FOLIA MEDICA CRACOVIENSIA
Vol. LIV, 4, 2014: 35–44
PL ISSN 0015-5616

Tomasz Bonczar[1], Bartosz Rutowicz[1], Ewa Mizia[1], Paweł Depukat[1,2], Ewa Walocha[3], Piotr Pełka[4], Krzysztof A. Tomaszewski[1,5], Jerzy A. Walocha[1]

PRELIMINARY VALIDATION OF THE IOF QLQ AND COMPARISON WITH THE SF-36 IN PATIENTS AFTER A DISTAL RADIUS FRACTURE

Abstract: Aim: The aim of this study was to report preliminary validation data on the Polish version of the International Osteoporosis Foundation Quality of Life Questionnaire (IOF QLQ) for patients with a distal radius fracture (DRF).
Materials and Methods: Patients were eligible if they were between 18–80 years and were within 1–3 days after a non-comminuted DRF. All patients filled out the Polish version of the IOF QLQ, the Short Form 36 (SF-36) and a demographic questionnaire. Assessment points were set as soon as possible after the fracture, 7 days, 6 weeks, and 3 months after the fracture. Standard validity and reliability analyses were performed.
Results: Fifty-eight patients (42 women — 72.4%) agreed to take part in the study (mean age of the group 65.7 ± 9.3 years). Cronbach's alpha coefficients showed positive internal consistency (0.82–0.87). The interclass correlations for the IOF QLQ domains and the overall score ranged from 0.82 to 0.93. Satisfactory convergent and discriminant validity of the IOF QLQ was seen.
Conclusions: Preliminary data show that the Polish version of the IOF QLQ for patients with a DRF is a reliable and valid tool for measuring health-related quality-of-life (HRQoL). However, further studies are needed to demonstrate the full psychometric and clinical properties of the IOF QLQ in patients with a fracture of the wrist.

Key words: distal radius fracture; IOF QLQ; pilot-testing; SF-36; validation; wrist.

INTRODUCTION

In the USA the prevalence of distal radius fractures (DRF) is estimated to exceed 600,000 per year [1]. Among the myriad of risk factors which may cause this condition are osteoporosis, long-term glucocorticosteroids use, vitamin D deficiency, as well as environmental and seasonal conditions [2, 3].

DRFs occur early in the course of osteoporosis while many patients are still employed and active. That is why the socioeconomic toll of this type of fracture should not be underestimated [4].

In modern days health-related quality-of-life (HRQoL) assessment after a DRF is as important as the functional outcome [5]. There are several tools available to assess recovery after a DRF — specific for wrist fracture (e.g. patient-rated wrist evaluation — PRWE), the whole upper extremity (e.g. disability of the arm, shoulder and hand questionnaire — DASH and its abbreviated version — quickDASH) or generic questionnaires such as the Short Form 36 (SF-36) or the EQ-5D [4, 6].

In 2010 a tool specific for HRQoL assessment in patients after a wrist fracture has been developed by the Working Group for Quality of Life of the International Osteoporosis Foundation (IOF) — the IOF quality of life questionnaire for patients with wrist fracture (IOF QLQ) [4]. Validation data from this study showed that this new tool is reliable and responsive in measuring HRQoL. The latter combined with the fact that Polish clinical practice lacks validated tools for HRQoL assessment in patients after a DRF encouraged us to undertake this study. Our group has previous experience with studies concerning questionnaire validation [7, 8].

The aim of this study was to provide preliminary validation data on the Polish version of the IOF quality of life questionnaire for patients with a DRF.

MATERIALS AND METHODS

The patients, for this preliminary prospective case-control study, were recruited between January 2013 and January 2014, in two hospitals in Krakow (Poland).

The study group comprised patients with a recent DRF (treated surgically or non-surgically). Patients were eligible if they were above 18 and below 80 years old and were within 1–3 days after a DRF. Exclusion criteria included lack of consent to participate in the study, inability to understand or complete the questionnaires, reoperation or remanipulation of the fracture, comminuted or pathological fractures, patients after polytrauma or patients with diseases having a severe impact on HRQoL (e.g. cancer).

INTERVIEW AND EXAMINATION PROCEDURE

The patients were approached during their visits at the outpatient clinics of the participating centers or during their stay at the clinic, and informed about the study. The interview and examination only took place after written informed consent was obtained. The whole procedure was performed by qualified clinical staff (medical doctors).

Baseline patient characteristics were gathered using a personal questionnaire. These included gender, age, date, side (left/right, dominant/non-dominant), type of fracture and type of treatment (surgical or non-surgical — closed reduction

and casting). Next the examining clinician asked the patient to fill in the IOF QLQ and the SF-36.

Each patient was first examined as soon as possible after the fracture (usually at the same day the fracture occurred or during the next 24 hours). Next the patients were reexamined during each control visit at 7 days, 6 weeks, and 3 months post fracture.

A subset of randomly chosen patients (based on a computer generated algorithm; n = 30) completed an additional interview for stability assessment at 13 weeks post fracture. All patients agreed to fill in the questionnaire a second time.

THE SF-36 HEALTH SURVEY

The SF-36 Health Survey is composed of 36 questions and standardized response choices, organized into eight multi-item scales: physical functioning (PF), role limitations due to physical health problems (RP), bodily pain (BP), general health perceptions (GH), vitality (VT), social functioning (SF), role limitations due to emotional problems (RE), and general mental health (MH). All raw scale scores are linearly converted to a 0 to 100 scale, with higher scores indicating higher levels of functioning or well-being. In this study we have used the pretranslated Polish version of the SF-36 [9].

THE IOF QUALITY OF LIFE QUESTIONNAIRE FOR PATIENTS WITH WRIST FRACTURE

The IOF QLQ is composed of 12 questions scored on a 1 to 5 Likert scale. The questions form four domains — pain (question no. 1), upper limb symptoms (questions no. 2–4), physical function (questions no. 5–11), and general health (question no. 12). The scores on individual questions were summed up to form an overall score ranging from 12 to 60. This was later recalculated by linear transformation of raw scores into a score from 0 to 100, with 0 representing the best possible HRQoL [4].

The translation of the IOF QLQ was performed as per the European Organization for Research and Treatment of Cancer (EORTC) translation procedure [10], as it is one of the best established, and tested translation procedures. The preliminary Polish version of the IOF QLQ was pilot-tested in a mixed group of 12 Polish patients with a DRF (mixed time since fracture occurred, different treatment methods). Patients found all of the IOF QLQ questions acceptable and understandable. No language changes were needed to be made to the original translation.

STATISTICAL ANALYSIS

Several pre-planned standard psychometric tests were conducted. These approaches can be seen in the EORTC Module Development Guidelines [11]. To analyze the data descriptive statistics (mean, standard deviation, percentage distribution) were used. Pearson product-moment correlations or Spearman rank correlations (as appropriate) were calculated between similar domains of the two questionnaires.

The significance level was set at $p < 0.05$. Statistical analysis was conducted using computer software Statistica 10.0 PL by StatSoft Poland (licensed to the Jagiellonian University Medical College).

VALIDITY

To confirm the hypothesized domain structure of the IOF QLQ convergent and discriminant validity were used. Convergent validity was assessed by correlating each item with its own domain of the IOF QLQ [12–14]. Evidence of item convergent validity was defined as a correlation of 0.40 or greater between an item and its own domain (corrected for overlap). Discriminant validity was assessed by correlating each item with any other domain of the IOF QLQ [15, 16]. A scaling success for an item was seen when the correlation between an item and its own domain (corrected for overlap) was significantly higher (i.e. two standard errors or greater) than its correlation with other scales [14, 16]. Calculating convergent and discriminant validity was only performed for "upper limb symptoms" and "physical function" domains because of the original structure of the questionnaire.

RELIABILITY

Cronbach's alpha coefficient was calculated to assess the internal consistency of the preliminary Polish version of the IOF QLQ. Internal consistency estimates of a magnitude of >0.70 were considered acceptable for group comparisons [14, 17]. Cronbach's alpha was calculated for "upper limb symptoms" and "physical function" domains as well as for the overall questionnaire score.

Test-retest reliability (stability) of the IOF QLQ was assessed using interclass correlations (ICC) between baseline at 3 months and retest one week later. A correlation of >0.80 was considered 'good' [13, 14].

STATISTICAL ANALYSIS — RESPONSIVENESS TO CHANGE OVER TIME

Assessment of responsiveness of the scales to treatment was done by comparing IOF QLQ scores at different time points of the study (baseline vs. 7 days, 6 weeks, and 3 months) using the Students' t-test.

MEASURES OF IOF QLQ ACCEPTABILITY

The acceptability of the IOF QLQ was assessed by the response rate, percentage of missing data, assistance and time needed to complete the questionnaire and details of items considered upsetting, confusing or difficult in the questionnaire [7, 8, 13]. This assessment was carried out in the same way as in the pilot-testing phase.

ETHICS

The research protocol was approved by the Jagiellonian University Bioethics Committee (Registry No. KBET/176/B/2011 and KBET/187/B/2014). The study has been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. Written, informed consent was obtained from every participant before beginning the interview.

RESULTS

PATIENT CHARACTERISTICS AND ACCEPTABILITY

During the 12 month recruitment period a total of 58 patients (42 women — 72.4%), with a mean age of 65.7 ± 9.3 years, agreed to take part in the study and were included in the study group. Table 1 presents baseline characteristics of the study group and attrition to follow-up. All patients suffered from Colles type fractures.

Table 1

Baseline characteristics of study participants.

Feature	Study group (n = 58)
Gender (male:female) (%)	16:42 (27.6% : 72.4%)
Age (mean ± SD) [years]	65.7 ± 9.3
Side of fracture (right:left) (%)	21:37 (36.2% : 63.8%)
Fracture of the dominant:non-dominant extremity (%)	29:29 (50% : 50%)
Treatment type (surgical:non-surgical) (%)	19:39 (32.8% : 67.2%)
Attrition to follow-up (n) (%) 0 days — 7 days — 6 weeks — 3 months	58 (100%) — 58 (100%) — 55 (94.8%) — 48 (82.8%)

SD — standard deviation; n — number.

Thirty-nine interviewees (67.2%) required assistance completing the questionnaires. Help was required mostly in order to mark the answers due to the dominant extremity being fractured or because of eye-sight problems and lack of reading glasses. The total time for completion of the questionnaires (excluding

physical examination) was 18.5 ± 5.0 minutes without assistance and 25.4 ± 5.9 with assistance.

VALIDITY AND RELIABILITY

For the IOF QLQ "upper limb symptoms" domain convergent validity was 0.63–0.74, discriminant validity was 0.19–0.37 and Cronbach's alpha was 0.82. For the "physical function" domain convergent validity was 0.58–0.64, discriminant validity was 0.10–0.24 and Cronbach's alpha was 0.85. Cronbach's alpha calculated for the overall questionnaire score was 0.87.

The ICCs for the IOF domains and the overall score ranged from 0.82 to 0.93, showing good repeatability of the scales.

RESPONSIVENESS TO CHANGE OVER TIME

The IOF QLQ and the SF-36 mean scores, and their change over time is shown in Table 2.

Table 2

The IOF QLQ and the SF-36 score changes over time.

Scale/Domain	Baseline n = 58	7 days n = 58	6 weeks n = 55	3 months n = 48
IOF-QLQ				
Pain	71.8 (7.3)	54.2 (16.9) p <0.0001	27.1 (12.1) p <0.0001	14.6 (10.1) p <0.0001
Upper limb symptoms	49.1 (17.3)	61.0 (21.1) p <0.0001	33.5 (11.0) p <0.0001	19.8 (13.7) p <0.0001
Physical function	82.2 (10.7)	84.1 (16.5) p = 0.46	63.7 (13.8) p <0.0001	30.5 (12.6) p <0.0001
General health	81.3 (20.3)	84.5 (15.7) p = 0.32	59.0 (13.4) p <0.0001	35.1 (13.7) p <0.0001
Overall score	73.3 (13.7)	65.9 (11.0) p = 0.33	48.3 (10.8) p <0.0001	27.8 (9.7) p <0.0001
SF-36				
PF	57.1 (24.1)	53.5 (22.5) p = 0.41	67.2 (24.4) p = 0.03	72.5 (19.3) p = 0.0003
RP	17.0 (25.6)	26.9 (30.1) p = 0.06	39.4 (24.9) p = 0.0001	54.0 (27.3) p <0.0001
BP	38.7 (24.4)	45.1 (19.3) p = 0.12	77.2 (23.1) p <0.0001	81.0 (20.9) p <0.0001

Scale/Domain	Baseline n = 58	7 days n = 58	6 weeks n = 55	3 months n = 48
GH	61.7 (18.5)	64.8 (21.0) p = 0.40	75.3 (19.8) p = 0.0003	75.9 (21.4) p = 0.0004
VT	53.3 (16.5)	62.0 (23.6) p = 0.02	67.2 (20.9) p <0.0001	73.4 (16.6) p <0.0001
SF	50.5 (14.6)	51.8 (20.1) p = 0.69	70.0 (21.3) p <0.0001	82.4 (23.0) p <0.0001
RE	42.4 (21.7)	46.3 (21.5) p = 0.33	70.9 (25.1) p <0.0001	83.0 (19.5) p <0.0001
MH	65.8 (21.0)	70.9 (21.7) p = 0.20	79.0 (24.1) p = 0.003	85.8 (19.1) p <0.0001

Data presented as mean values ± (SD) and p values comparing baseline and specific time point scores.
SD — standard deviation; n – number; PF — physical functioning; RP — role limitations due to physical health problems; BP — bodily pain; GH — general health perceptions; VT – vitality; SF — social functioning; RE — role limitations due to emotional problems; MH — general mental health.

CORRELATIONS BETWEEN SIMILAR DOMAINS OF THE IOF QLQ AND THE SF-36

The majority of correlations between corresponding domains of the IOF QLQ and the SF-36 questionnaires were highly significant ($p < 0.001$), and all were strongly negative ($r = -0.47$ to $r = -0.71$) due to the difference in scoring of the two questionnaires. The strongest correlations were noted between the "pain" and "bodily pain" scales ($r = -0.71$; $p < 0.001$), both "physical function" scales ($r = -0.65$; $p < 0.001$), and the "upper limb symptoms" and the "role limitations due to physical health problems" ($r = -0.58$; $p < 0.001$) scales.

DISCUSSION

This manuscript reports on the preliminary validation of the IOF QLQ for patients with wrist fracture. The current study, though based on data received from a limited amount of patients has confirmed that the tested questionnaire is an acceptable and psychometrically adequate measure to collect HRQoL data in Polish patients with a DRF.

It is important to bear in mind that HRQoL can be both assessed in a broad spectrum — i.e. by using generic instruments, but also in a tailored way by using tools made specifically for HRQoL assessment in patients with a certain disease. The latter, if they exist for a specific condition, should be used preferentially.

Results presented in this study have shown that the IOF QLQ can be regarded as an acceptable tool for HRQoL assessment in patients after a DRF. It is

worth to underline that time to questionnaire completion or the fact if a patient requires assistance to complete the questionnaire is not something that is widely reported in orthopedic HRQoL studies. This unfortunately precludes from comparing our results to other studies.

Data analysis revealed that both tested IOF QLQ domains as well as its overall score demonstrated appropriate Cronbach's alpha values, confirming the results from the international field study [4].

All of the four IOF QLQ domains, as well as its overall score, showed adequate responsiveness to change at almost every time-point, apart from the second assessment 7 days after the fracture. This early post-trauma period is characterized by a varying clinical course, which may lead to significant short-term changes in HRQoL perception among different patients. Though the study is only a preliminary report, it has demonstrated that the IOF QLQ has adequate responsiveness to change over time during a 3 month period in patients after a DRF. The rapid and significant HRQoL changes seen in the first 3 months after the fracture stand in agreement with other similar studies [4, 6]. Seeing the results at 3 months, we could speculate that after one year post DRF a patients' HRQoL could return to the pre-injury level. The SF-36 scores back up a similar thesis. However the SF-36 added the information that the return to health was not only limited to physical function but also signaled improvement of the patients mental aspect of HRQoL.

The strong correlations between similar IOF QLQ domains and the SF-36 scales are an important finding. Though generic measures, like the SF-36, have some degree of specificity, it should be recognized that the term generic is relative and does not indicate universal applicability [18]. Due to the similarities between the two questionnaires it would be possible to use the IOF QLQ and the SF-36 in conjunction to comprehensively assess HRQoL in patients with a DRF. This warrants further studies, but perhaps it could be possible to shorten the time needed for questionnaire completion by excluding the SF-36 questions pertaining to physical function, as this part would be adequately covered by the IOF QLQ.

This study reports preliminary validation data on the IOF QLQ, but it is not without other limitations. The inclusion/exclusion criteria may have biased the HRQoL score. Patients with comminuted fracture were excluded from the study, and their HRQoL would most probably be lower than the scores obtained in this study. However this would most probably have no impact on the overall psychometric properties of the IOF QLQ. It would only influence HRQoL score changes over the follow-up period. We decided against including these patients in our study group as the clinical course of their disease may significantly vary from patients who do not suffer from a comminuted DRF, due to the complex nature of the fracture itself. We also did not compare the IOF QLQ to other "wrist-specific" instruments such as the DASH or the PRWE. However this was done intentionally, as this study was just aimed at reporting preliminary IOF QLQ validation data and

comparing them to those obtained using a generic HRQoL measure — the SF36. We plan to compare the IOF QLQ to other "wrist-specific" tools in later studies.

Preliminary data show that the Polish version of the IOF QLQ for patients with a DRF is a reliable and valid tool for measuring HRQoL. However, further studies are needed to demonstrate the full psychometric and clinical properties of the IOF QLQ in patients with a wrist fracture.

ACKNOWLEDGMENTS, FUNDING, AND DISCLOSURES

This study has not been funded.
Conflict of interest — none declared.

REFERENCES

1. *Chung K.C., Spilson S.V.*: The frequency and epidemiology of hand and forearm fractures in the United States. J Hand Surg Am. 2001; 26: 908–915. **— 2.** *Oyen J., Gjesdal C.G., Brudvik C., et al.*: Low energy distal radius fractures in middle-aged and elderly men and women–the burden of osteoporosis and fracture risk: A study of 1794 consecutive patients. Osteoporos Int. 2010; 21: 1257–1267. **— 3.** *Oyen J., Apalset E.M., Gjesdal C.G., Brudvik C., Lie S.A., Hove L.M.*: Vitamin D inadequacy is associated with low-energy distal radius fractures: a case-control study. Bone. 2011; 48: 1140–1145. **— 4.** *Lips P., Jameson K., Bianchi M.L., et al.*: Validation of the IOF quality of life questionnaire for patients with wrist fracture. Osteoporos Int. 2010; 21: 61–70. **— 5.** *Karantana A., Downing N.D., Forward D.P., et al.*: Surgical treatment of distal radial fractures with a volar locking plate versus conventional percutaneous methods: a randomized controlled trial. J Bone Joint Surg Am. 2013; 95: 1737–1744. **— 6.** *MacDermid J.C., Richards R.S., Donner A., Bellamy N., Roth J.H.*: Responsiveness of the SF-36, disability of the arm, shoulder, and hand questionnaire, patient-rated wrist evaluation, and physical impairment measurements in evaluating recovery after a distal radius fracture. J Hand Surg. 2000; 25: 330–340. **— 7.** *Chmielowska K., Tomaszewski K.A., Pogrzebielski A., Brandberg Y., Romanowska-Dixon B.*: Translation and validation of the Polish version of the EORTC QLQ-OPT30 module for the assessment of health-related quality of life in patients with uveal melanoma. Eur J Cancer Care (Engl). 2013; 22: 88–96. **— 8.** *Paradowska D., Tomaszewski K.A., Bałajewicz-Nowak M., et al.*: Validation of the Polish version of the EORTC QLQ-CX24 module for the assessment of health-related quality of life in women with cervical cancer. Eur J Cancer Care (Engl). 2014; 23: 214–220. **— 9.** *Tylka J., Piotrowicz R.*: Quality of life SF-36 questionnaire — the Polish version. Kardiol Pol. 2009; 67: 1166–1169 (in Polish). **— 10.** *Dewolf L., Koller M., Velikova G., et al.*: EORTC quality of life group translation procedure. European Organisation for Research and Treatment of Cancer; Brussels 2009.

11. *Johnson C., Aaronson N., Blazeby J.M., et al.*: Guidelines for developing Quality of Life Questionnaires. 4th ed. Brussels (EORTC Publications), 2011. **— 12.** *Püsküllüoğlu M., Tomaszewski K.A., Bottomley A., et al.*: Validation of the Polish version of the EORTC QLQ-BM22 module for the assessment of health-related quality of life in patients with bone metastases. Qual Life Res. 2014; 23: 527–532. **— 13.** *Paradowski J., Tomaszewski K.A., Bereza K., et al.*: Validation of the Polish version of the EORTC QLQ-OV28 module for the assessment of health-related quality of life in women with ovarian cancer. Expert Rev Pharmacoecon Outcomes Res. 2014; 14: 157–163. **— 14.** *Fayers P., Machin D.*: Quality of Life: The Assessment Analysis and Interpretation of Patient Reported Outcomes. Chichester (Wiley), 2007. **— 15.** *Wrażeń W., Golec E.B., Tomaszewska I.M., Walocha E., Dudkiewicz Z.,*

Tomaszewski K.A.: Preliminary psychometric validation of the Polish version of the EORTC Elderly module (QLQ-ELD14). Folia Med Carcov. 2014; 54: 35–45. **— 16.** *Tomaszewska I.M., Głowacki R., Paradowska D., Walocha E.*: Preliminary psychometric validation of the Polish version of the EORTC Head and Neck module (QLQ-H&N35). Folia Med Cracov. 2013; 53: 55–63. **— 17.** *Püsküllüoğlu M., Tomaszewski K.A., Zygulska A.L., et al.*: Pilot testing and preliminary psychometric validation of the Polish translation of the EORTC INFO25 questionnaire. Appl Res Qual Life. 2014; 9: 525–535. **— 18.** *Baron R., Elashaal A., Germon T., Hobart J.*: Measuring outcomes in cervical spine surgery: think twice before using the SF-36. Spine (Phila Pa 1976). 2006; 31: 2575–2584.

[1] Department of Anatomy
Jagiellonian University Medical College
ul. Kopernika 12, 31-034 Kraków, Poland
Head: prof. Jerzy A. Walocha MD, PhD

[2] Department of Traumatology
and Neuroorthopaedics
Rydygier Specialistic Hospital
os. Zlotej Jesieni 1, 31-826 Kraków, Poland
Head: Piotr Kłosiński MD, PhD

[3] Department of Clinical Nursing,
Institute of Nursing
Jagiellonian University Medical College
ul. Kopernika 25, 31-501 Kraków, Poland
Head: Asst. Prof. Maria Kózka MSc, PhD

[4] Department of Orthodontics,
Institute of Dentistry
Jagiellonian University Medical College
ul. Montelupich 4, 31-155 Kraków, Poland
Head: prof. Bartłomiej Loster DDS, PhD

[5] Department of Orthopaedics and Trauma Surgery
5th Military Hospital
ul. Wrocławska 1–3, 30-901 Kraków, Poland
Head: col. prof. Edward B. Golec MD, PhD

Corresponding author:
Krzysztof A. Tomaszewski
Department of Anatomy
Jagiellonian University Medical College
ul. Kopernika 12, 31-034 Kraków, Poland
Phone/Fax: +48 12 422 95 11
E-mail: krtomaszewski@gmail.com