Incorporating Quality of Life Metrics in Interventional Oncology Practice

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Abstract

Keywords

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- interventional radiology
- quality of life
- visual analog scale
- numeric rating scale
- brief pain inventory
- EORTC-30
- FACT-G

Interventional radiologists care for a large number of cancer patients with the breadth of palliative intent minimally invasive procedures that we provide. Understanding our meaningful impact on patients' quality of life is essential toward validating our role in the palliation of cancer patients. As such, it is critically important for interventional radiologists to understand common instruments used for the reporting of patient's quality of life measures. Common instruments used to measure pain and quality of life for cancer patients include the numerical rating scale, visual analog scale, brief pain inventory, the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire, and the Functional Assessment of Cancer Therapy. An ideal quality of life instrument should be a patient reported outcome measure across multiple domains (e.g., physical health, psychological, social), and be both validated and reliable.

Objectives: Upon completion of this article, the reader will be able to identify common instruments used to measure quality of life metrics for the expanding number of patients under the care of interventional radiologists for palliative intent treatments.

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Increased Role of Palliative Care in Oncology

Multiple randomized controlled trials have associated the early integration of palliative care with improvements in patient's

quality of life (QOL) and overall survival.^{1–5} A pivotal trial by Temel et al demonstrated improved overall survival benefit in patients with metastatic non-small cell lung cancer who received early adjunctive palliative care as compared with those who did not.³ As the integration and expansion of palliative care services for patients with advanced cancer continues to meet growing demands, multidisciplinary approaches to the management of patient's well-being, including symptom management, will be necessary. Integration of interventional radiology with palliative care, medical oncology, radiation oncology, and surgical oncology toward the investigation of patient-centric outcomes will further define our role in the palliation of cancer patients.⁶ As such, it is critically important for interventional radiologists to understand common instruments used for the reporting of patient's QOL measures.

Role of Interventional Radiology in the Palliative Care of Cancer Patients

Interventional radiologists are a subspecialty of physicians with the expertise in performing minimally invasive image-guided procedures. Our national societies have drafted a

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consensus “Global Statement Defining Interventional Radiology,”⁷ listing the following core features of interventional radiology:

1. Expertise in diagnostic imaging and radiation safety.
2. Expertise in image-guided, minimally invasive procedures and techniques as applied to multiple disease and organs.
3. Expertise in the evaluation and management of patients suitable for the image-guided interventions included in the scope of interventional radiology practice.
4. Continual invention and innovation of new techniques, devices, and procedures.

As such, the core skills of an interventional radiologist translate exceptionally well to the palliation of patients with advanced cancer. Oncology patients in need of palliation usually have complex anatomy and comorbidities as a consequence of advanced stage cancer, which preclude them from invasive procedures requiring anesthesia or surgery. Minimally invasive image-guided interventions provide alternatives to patients with otherwise limited treatment options.

The breadth of procedures interventional radiologists can offer for palliation is vast and includes ablation for pain control, tunneled peritoneal or pleural catheter placement for symptomatic fluid drainage, peritoneovenous shunt placement for symptomatic fluid, decompressive gastrostomies or cecostomies for gastric and bowel obstruction, biliary drainage for obstructive jaundice, blocks and neurolysis for pain control, transarterial embolization for uncontrolled hemorrhage, and venous stenting for superior vena cava syndrome and symptomatic lower extremity swelling.^{8,9} The innumerable procedures interventional radiologists have developed and implemented into clinical practice speak to our integral role in the palliation of cancer patients.

Quality of Life Measures

Quality of life can be simply defined as a personal sense of well-being;¹⁰ however, as Tchekmedyian et al noted “quality of life cannot be validly measured, because it means so many different things to so many different people.”¹¹ In one of the original published works on the QOL in cancer patients, Olschewski et al summarized QOL as: “1. Multidimensional, comprising important elements of a patient’s emotional, social, and physical well-being; 2. Subjective, relying primarily on the patient’s own judgements; and 3. Non-static and subject to changes over a patient’s lifetime.”¹² The principles underlying this definition of QOL still resonate in current medical practice and serve as the foundation from which current QOL instruments are based. An ideal QOL assessment should (1) encompass multiple domains (emotional, social, and physical well-being), (2) be patient reported (subjective), (3) be valid and reliable, and (4) easily be implemented into practice. Reliability is the ability for the instrument to obtain similar results for stable patients undergoing repeat assessments. Validity is the extent the instrument is appropriately measuring what it is intended to measure.

One of the most ubiquitous QOL assessments is the numeric rating scale (NRS) combined with the visual analog scale (VAS; ▶Fig. 1). The NRS asks patients to rate their pain on a scale of 0 to 10 with 0 indicating no pain and 10 indicating worst pain.¹³ The VAS is the associated straight line for which patients can demarcate their pain, with one end of the line representing no pain and the other end representing the worst pain. Adaptions of the scale have associated faces (Wong-Baker) to correspond with the demarcated level of pain (▶Fig. 1).¹⁴ Advantages of the NRS and VAS include its ease of implementation into practice and its reliability. However, the NRS and VAS

Fig. 1 Numerical rating scale/visual analog scale.

lack depth in assessment of multiple domains and are primarily used to evaluate the sole symptom of pain.

The current brief pain inventory (BPI) is a modification of the original Wisconsin Brief Pain Questionnaire developed by Daut et al.¹⁵ The questionnaire was designed to improve upon the validity of preexisting pain assessments such as the NRS or VAS. As stated by Cleeland, “the BPI was designed to capture two dimensions of pain: severity and interference. The BPI was also intended to capture two components of interference—activity and affect (emotions).”¹⁶ Current versions of the BPI include both a short form which takes approximately 5 minutes to complete and a long form which takes approximately 10 minutes to complete.¹⁶ In addition to evaluating the “sensory” dimension of pain similar to NRS or VAS, the BPI also evaluates for a “reactive” dimension of pain.¹⁷ As such, measures of the short-form BPI not only include ratings of pain on a 0 to 10 numerical scale at its “worst,” “least,” “average,” and “right now” but also include ratings on a 0 to 10 numerical scale of how pain affects a patient’s “general activity,” “mood,” “walking ability,” “normal work,” “relations with other people,” “sleep,” and “enjoyment of life” (►Fig. 2). The BPI has been validated and used in over 400 studies worldwide and was used as an endpoint in many of the trials for cancer bone pain that have involved interventional radiology.^{18–22}

The European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire (QLQ) core 30 (C30) is one of the most commonly used QOL instruments for oncology trials. The EORTC-QLQ-C30 has been used in over 3,000 studies and been validated in over 100 languages.¹⁶ The EORTC-QLQ-C30 instrument consists of five functional scales

(physical, role, emotional, cognitive, and social), three symptom scales (fatigue, nausea, and vomiting and pain), and a global health status/QOL scale. It contains six single items (dyspnea, insomnia, appetite loss, constipation, diarrhea, and financial difficulties; ►Fig. 3).^{23,24} Similar to the scales described earlier (NRS, VAS, BPI), the EORTC-QLQ-C30 is easy to implement with most patients being able to complete the questionnaire with no assistance in an average time of approximately 11 minutes.²³ The EORTC-QLQ-C30 is a core set of questions designed for general use in oncology patients; cancer-specific modules are used in conjunction with the core questions to capture aspects of QOL important to specific patient subgroups.²⁵

Schaafsma and Osoba cross-validated Karnofsky Performance Status (KPS) to the EORTC-QLQ-C30.²⁶ The authors and found that the EORTC-QLQ-C30 was a much broader concept, capturing measures of functioning in the non-physical dimensions of social, emotional, and cognitive well-being as well as the level of distress in the physical dimensions of pain, breathing, and fatigue as compared with the KPS.

The Functional Assessment of Cancer Therapy—General (FACT-G) developed by Cella et al.²⁷ is a commonly used alternative instrument to the EORTC-QLQ-C30. The FACT-G is also designed as a core set of questions for general use in cancer patients, with additional cancer-specific questionnaires available. The current version of FACT-G (Version 4) comprises 27 items, measured on Likert scales of 0 (Not at all) to 4 (Very much), which encompass four domains: physical well-being, social/family well-being, emotional well-being,

Figure 2a: Brief Pain Inventory (Short Form)

STUDY ID # _____ DO NOT WRITE ABOVE THIS LINE HOSPITAL # _____

Date _____ Time _____

Name _____ Last _____ First _____ Middle Initial _____

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and lumbagoes). Have you had pain other than these everyday kinds of pain today?

1. Yes 2. No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.

3. Please rate your pain by circling the one number that best describes your pain at its **worst** in the last 24 hours.

0 1 2 3 4 5 6 7 8 9 10
No Pain Pain as bad as you can imagine

4. Please rate your pain by circling the one number that best describes your pain at its **least** in the last 24 hours.

0 1 2 3 4 5 6 7 8 9 10
No Pain Pain as bad as you can imagine

5. Please rate your pain by circling the one number that best describes your pain on the **average**.

0 1 2 3 4 5 6 7 8 9 10
No Pain Pain as bad as you can imagine

6. Please rate your pain by circling the one number that tells how much pain you have **right now**.

0 1 2 3 4 5 6 7 8 9 10
No Pain Pain as bad as you can imagine

Figure 2b: Brief Pain Inventory (Long Form)

STUDY ID # _____ DO NOT WRITE ABOVE THIS LINE HOSPITAL # _____

Date _____ Time _____

Name _____ Last _____ First _____ Middle Initial _____

7. What treatments or medications are you receiving for your pain?

8. In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
No Relief Complete Relief

9. Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere Completely Interferes

B. Mood

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere Completely Interferes

C. Walking Ability

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere Completely Interferes

D. Normal Work (includes both work outside the home and housework)

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere Completely Interferes

E. Relations with other people

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere Completely Interferes

F. Sleep

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere Completely Interferes

G. Enjoyment of life

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere Completely Interferes

Fig. 2 Brief pain inventory—short form (a and b).

and functional well-being (–Fig. 4). It is easy to implement with patients able to complete the instrument in approximately 5 to 10 minutes.

Many studies have investigated the differences between the EORTC-QLQ-C30 and FACT-G instruments.^{28–33} Lockett et al summarized details of major differences between the two instruments in a systematic review.³⁰ Eight articles which directly compared the two instruments found that the correlation between corresponding scales is generally moderate to high except for in the social domain. Overall, both instruments have been demonstrated to be easy to implement, and have reliability and validity.

Incorporation of Quality of Life Measures in Interventional Radiology

Evaluation of QOL metrics has been extremely limited in the field of interventional radiology. Very few studies have robust information regarding the impact of our interventions on patient’s QOL.³⁴ In a summary of interventional oncology clinical trials by Arai, the predominant number of trials studied overall survival, progression-free survival, and adverse events. Of the registered interventional oncology trials conducted for palliative care, greater than one-third had a primary endpoint of safety rather than QOL.³⁵

ENGLISH

EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials:

--	--	--	--

Your birthdate (Day, Month, Year):

--	--	--	--	--	--	--	--	--	--

Today's date (Day, Month, Year): 31

--	--	--	--	--	--	--	--	--	--

	Not at All	A Little	Quite a Bit	Very Much
1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2. Do you have any trouble taking a <u>long</u> walk?	1	2	3	4
3. Do you have any trouble taking a <u>short</u> walk outside of the house?	1	2	3	4
4. Do you need to stay in bed or a chair during the day?	1	2	3	4
5. Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

During the past week:

	Not at All	A Little	Quite a Bit	Very Much
6. Were you limited in doing either your work or other daily activities?	1	2	3	4
7. Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8. Were you short of breath?	1	2	3	4
9. Have you had pain?	1	2	3	4
10. Did you need to rest?	1	2	3	4
11. Have you had trouble sleeping?	1	2	3	4
12. Have you felt weak?	1	2	3	4
13. Have you lacked appetite?	1	2	3	4
14. Have you felt nauseated?	1	2	3	4
15. Have you vomited?	1	2	3	4
16. Have you been constipated?	1	2	3	4

a

Please go on to the next page

Fig. 3 European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire (QLQ)—Core 30 (a and b).

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ENGLISH

During the past week:

	Not at All	A Little	Quite a Bit	Very Much
17. Have you had diarrhea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your <u>family</u> life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your <u>social</u> activities?	1	2	3	4
28. Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you29. How would you rate your overall health during the past week?

1 2 3 4 5 6 7

Very poor

Excellent

30. How would you rate your overall quality of life during the past week?

1 2 3 4 5 6 7

Very poor

Excellent

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b

Fig. 3 (Continued)

Investigation of the impact on QOL of procedures performed primarily for palliative intent by interventional radiologists is warranted. For example, even though tunneled peritoneal and pleural catheters are primarily placed for symptomatic fluid relief, there is sparse data regarding their impact on QOL. The largest series of patients with indwelling peritoneal drainage catheters reported on by Lungren et al and Maleux et al both evaluated technical success, safety, and complication rates without assessing QOL measures.^{36,37} In a smaller series of 30 patients, Monsky et al evaluated the impact on QOL of both pleural and peritoneal drainage catheters; however, the QOL instrument

used was limited, consisting of a 10-point scale which included both patient- and physician-reported outcomes.³⁸

Interventional radiologists have a robust role in the multidisciplinary management of liver cancer and are incorporated in standard-of-care guidelines for both primary and secondary liver cancers.³⁹⁻⁴³ Both transarterial embolization and percutaneous ablation are well-established treatment options performed by interventional radiologists. The greatest evidence examining the effect of interventional radiology on QOL exists for the treatment of liver cancer. In a review of available literature, Ahmed et al evaluated the QOL of patients with hepatocellular carcinoma who were treated with transarterial

embolization.⁴⁴ From a total of 3,469 studies regarding transarterial embolization, the authors identified 14 studies that reported on QOL measures. For the 14 identified studies, a wide range of instruments were used to assess QOL including four groups which used their own unique assessments. Several of these studies will be detailed further later.

Several groups have longitudinally assessed the QOL of patients after transarterial embolization.^{45–47} Wible et al assessed the effect of primary chemoembolization on the health-related QOL in a series of 73 patients with hepatocellular carcinoma using the short form-36 (SF-36) assess-

ment tool. The investigators found improved mental health during the first 4 months of treatment; however, patient-perceived vitality worsened after the initial chemoembolization.⁴⁶ Xing et al evaluated the effect of drug-eluting bead chemoembolization on the health-related QOL in a series of 118 patients with hepatocellular carcinoma using the SF-36 assessment tool.⁴⁵ The authors found no significant changes in QOL immediately, 6 months, and 12 months after therapy as compared with baseline assessments.

Salem et al differentiated between radioembolization and chemoembolization by evaluating QOL measures.⁴⁸ In their

FACT-G (Version 4)

Below is a list of statements that other people with your illness have said are important. Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

<u>PHYSICAL WELL-BEING</u>		Not at all	A little bit	Some- what	Quite a bit	Very much
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

<u>SOCIAL/FAMILY WELL-BEING</u>		Not at all	A little bit	Some- what	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Q1	<i>Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please mark this box ☐ and go to the next section.</i>					
GS7	I am satisfied with my sex life	0	1	2	3	4

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Fig. 4 Functional assessment of cancer therapy—general (version 4). The first part is physical well-being and social/family well-being. The second part is emotional well-being and functional well-being.

FACT-G (Version 4)

Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

EMOTIONAL WELL-BEING		Not at all	A little bit	Some- what	Quite a bit	Very much
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness.....	0	1	2	3	4
GE3	I am losing hope in the fight against my illness.....	0	1	2	3	4
GE4	I feel nervous.....	0	1	2	3	4
GE5	I worry about dying.....	0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

FUNCTIONAL WELL-BEING		Not at all	A little bit	Some- what	Quite a bit	Very much
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling.....	0	1	2	3	4
GF3	I am able to enjoy life.....	0	1	2	3	4
GF4	I have accepted my illness.....	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now.....	0	1	2	3	4

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Fig. 4 (Continued)

study, patients undergoing either radioembolization ($n = 29$) or chemoembolization ($n = 27$) were prospectively evaluated with the FACT-Hepatobiliary (FACT-Hep) instrument. The authors found trends toward better overall QOL in the radioembolization as compared with the chemoembolization cohorts. Though significance was unable to be reached, the study serves as one of the few prospective interventional radiology trials to address QOL as the primary endpoint when evaluating between two potential treatment options.

Huang et al reported on QOL measures (FACT-Hep) in a prospective study of 389 patients who underwent either hepatic resection or percutaneous radiofrequency ablation in two similar cohorts of patients with solitary hepatocellular carcinomas.⁴⁹ The authors demonstrated that patients who were treated with percutaneous radiofrequency ablation had significantly better health-related QOL using the FACT-Hep instrument at all time points of the study ($p < 0.001$, $p < 0.001$, $p = 0.001$, $p = 0.003$ and $p = 0.025$; at 3, 6, 12, 24, and 36 months after intervention, respectively) as compared with patients treated with surgical resection. The dif-

ference in QOL can be attributed to a worsened QOL after surgery as compared with radiofrequency ablation at 3 months that persists throughout the study period. There was no reported difference in either overall or progression-free survival. Toro et al found conflicting results with better FACT-Hep scores reported in patients who underwent hepatic resection ($n = 14$) as compared with radiofrequency ablation ($n = 9$) at 24 months; however, their study reported on much fewer patients and was susceptible to selection bias as the patients who underwent surgical resection had better baseline liver reserve (100% as compared with 22% Child-Pugh A).⁵⁰

Further incorporation of QOL measures is necessary, as only 14 of several thousand potential transarterial embolization trials reported on QOL. In addition, multiple different QOL instruments were used in the studies. As interventional radiologists continue to integrate into standard-of-care paradigms for cancer patients, we should familiarize ourselves with common instruments for the assessment of their QOL, such as EORTC-QLQ-C30 and FACT-G. Nonetheless, the impact of embolization and ablation treatments on the QOL

of liver cancer patients is promising for the field of interventional radiology. The limited longitudinal information available suggests that minimally invasive options such as transarterial embolization are not detrimental to QOL. Minimally invasive options such as radiofrequency ablation may be QOL preserving as compared with more invasive alternatives such as hepatic resection. As such, interventional radiologists are poised to prove added value to the palliation of cancer patients. Further investigation of patient-centric outcomes related to palliative intent procedures interventional radiologists provide is necessary.

Conclusion

The integration of palliative care into standard oncologic practice is well merited, given its proven benefit toward patient's QOL and overall survival. Interventional radiologists care for a large number of cancer patients with the breadth of palliative intent minimally invasive procedures that we provide. Understanding our meaningful impact on patient's QOL is essential toward validating our role in the palliation of cancer patients. Ideally, a QOL measure should be patient reported, measure outcomes across multiple domains (e.g., physical health, psychological, social), and be both validated and reliable. Multidisciplinary investigation of patient-centric outcomes will further define the expanding role of interventional radiology in the palliation of cancer patients.

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