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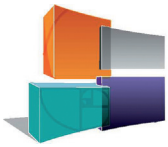

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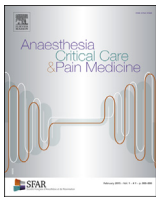

Original Article

A French version of Ringsted's questionnaire on pain-related impairment of daily activities after lung surgery: A cohort study

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ABSTRACT

Background: The questionnaire from Ringsted et al. (RQ) assesses the consequences on daily activities of a post–thoracotomy pain syndrome. Our study aimed at translating the RQ into French and to validate its metrological properties.
Methods: Four months after thoracotomy, 134 patients participating in a prospective comparative study of two surgical thoracotomy approaches (axillary and posterolateral) scored the translated questionnaire. The sensitivity of this version was assessed by comparing scores from patients complaining of pain to that of non-complainers. Concurrent validity was assessed using ratings from direct questions on pain, mood, anxiety and enjoyment of life. Homogeneity was assessed with Crombach's coefficient and dimensionality with PCA.
Results: A scoring system was devised to homogenise pain-related impairment with activities that were never performed before surgery and activities that had to be abandoned due to pain. The French version is bi-dimensional: routine activities (carrying heavy loads, raising the arms above the head, housework, getting out of bed, car driving, lying on the operated side, coughing, sitting for half an hour) are opposed to running, walking 1 km, climbing stairs, bending knees, standing for half an hour, swimming and cycling; both these factors contribute independently to the global score. Global and factor scores are sensitive to presence of pain while direct questions account for 20 to 50 % of the information provided by the questionnaire.
Conclusion: The French version of the RQ is suitable to assess chronic repercussions of lung surgery on the ability of patients to perform their daily activities.

1. Introduction

Optimal management of postoperative pain requires the use of procedure-specific pain management [1,2]; this is particularly important in cancer patients. As progress in surgery and oncology leads to clearly improved prognoses for operated cancer patients, patients' chronic pain and long-term quality of life, which are often linked, have become topics that receive more and more attention [3]. Although the intensity of chronic post-surgical pain is often mild, its consequences can be significant and independent of changes in cancer status. This is especially true for patients who underwent thoracotomy since many patients suffer from a post-thoracotomy pain syndrome (PTPS) [4,5], which can have a neuropathic component [6].

Visual Analog Scales (VAS) or Numerical Rating Scales (NRS) are generally considered sufficient to assess pain intensity [7]. They are supplemented by scores quantifying neuropathic pain such as the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) [8] or the Douleur Neuropathique 4 Questions (DN4) [9]. Evaluation of quality of life (QoL) in patients suffering from post-thoracotomy pain syndrome often relies on general-purpose questionnaires such as the Short Form (36) Health Survey (SF-36) [10], or its shorter form the 12-Item Short Form Health Survey (SF-12) [11], the Hospital Anxiety and Depression Scale (HADS) [12], or the

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30 item Quality of Life Questionnaire (QLQ-C30) from the European Organisation for Research and Treatment of Cancer (EORTC) [13]. The Functional Assessment of Cancer Therapy—Lung (FACT-L) has been developed to evaluate multidimensional QoL for people with lung cancer [14].

To address the relationship between pain and QoL more specifically, and in particular patients' daily life activities, a Danish multidisciplinary team drew up lists of tasks [15] so as to develop a questionnaire in English [16]. This 17-item questionnaire, Ringsted's questionnaire (RQ), can be completed in a few minutes. A specific scoring system was used combining a Likert scale for impairment (from "not at all" to "much") and the possibility to indicate that an activity was never practiced or had to be abandoned due to pain. A pilot study plus a series of interviews with patients who had undergone thoracotomy one to three years earlier and with expert surgeons led to the final version of the questionnaire, which was released after its metrological properties had been validated. This questionnaire has shown suitable validity, reliability and internal consistency, and was considered sensitive to persistent PTPS.

Despite some indications to the contrary, it was stated in the original paper that the questionnaire although it dealt with 17 different activities provided a uni-dimensional measurement of the impact of post-thoracotomy thoracic pain on patients' daily life. The present study aimed at validating a French version of this questionnaire using methods that could help determine if the questionnaire was actually uni-dimensional or, as could be suspected, bi-dimensional, with a uni-dimensional global score. These translations should be done for questionnaires that are intended to be used in usual practice and to allow comparisons with the Anglo-Saxon medical literature, as was recently the case with the Confusion Assessment Method for the ICU (CAM-ICU) [17]. This is particularly relevant as French is the fifth most spoken language in the world (274 million speakers).

2. Patients and methods

The present study was performed in accordance with relevant guidelines (STROBE Standard for Observational studies) and regulations and was carried out in two steps. The first one was the cross-cultural translation of the English version of the questionnaire into a French version. The second step was designed to test the psychometric properties of the French version.

2.1. Ethics

This validation study was done during a prospective single-centre study entitled "Influence of the surgical approach on the development of a chronic pain after thoracic surgery". Ethical approval for this study (Ethical Committee No.°14001) was provided by the Ethical Committee Ile-de-France XI, Saint-Germain, France (Chairperson M. Catz) on 16 January 2014. This study has been registered on the international platform www.clinicaltrials.gov (NCT02237963).

2.2. Study population

Adult patients who underwent a resection of lung parenchyma by posterolateral or axillary thoracotomy, from July 2014 to July 2015 at hospital Foch, a tertiary referral hospital, were included in the research after they gave their written informed consent. Patients who underwent a thoracoscopic intervention, patients in whom parietectomy was performed and patients unable to read or understand French were not included in the research.

Four months after surgery, a questionnaire was mailed to each patient. It comprised questions exploring pain and generic questions on the patient's QoL plus the proposed translation of the RQ.

2.3. Translation and adaptation of the RQ on self-reported pain impairment of daily activities after thoracotomy and videothoracoscopy

Translating the English version of the questionnaire was the topic of a full session of the Seminar on Medical Translation of the French Society of Translators in Lyon (2014) of which the guest moderator was one of the co-authors of the present paper (JFD). The sixty professional medical translators (mostly French and British, but also Belgian, Canadian, Dutch and Swiss) were provided with the published English version of the questionnaire, one month prior to the Seminar. The session was devoted to the collation of the translations prepared by each participant for the rating instructions, scoring levels and the question wordings. The proposed translations were compared to a preliminary version that had been used in a pilot study. The steering committee of the Seminar, who did not attend the session, then made a back translation of the amended French version constructed during the session. Discrepancies between the back translation and the original were then resolved during a plenary session.

Considering that this questionnaire was intended for the general population, great care was taken to use words that would be understood by more than 95% of the population. Thus, the moderator checked that each word retained in the French version was present in a dictionary meant for children aged 7 to 10 years [18]. Prior to its use, the questionnaire was also reviewed by some members of the research team involved in contacts with patients so as to obtain ratings and included in a pilot assessment of patients with lung transplantation.

The original and translated questionnaires are presented in Table 1 and Table 2.

2.4. Psychometric properties

Concerning reliability, as suggested by Bouletreau et al. [19] the following steps were taken to ensure a proper validation of the questionnaire: description of the population assessed, assessment of the floor and ceiling effects, correlation of each item with the total score, Cronbach's coefficient, principal component analysis (PCA), varimax rotation of the retained axis, and saturation of factors for each item, plus concurrent validity.

Face validity was considered to have been achieved by the original developers of the questionnaire.

2.5. Statistical analysis

Only those patients for whom the RQ had been fully completed were retained for the analysis; when patients had ticked two scores on the form, the mean of the two values was assigned to the item. Although the specific scoring system of the questionnaire makes it quite easy for patients to complete, as far as we are aware no instruction is given by the authors to obtain a homogeneous single score for each activity. It was decided that if an activity had never been performed before surgery the discomfort generated by postoperative pain could be considered as nil. On the other hand, if a previously performed task could no longer be undertaken due to pain, discomfort was to be rated at the highest level. Scores were transformed to be 0 when discomfort was absent and 4 if discomfort was maximal.

Table 1
Original questionnaire in English.

	Activity					
	Never performs this activity due to pain	Never performs this activity	Pain impairs me			
			a lot	somewhat	a little	not at all
Running	☐	☐	☐	☐	☐	☐
Carrying groceries, heavy bags or luggage	☐	☐	☐	☐	☐	☐
Washing hair, lifting the arm, moving shoulder or opening cupboards over shoulder height	☐	☐	☐	☐	☐	☐
Cleaning (vacuum, washing floor)	☐	☐	☐	☐	☐	☐
Walking 1 km	☐	☐	☐	☐	☐	☐
Ascending stairs	☐	☐	☐	☐	☐	☐
Kneeling or stooping	☐	☐	☐	☐	☐	☐
Standing for 30 mins	☐	☐	☐	☐	☐	☐
Getting out of bed	☐	☐	☐	☐	☐	☐
Swimming	☐	☐	☐	☐	☐	☐
Cycling,	☐	☐	☐	☐	☐	☐
Driving a car (driver)	☐	☐	☐	☐	☐	☐
Lying on the operated side	☐	☐	☐	☐	☐	☐
Coughing or taking a deep breath	☐	☐	☐	☐	☐	☐
Sitting in a chair for 30 mins	☐	☐	☐	☐	☐	☐
Concentrating on watching TV	☐	☐	☐	☐	☐	☐
Sleeping	☐	☐	☐	☐	☐	☐

Table 2
Translated questionnaire in French.

Activité						
	Jamais pratiquée du fait de la douleur	Jamais été pratiquée	La douleur me gêne pour pratiquer cette activité			
			Beaucoup	Moyennement	Un peu	Pas du tout
Courir	☐	☐	☐	☐	☐	☐
Porter des courses, des sacs lourds, des bagages	☐	☐	☐	☐	☐	☐
Laver ses cheveux, lever le bras, faire un mouvement de l'épaule, ouvrir un placard plus haut que l'épaule	☐	☐	☐	☐	☐	☐
Faire le ménage (passer l'aspirateur, nettoyer par terre)	☐	☐	☐	☐	☐	☐
Marcher 1 km	☐	☐	☐	☐	☐	☐
Monter les escaliers	☐	☐	☐	☐	☐	☐
S'agenouiller, se baisser	☐	☐	☐	☐	☐	☐
Rester debout une demi-heure	☐	☐	☐	☐	☐	☐
Sortir du lit	☐	☐	☐	☐	☐	☐
Nager	☐	☐	☐	☐	☐	☐
Faire du vélo	☐	☐	☐	☐	☐	☐
Conduire une voiture	☐	☐	☐	☐	☐	☐
Etre allongé du côté opéré	☐	☐	☐	☐	☐	☐
Tousser ou respirer profondément	☐	☐	☐	☐	☐	☐
Etre assis sur une chaise pendant une demi-heure	☐	☐	☐	☐	☐	☐
Se concentrer sur une émission télévisée	☐	☐	☐	☐	☐	☐
Dormir	☐	☐	☐	☐	☐	☐

Continuous variables are summarised by the median and using the 25th and 75th percentiles. Counts, proportions and Confidence Interval 95% are used for categorical variables, which allows assessment of floor and ceiling effects. Level of significance was set at 0.05.

The construct validity of the questionnaire was assessed by Pearson's correlation coefficient between each item and the global questionnaire score (sum of all items with this item omitted) while internal consistency was assessed using Cronbach's alpha coefficient; for the latter, a value above 0.70 is generally considered as sufficient [20]. Dimensionality of the questionnaire was tested by conducting a PCA. To select the relevant, i.e., non-artefactual number of factors, the method of Lébart and Dreyfus was used [21]. A table with m lines (m = number of analysable

questionnaires) and n columns (n = number of items in the questionnaire) was filled with random numbers from a uniform [0–4] distribution and a PCA done on this table. Since k simulations were performed, the maximal value for each (ranked) eigenvalue can be considered as the minimum to be reached by a non-artefactual eigenvalue with a probability of 1/k. A varimax rotation was performed after the PCA of the actual questionnaire and a screen test was performed to determine which saturation led to an optimal coverage of questionnaire items by the rotated factors.

Sensitivity was assessed by comparing global and factor scores in patients complaining from pain versus non-complainers.

To investigate concurrent validity, the global score and the factor scores (i.e., the sum of item values ascribed to a factor) were correlated (using Spearman's coefficient) to NRS that had been obtained at the same time.

All statistical analyses were made using NCSS, version 11 (NCSS Ltd, Kaysville, Utah, USA).

3. Results

The questionnaire was sent to 209 patients and 134 sent back a fully completed questionnaire. Table 3 lists the relevant parameters characterising these patients.

3.1. Floor and ceiling effects

Fig. 1 permits analysis of these effects. Most RQ items showed a floor effect (i.e., the proportion at level 0 was higher than the proportion reporting an absence of pain). Notable exceptions are represented by item 2 (33% of 0 s) and item 14 (37%); three additional questions had a proportion of 0 above 50% and below 55%: item 4 (51%), item 6 (51%) and item 13 (54%). As to a ceiling effect, it is worth noting that the top score was reached for only six items (1, 2, 5, 10, 11, 13).

Table 3
Patient characteristics (total number analysable: 134).

	Count	Values
Demographics		
Gender (men)	134	57 (43%) {34 to 51}
Age	134	62 [52.5 to 70]
Preoperative status		
Cancer	110	87 (79%) {70–86}
Considering themselves to be in pain	134	53 (40%) {31–48}
Pain (NRS)	127	4 [2 to 7]
Analgesic treatment	91	35 (38%) {28–49}
Anxiety (NRS)	130	2 [1 to 3.25]
Postoperative status (4 months post-surgery)		
Complaining of pain	134	67 (50%) {41–59}
Severity of pain (NRS)	82	2 [1 to 4]
Pain severity in complainers	65	3 [2 to 4]
Generic questions relating to quality of life		
General activity (NRS)	84	2 [0 to 4.75]
Mood (NRS)	83	1 [0 to 3]
Ability to walk (NRS)	84	0 [0 to 3]
Chores (NRS)	82	2 [0 to 5]
Social relationships (NRS)	82	2 [0 to 2]
Sleep (NRS)	82	1 [0 to 5]
Enjoyment of life (NRS)	84	0 [0 to 2]

NRS: from 0 (no symptom, no trouble related to this area of functioning) to 10 (maximal symptom, totally unable to function due to symptomatology).
Data are presented as number (percentage) {Confidence Interval 95%} and median [interquartile range].

3.2. Dimensionality

After 20 simulations, the maximal value for the second-rank eigenvalue was 1.02. Thus, the two principal axes of the PCA were to be retained for the Varimax rotation. With a cut-off saturation of 0.22, all items were assigned to one and only one factor. Although they only represent mathematical objects, it is possible to give some meaning, which may of course be debatable, to each Factor; Factor 1 is related to daily chores (carry heavy loads, move arm above head, do housekeeping tasks, get out of bed, drive a car, lie on the operated side, cough/take a deep breath, sit on a chair for half an hour, sleep), whereas Factor 2 relates to activities one elects (more or less) to do (run, walk for 1 km, climb stairs, bend/kneel, stand for half an hour, swim, cycle, concentrate on a TV show).

Since saturations range from 0.24 to 0.59 for Factor 1 and from 0.22 to 0.55 for Factor 2, one could argue that item scores should be weighted to obtain representative scores [22] but such a method is seldom used as it makes calculations impractical (Table 4).

3.3. Internal consistency

Cronbach α coefficient was 0.76 (0.93 after standardisation). Pearson's correlation coefficient of items with the global score ranged from 0.53 (item 12) to 0.77 (item 2); R^2 is superior to 0.5 for items 2, 4, 7, 9 and 17.

3.4. Sensitivity

The results of comparisons for the global RQ and the two factor scores in patients complaining of pain versus non-complainers are summarised in Table 5. All three parameters show highly significant between-group differences.

3.5. Concurrent validity

Since direct assessments of various consequences of surgery were obtained at the same time as the RQ data, Spearman's correlation coefficient was used to investigate if these NRS were correlated to RQ's Factor 1, Factor's 2 and Global Scores. All these correlations were highly significant ($P < 0.005$) (Table 6).

The global score and Factor 1 are highly correlated to specific NRS; however, the correlation is not perfect, which reflects the additional information brought by using a set of items; Factor 2 although also correlated to NRS appears to explore some additional issues, possibly related to autonomy.

4. Discussion

Although the structure of the French version of the RQ clearly differs from that of the original English version, the results of the present study show that the former is acceptable and valid, with suitable metrological properties to assess patients with a PTPS.

Our version clearly shows a bi-dimensional structure, a finding that was indeed hinted at by Ringsted and his colleagues. Despite this important difference, the global score remains uni-dimensional as in the original article.

For too long the attention of the teams, practicing pulmonary surgery has focused on the postoperative period to prevent and treat postoperative complications and pain. The improvement in survival of cancer patients i.e., a majority of those undergoing lung-oriented thoracotomy, leads teams to search for techniques that can reduce postoperative chronic pain and their functional consequences. Thoracotomies are reported to be followed by persistent pain in 25% to 60% of cases [15,23] and the advantage of video-assisted thoracic surgery is disputable concerning chronic

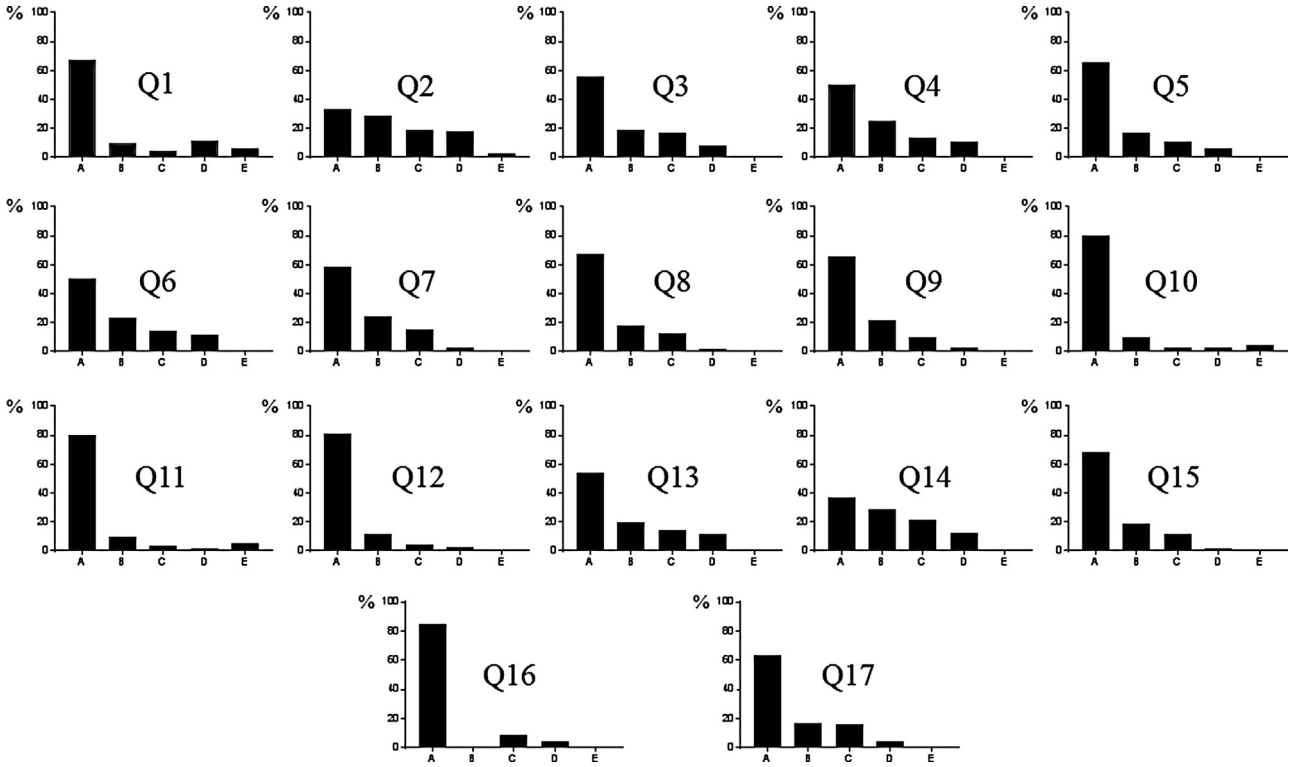

Fig. 1. Graphical representation of the responses to each question (Q1 to Q17). A. Never performs this activity or Pain impairs me not at all. B. Pain impairs me a little. C. Pain impairs me somewhat. D. Pain impairs me a lot. E. Never performs this activity due to pain.

Table 4
Dimensionality.

Variables	Factor 1 saturation	Factor 2 saturation
Run	0.095	**0.293**
Carry heavy loads	**0.441**	0.182
Move arm above head	**0.590**	0.067
Do housekeeping tasks	**0.419**	0.191
Walk one kilometre	0.098	**0.460**
Climb stairs	0.107	**0.549**
Bend or kneel	0.212	**0.388**
Stand for half an hour	0.164	**0.384**
Get out of bed	**0.557**	0.116
Swim	0.069	**0.228**
Cycle	0.028	**0.435**
Drive a car	**0.238**	0.089
Lie on the operated side	**0.576**	0.074
Cough or take a deep breath	**0.331**	0.088
Sit on a chair for half an hour	**0.395**	0.149
Concentrate on a TV show	0.108	**0.224**
Sleep	**0.513**	0.111

A saturation cut-off value allows assigning every item to a single factor. Bold characters are used to show whether an item is assigned to factor 1 or factor 2. Inspection of the items pertaining to a factor is used to define the latent meaning of a factor.

Table 5
Sensitivity (comparison of global and factor scores according to the presence/absence of pain).

	Complaining of pain (n = 67)	Not complaining (n = 67)	P-value
Global score	17 [9–22]	3 [0–9]	0.0001
Factor 1 (routine daily activities)	10 [5–15]	2 [0–5]	0.0001
Factor 2 (purposeful activities)	5 [2–9]	0 [0–4]	0.0001

Results are presented as median [interquartile range].

pain and QoL [12]. In a small cohort study, it was reported that 84% of the patients suffering from PTPS one year after surgery have a limitation of daily activities [24].

General questionnaires on QoL are insufficient to precisely evaluate patients with PTPS as they do not deal with the impact of pain on activities of daily life. The RQ fulfils this function and can therefore be considered as a significant progress. As we wanted to compare the long-term consequences of two different interventional approaches on the lungs and to be prepared to assess whether video interventions have less severe consequences, it was considered necessary to validate a French version of the questionnaire. The steering committee of a medical translation seminar provided a definitive solution to the translation problems so often encountered when questionnaires are validated in a country with cultural and linguistic differences.

Since such a questionnaire is meant for the general population, its ergonomics is a critical point. Patients were encouraged to comment on the usability of the questionnaire; none complained of the questionnaire being too long or too difficult to rate. This is not surprising in view of the precautions taken by the developers to select themes that could be relevant to any patient. The English version appears to be homogeneous meeting the Rasch model requirements with all questions pointing in the same direction. However, three items "Run", "Swim" and "Cycle" had a non-monotonously decreasing proportion for increasing scores and the developers wondered if such items had to be left in a newer version. We have shown these items to belong to an independent dimension, which is well correlated to the global score.

Table 6
Concurrent validity (correlation between numeric rating scales on topics related to QoL and RQ global and factor scores).

Domain	Correlation to Global RQ	Correlation to RQ 's factor 1	Correlation to RQ 's factor 2
Global activity	0.56	0.60	0.37
Mood	0.60	0.62	0.42
Ability to walk	0.50	0.45	0.44
Work/housekeeping	0.67	0.68	0.49
Social relationships	0.48	0.49	0.35
Sleep	0.62	0.68	0.38
Enjoyment of life	0.41	0.43	0.30

QoL: quality of life; RQ: Ringsted's questionnaire.
Spearman's rank correlation coefficient with at least 82 pairs of results; the critical value of the coefficient (2-sided) corresponding to $P = 0.005$ is 0.30.

On the other hand, one may be surprised by the total lack of reference to sexual activities, which may be ascribed to a concern about such questions hampering the willingness of patients to answer other items.

There exists a high degree of correlation between the RQ (global and proposed factor scores) and direct assessments by NRS; however, these correlations only explain 20 to 50% of the variability of the RQ showing that the RQ adds some information to these direct ratings; our results demonstrate that it has two independent dimensions that concur with its global score, which should be considered an important benefit of its use. It is worth noting that our results concur with the suggestion made by Wildgaard et al. in their critical review of literature that one should separate the consequences of pain in daily life activities and those linked to a loss of autonomy in voluntary activities [15]. In fact, Kehlet and his team suggested that the RQ explores two dimensions of pain: impact on mobility (swimming, biking, driving a car), and repercussion on "mandatory" daily activities (breathing, watching TV, standing up for half an hour).

As the questionnaire was well-received by patients, it may be possible to repeat assessments at frequent intervals, thus providing longitudinal data on the evolution of their status, which is particularly important since Perttunen et al. reported that one year after surgery 60% of thoracotomised patients were incapacitated by their PTPS [25].

As far as long-term postoperative pain is concerned, our sample of patients differed from that of Ringsted et al., 50% of our patients complained of pain against 38%: but if the proportion of patients considering themselves to be in pain is higher, pain severity is probably lower in our sample: only four items in the developers' sample did not reach the maximal score ("Washing hair", "Getting out of bed", "Sit on chair for 30 min", and "Sleep" whereas 11 items did not reach this level in our sample. This may be due to the use of postoperative loco-regional analgesia in 92% of our sample.

4.1. Limitations

As early as in 1994, Dales and al. mentioned that cancer patients fared quite differently from other patients having had a thoracotomy [26]. Our sample includes a vast majority of cancer patients. We have no reason to believe that the results in the 23 non-cancerous patients differ from those of the whole group but were not able to prove it, as the size of the noncancerous patient group was too small to perform worthwhile multidimensional calculations while removing such patients from our sample would have marred the external validity of our study.

We should also insist that we performed a monocentric study in a tertiary hospital. Consequently, our results may not be directly transferable to other locations.

Our proposed scoring system lumps together (a) tasks that were never performed by the patient, and tasks that were performed previously but are not impacted (b) because the patient has no residual pain or (c) because current pain has no ill-effects on this task.

Since the tasks assessed in the RQ are fairly common, (a) is unlikely to be a major issue but some of the activities for which a floor effect was shown may be culture-bound; for instance, playing "*pétanque*" (a form of lawn bowling), is certainly an activity that is more relevant to most French individuals than swimming while biking is more often considered as a leisure activity than as a means of transport. Regarding (b) and (c) since a question on "being in pain" was opening the bundle mailed to participants, 4 months after surgery, it can be said that 244 items (21.4% of all scored) were given non-zero scores by 47 patients, i.e. 69% of those that had reported no residual pain (data not shown). It may be worthwhile to add a dichotomous question (pain/no pain) to the RQ before attempting to clarify its scoring system.

For many questions, the maximal score was not reached, an unlikely situation for some activities such as "getting out of bed", "coughing" or "sleeping". One may hypothesise that patients have learnt to "live with it"; fortunately, the reduction of scoring range for some items does not seem to impair the discriminating potency (sensitivity) of the instrument.

5. Conclusion

The flawless translation of the RQ leads to a questionnaire that is easily accepted by French speaking patients. Given the scoring approach that was used, the questionnaire has suitable basic psychometric properties. Due to the limitations of our experimental paradigm, we were not able to verify its intra-rater reliability. Given this caution, RQ adds to the armamentarium of assessment tools that allow choosing thoracotomy solutions not only from an economic point of view but based on the patients' view of the surgery outcome.

Disclosure of interest

The authors declare that they have no competing interest.

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