$r = 0.71 \ (P < 0.01)$
Peripheral arterial of	cclusive diseas	e (PAOD)	
Number of data	68	` 68 [°]	68 [§]
$Mean \pm SD$	66.2 ± 22.9	431 \pm 711	$r = 0.30 \ (P = 0.02)$

 $^{^*}$ QoL global scores were assessed by the CIVIQ, FDDQL, and CLAU-S questionnaires for CVD, IBS, and PAOD, respectively. QoL scores ranged between 0 (bad QoL) and 100 (good QoL).

QoL. CVD results were similar. In PAOD, the QoL/pain-free walking distance correlation was weak (r = 0.30, P = 0.02), making it impossible to affirm that global QoL scores increased (indicating better QoL) with the pain-free walking distance.

QoL Scores According to Patients and GPs

Overall, CVD patients considered their QoL more adversely affected than did their GP (Table 3). In con-

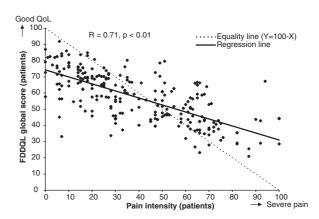


Figure 2 Patient-estimated pain intensity partially reflected quality of life (QoL) estimated by patients suffering from irritable bowel syndrome (IBS). The regression line shows global QoL score variation per pain intensity value.

trast, in case of PAOD, the GPs deemed the patients' QoL more badly affected than did the patients themselves (Table 3). In IBS, finally, global scores were similar for GPs and patients, but differences emerged according to the dimension: GPs underestimated the impact of the disease on the dimensions of diet, sleep, discomfort, coping with disease, control of disease, and stress, and overestimated it on the daily activities and anxiety dimensions (Table 3). The correlation

Table 3 Quality of life (QoL) scores (mean \pm SD) according to patients and general practitioners. Relationship between patients' and general practitioners' QoL scores

	Patients	General practitioners	Relationship between scores
Chronic venous disease (CVD)*			
Number of data	240	291	240 [†]
Global score	60.9 ± 20.3	72.4 ± 18.6	$Kw = 0.17^{\ddagger}$
Physical dimension	56.3 ± 25.4	69.3 ± 22.2	$P < 0.01^{\S}$
Pain dimension	55.3 ± 20.1	70.0 ± 19.9	P < 0.01 [§]
Social dimension	62.5 ± 23.9	75.6 ± 21.0	$P = 0.08^{\S}$
Psychological dimension	64.9 ± 22.9	74.I ± 21.I	$P = 0.03^{\S}$
Irritable bowel syndrome (IBS)*			
Number of data	239	307	239 [†]
Global score	57.4 ± 15.4	59.2 ± 19.0	$Kw = 0.28^{\ddagger}$
Daily activities dimension	71.6 ± 21.2	57.8 ± 25.4	$P < 0.01^{\S}$
Anxiety dimension	62.5 ± 22.2	53.6 ± 28.0	P < 0.01 [§]
Diet dimension	56.4 ± 22.6	60.0 ± 26.2	P < 0.01 [§]
Sleep dimension	66.1 \pm 20.3	72.4 ± 25.8	P < 0.01 [§]
Discomfort dimension	51.0 ± 18.2	69.0 ± 25.2	$P < 0.01^{\S}$
Coping with disease dimension	54.6 ± 19.8	57.2 ± 26.4	P < 0.01 [§]
Control of disease dimension	55.3 ± 22.8	59.0 ± 26.2	$P < 0.01^{\S}$
Stress dimension	31.5 ± 24.8	42.8 ± 26.6	P < 0.0 I [§]
Peripheral arterial occlusive disease (PAOD)*			
Number of data	68	90	58 [†]
Global score	66.2 ± 22.9	53.6 ± 20.8	$Kw = 0.26^{\ddagger}$
Daily living dimension	57.4 ± 27.8	47.0 ± 27.0	$P = 0.14^{\S}$
Pain dimension	64.5 ± 20.2	55.0 ± 21.4	$P = 0.07^{\S}$
Social life dimension	75.6 ± 17.9	57.4 ± 26.2	$P = 0.02^{\S}$
Disease-specific anxiety dimension	64.9 ± 27.9	56.2 ± 26.0	P < 0.01 [§]
Mood dimension	72.3 ± 23.8	63.0 ± 27.8	P < 0.01 [§]

^{*}QoL was assessed by the CIVIQ, FDDQL, and CLAU-S questionnaires for CVD, IBS, and PAOD, respectively (patients) and by computerized extra question pages (GPs). QoL scores ranged from 0 (bad QoL) to 100 (good QoL).

[†]Pain intensity was assessed using a visual analog scale, ranging from 0 (no pain) to 100 (severe pain) for CVD and IBS, and pain-free walking distance (m) for PAOD. [‡]The relationship between the two parameters was analyzed using a regression; the

correlation coefficient r assessed the quality of the relationship.

 $^{^{\}S}$ Number of (paired patient + GP) data.

[†]Number of (patient-physician pairs) data available for the regression, all the available data were included in the analysis of variance.

 $^{{}^{\}ddagger}\! The \ relationship \ between \ QoL$ scores was analyzed using weighted Kappa coefficients.

[§]The relationship between QoL scores was analyzed using an analysis of variance.

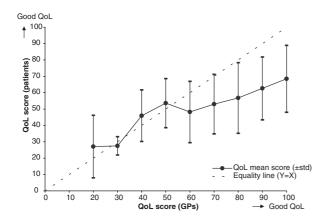


Figure 3 Pain dimension of the Chronic Venous Insufficiency Questionnaire (CIVIQ): General practitioners (GPs) underestimated the impact of chronic venous disease (CVD) on patients' quality of life (QoL). QoL was assessed by patients by means of the CIVIQ [10]. All values under the equality line indicate GPs' underestimation of the impact of CVD on QoL.

between patient and GP estimates of QoL global score was moderate: Kw = 0.17, Kw = 0.28, and Kw = 0.26, for CVD, IBS, and PAOD, respectively (Table 3).

Figures 3–5, respectively, present patients' mean QoL scores in relation to the corresponding GP QoL estimates for the CIVIQ pain dimension, the FDDQL control of disease dimension, and the CLAU-S daily living dimension. These figures can be taken as representative of all of the dimensions of these three questionnaires: the GPs underestimating (Fig. 3) and overestimating (Fig. 5) disease impact on patient QoL, and total disagreement as to QoL between patients and GPs (Fig. 4).

In CVD, GPs underestimated disease impact on QoL in patients they considered as enjoying a good QoL on the physical dimension (Fig. 3). Similar results were found for the pain and psychological dimensions.

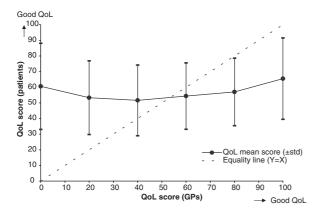


Figure 4 Control of disease dimension of the Functional Digestive Disorders Quality of Life (FDDQL): General practitioners (GPs) were unable to estimate the impact of irritable bowel syndrome (IBS) on patients' quality of life (QoL). QoL was assessed by patients by means of the FDDQL [11,12]. The equality line shows discrepancies between patients and GPs.

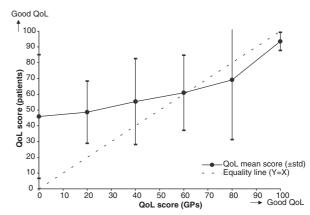


Figure 5 Daily living dimension of the Claudication Scale (CLAU-S): General practitioners (GPs) overestimated the impact of peripheral arterial occlusive disease (PAOD) on patients' quality of life (QoL). QoL was assessed by patients by means of the CLAU-S [13,14]. All values above the equality line indicate GPs' overestimation of the impact of PAOD on QoL.

On the CIVIQ social dimension, irrespective of GP ratings, patients' mean QoL scores were all very similar and not statistically different from the mean score of those patients rated 0 by their GP, suggesting that patients and GPs had utterly discrepant perceptions of the disease's impact on the social dimension.

In IBS, GPs overestimated disease impact on QoL on the daily activities dimension. On the diet dimension, they overestimated disease impact on QoL in those patients they esteemed to have poor QoL and underestimated disease impact on QoL in those patients they esteemed to have good QoL. On the control of disease dimension, irrespective of GP ratings, patients' mean QoL scores were all very similar and not statistically different from the mean score of those patients rated 0 by their GP, suggesting that patients and GPs had utterly discrepant perceptions of the disease's impact on this dimension (Fig. 4). Findings were similar on the FDDQL dimensions of anxiety, sleep, discomfort, coping with disease, and stress.

In PAOD, GPs overestimated disease impact on QoL on the daily living dimension in patients they considered to enjoy poorer QoL (Fig. 5). Findings were similar on the dimensions of pain, social life, and disease-specific anxiety. On the mood dimension, irrespective of GP ratings, patients' mean QoL scores were all very similar and not statistically different from the mean score of those patients rated 0 by their GP, suggesting that patients and GPs had utterly discrepant perceptions of the disease's impact on this dimension.

Discussion

The present study sought to investigate agreement between patient and GP estimates of QoL and pain experienced. Three disabling chronic pathologies (CVD, IBS, and PAOD), for which a French-version 44 Chassany et al.

QoL questionnaire existed at the time of the study, were selected [6–14].

The first finding is that GPs correctly identified those patients who were suffering the least and the most, but systematically underestimated the pain experienced. Second, it emerged that QoL scores and patient-estimated pain intensity correlated significantly, but that the intensity of the pain experienced by the patients was only a partial reflection of their QoL. In CVD and IBS patients, QoL scores varied widely for any given level of pain. In PAOD, moreover, the correlation was quite weak, and it was not possible to affirm that global QoL scores fell as the walking-distance threshold for onset of pain grew shorter. Likewise, Marquis et al. [20], validating the ARTEMIS QoL questionnaire dedicated to intermittent claudication, found walking test and QoL scores to be indeed related, but that QoL scores varied widely for pain-free walking distances shorter than 1000 m. Third, it was found that the QoL of the patients was diminished even though they were being followed by their GPs without any medical treatment; these patients were thus presumably deemed by their GPs not to require any such management. Finally, it was shown that GPs underestimated the QoL impact of CVD and IBS. On the other hand, GPs overestimated the QoL impact of PAOD. It further appeared that GPs did not have a very good idea of which QoL dimensions were affected by which pathology. This was especially true as regards IBS, where the global FDDQL score was close to GP estimates, but completely illogical discrepancies emerged on all of the individual dimensions, including those that might be supposed to be easy to assess, such as diet and sleep.

The limitations inherent in this kind of crosssectional study, regarding GPs, patients, and methodology, might be thought to account for some of the discrepancies between patient and GP judgments. There may indeed be some question as to whether the GPs taking part in the present study were truly representative of French GPs as a whole. The experience of Thalès Medical Observation Center, however, allays this doubt [15,16]. There may also be some question as to whether the patients included in the present study were truly representative of those suffering from the three pathologies. Nevertheless, although slightly older than those recruited for the validation of the CIVIQ, FDDQL, and CLAU-S questionnaires, our patients showed characteristics broadly similar to those in previous studies [6–14,21–26]. Furthermore, although it is admittedly difficult to compare QoL scores between studies (there being few publications, and with differences in how the scores are presented and also between the populations studied), it nevertheless remains that the QoL scores of our patients agree with those generally found on the same questionnaires in other reports [11,14,27]. Finally, concerning the methodology, it may be asked whether the question page provided on the software for the GPs was sufficiently precise, with just one question per dimension. The CIVIQ, FDDQL, and CLAU-S questionnaires were all developed as patient-reported outcome (PRO) instruments, and could not be used directly by the GPs. The questions retained for each pathology had to mimic questions that could be routinely used by the GPs during consultation. The choice of a single question, focusing on the main concept of each dimension of each questionnaire, was adopted to allow comparison, and for reasons of feasibility. The questionnaire incorporated into the software had to be short (four to eight questions) if the GPs were not to be put off: otherwise, lack of time would probably mean that they would fill it in incompletely if at all. The appropriateness of a short questionnaire was indeed borne out by the good response rate.

Thus, the differences found between the GPs' and the patients' judgments of pain and QoL are to be accounted for by the GPs' difficulty in getting to understand the problems encountered by the patient in relation to his or her disease—especially when it is difficult to speak about a topic during consultation: it is doubtless easier for a patient to talk about the problems that lower limb pain causes in everyday life than to speak about their fear of having flatulence in public. It would seem that the GPs were relying on their medical knowledge and on the clinical signs in assessing their patients' QoL: they were better at estimating the intensity of pain than OoL itself, doubtless because pain is directly linked to clinical signs, unlike QoL, which is a more complex matter. Moreover, they overestimated the QoL impact of PAOD, an organic affection with serious consequences, but underestimated that of the two functional pathologies. As far as IBS and CVD were concerned, the QoL dimensions the GPs had the best grasp of were those directly relating to the impairment: physical and pain dimensions in the case of CVD, daily activities and diet in that of IBS. In PAOD, in contrast, dimensions directly relating to functional impairment, such as daily Living and pain, were misjudged by the GPs. This is undoubtedly due to the fact that, in PAOD, the pain-free walking distance and the pain experienced do not impact QoL directly, but rather alter the patients' behavior, which in turn ends up affecting the QoL [14]. The present study was only descriptive and was not able to go further in analyzing these differences in judgment between GPs and patients. It would certainly have been of interest to try to identify the patient profiles (e.g., in terms of age, sex, depression) for which the GPs had a better or poorer grasp of QoL.

In conclusion, clinicians' and patients' perspectives, although overlapping to some extent, differed. Clinicians tended to underestimate the intensity of the pain experienced by their patients. The pain experienced could not therefore be accurately inferred from the clinician's point of view. Similarly, the patient's perception of pain did not fully reflect the impact on QoL. In addition, clinicians tended to underestimate or overestimate QoL impairment in patients, probably relying on the inherent severity of the disease as perceived by the medical community (e.g., functional vs. organic diseases). These results demonstrate that PROs are essential for taking account of all the aspects of disease [28].

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References

- 1 Patrick D, Erickson P. Health Status and Health Policy. Quality of Life in Health Care Evaluation and Resource Allocation. New York: Oxford University Press, 1993.
- 2 World Health Organization. Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, June 19–22, 1946; signed on July 22, 1946 by the representatives of the 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948.
- 3 Schipper H, Clinch J, Powell V. Definitions and conceptual issues. In: Spilker B, ed., Quality of Life Assessments in Clinical Trials. New York: Raven Press, 1991.
- 4 Patrick DL, Deyo RA. Generic and disease-specific measures in assessing health status and quality of life. Med Care 1989;27:S217–32.
- 5 Reflection paper on the regulatory guidance for the use of health-related quality of life (HRQL) measures in the evaluation of medicinal products. EMEA/ CHMP/EWP/139391/2004. Available from: http://www.emea.eu.int [Last accessed on August 23, 2005].
- 6 Nicolaides AN. Investigation of chronic venous insufficiency. A consensus statement. Circulation 2000;102:e126-63.
- 7 Frexinos J, Denis P, Allemand S, et al. Etude descriptive des symptômes fonctionnels digestifs dans la population générale française. Gastroenterol Clin Biol 1998;22:785–91.
- 8 Lynn RB, Friedman LS. Review article. Irritable bowel syndrome. N Engl J Med 1993;329:1940–5.
- 9 Diehm C, Schuster A, Allenberg JR, et al. High prevalence of peripheral arterial disease and co-morbidity in 6880 primary care patients. Cross-sectional study. Atherosclerosis 2004;172:95–105.
- 10 Launois R, Reboul-Marty J, Henry B. Construction and validation of a quality of life questionnaire in

- chronic lower limb venous insufficiency (CIVIQ). Qual Life Res 1996;5:539–54.
- 11 Chassany O, Marquis P, Scherrer B, et al. Validation of a specific quality of life questionnaire for functional digestive disorders. Gut 1999;44:527–33.
- 12 Chassany O, Bergmann JF. Quality of life in irritable bowel syndrome, effect of therapy. Eur J Surg 1998; 83(Suppl. 5):81–6.
- 13 Spengel FA, Brown TM, Dietze S, et al. The claudication scale (CLAU-S). A new disease-specific quality-of-life instrument in intermittent claudication. Dis Manag Health Outcomes 1997;2(Suppl. 1):S65–70.
- 14 Boccalon H, Lehert P, Comte S. Claudication intermittente et qualité de vie. Validation des qualités psychométriques de la version française du questionnaire CLAU-S. J Mal Vasc 2000;25:98–107.
- 15 Mousquès J, Renaud T, Sermet C, et al. La variabilité des pratiques médicales en médecine générale: le cas des hyperlipidémies. Paris: Centre de Recherche, d'Etudes et de Documentation en Economie de la Santé (CREDES); Octobre 2001. Biblio No. 1360.
- 16 Faggionato D, Pigeon M, Naudin F, et al. La diffusion des anti-COX2 dans la prescription des médecins. Paris: Centre de Recherche, d'Etudes et de Documentation en Economie de la Santé (CREDES), Décembre 2002. Bulletin d'information en économie de la santé. No. 60.
- 17 Porter JM, Moneta GL. Reporting standards in venous disease: an update. International Consensus Committee on Chronic Venous Disease. J Vasc Surg 1995;21:635–45.
- 18 Thompson WG, Longstreth GF, Drossman DA, et al. Functional bowel disorders and functional abdominal pain. Gut 1999;45(Suppl. 2):S43–7.
- 19 Fontaine R, Kim M, Kieny R. Die chirurgische Behandlung der peripheren Durchblutungsstörungen. Helvetica Chirurgica 1954;5/6:499–533.
- 20 Marquis P, Fayol C, McCarthy C, Fiessenger JN. Mesure de la qualité de vie dans la claudication intermittente. Validation clinique d'un questionnaire. Presse Med 1994;23:1288–92.
- 21 Launois R. At the crossroads of venous insufficiency and hemorrhoidal disease: Daflon 500 mg—repercussions of venous insufficiency on everyday life. Angiology 1994;45:495–504.
- 22 Jantet G, RELIEF Study group. Chronic venous insufficiency: worldwide results of the RELIEF Study. Angiology 2002;53:245–56.
- 23 Dapoigny M, Dyard F, Grimaud JC, et al. Irritable bowel syndrome and healthcare consumption. An observational study in private gastroenterology. Gastroenterol Clin Biol 2003;27:265–71.
- 24 Danchequin-Dorval E, Delvaux M, Allemand H, et al. Profile and evolution of irritable bowel syndrome. Prospective national epidemiological study of 1301 patients followed for 9 months in gastroenterology. Groupe d'Etude Nationale sur le Syndrome de l'Intestin Irritable (SII). Gastroenterol Clin Biol 1994;18: 145–50.
- 25 Creutzig A, Bullinger M, Cachovan M, et al. Improvement in the quality of life after i.v. PGE₁ therapy for intermittent claudication. VASA 1997;26:122–7.

- 26 Meilhac B, Montestruc F, Aubin F, et al. Etude comparative randomisée en double-aveugle de la nicergoline et du naftidrofuryl sur la qualité de vie dans l'artériopathie chronique oblitérante des membres inférieurs au stade de la claudication intermittente. Thérapie 1997;52:179–86.
- 27 Vayssairat M, Ziani E, Houot B. Efficacité versus placebo de la contention classe 1 dans l'insuffisance
- veineuse chronique des membres inférieurs. J Mal Vasc 2000;25:256-62.
- 28 Chassany O, Sagnier P, Marquis P, et al. Patient-reported outcomes. The example of health-related quality of life—A European guidance document for improved integration of health-related quality of life assessment in the drug regulatory process. Drug Inf J 2002;36:209–38.