Cardiovasc Intervent Radiol (2023) 46:1657–1661
https://doi.org/10.1007/s00270-023-03530-x

EDITORIAL OTHER

An Update on Patient-Reported Outcomes in Interventional Radiology: The Future Measure of Our Success

Iain Irvine[1] · Reiltin Hayden[1] · Laura Greene[1] · Anthony G. Ryan[1]

Received: 25 February 2023 / Accepted: 29 July 2023 / Published online: 24 August 2023

Abstract The field of interventional radiology continues to expand rapidly, offering an increasing range of alternatives to open surgical procedures. This minimally invasive imaging-guided approach promises faster recovery times and a theoretically improved patient experience; however, there is limited evidence documenting that these promises are actually delivered. Patient-reported outcomes are a way of collecting data on the patient experience increasingly used in clinical trials and the provision of surgical services and informing clinical practice across a range of elective procedures. Currently underutilised in interventional radiology, patient-reported outcomes have the potential to significantly impact how we deliver care by allowing evaluation of the perceived benefit derived by a patient after undergoing a procedure and to permit comparison with more invasive open procedures from the patient perspective.

Keywords Patient-reported outcomes · Clinical practice · Interventional radiology · Quality standards · Patient care · Practice development

Introduction

There is an increasing focus on the patient's perspective in healthcare evaluation and clinical research. A medical intervention's efficacy has been traditionally measured in technical outcomes such as survival or objective measures of reduction in disease burden; however, the addition of the patient's experience of symptoms and quality of life (QoL) offer a more comprehensive evaluation of a treatment's effect. This evaluation is increasingly comprised of not only an intervention's clinical efficacy, but also whether it achieves a "desirable outcome" from the patient's perspective.

A patient-reported outcome (PRO), as defined by the Food and Drug Administration (FDA) [1], is "any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else". It is a recording of the patient's experience of an intervention pertaining to the patient's symptoms, functional status, and their health-related QoL [2]. In clinical trials, PROs provide data on subjective outcomes such as symptoms, disabilities and QoL. They are an important research tool as this information is not reliably obtainable by other means and are often used as secondary outcomes in clinical trials; for example in the ATTRACT trial [3] which examined the change in QoL following catheter-directed thrombolysis for deep venous thrombosis (DVT) using the VEINES-QOL instrument. PROs are particularly valuable in situations where there are no adequate objective outcome measures, such as disease biomarkers or morbidity, and in these cases, PROs can be used as primary endpoints.

✉ Iain Irvine
irviner@tcd.ie

[1] Division of Interventional Radiology, Radiology Department, University Hospital Waterford, Dunmore Road, Co Waterford, Ireland

Patient-Reported Outcome Measures

Patient-reported outcome measures (PROMs) are validated instruments used to report and quantify PROs, initially developed for use in pharmacological and health service research [4]. Kwan et al. [5] outline the ideal characteristics of a research protocol PROM: "reliable, validated in the intended disease population, applicable to a range of therapeutic options for the disease in question, valid for both cross-sectional and longitudinal use, have an established minimally important clinical difference, and be short and easily administered". PROMs can either be disease-specific or generic. There are thousands of validated disease-specific PROMs, and these have greater validity and credibility than their generic equivalents [2]. Generic instruments usually deal with aspects of a patient's life like mobility and self-care and allow greater ease of comparison, an example of which is the EuroQol-5D which is used to measure QoL [6], as utilised in the BASIL trial for instance [7]. Clinical studies often use a combination of disease-specific and generic tools.

Clinical Use

The clinical use of PROs is well established in the surgical realm, mainly in the evaluation of some low-risk or high-volume elective procedures, for example varicose vein surgery and total joint arthroplasties [8]. Technical metrics such as post-operative infection or prosthetic implant failure rates capture only limited aspects of the treatment efficacy, whereas PROMs offer a validated and scientific method of collecting data pertaining to what constitutes a desirable outcome from the patient's viewpoint.

Interventional Radiology

Interventional radiology (IR) allows procedures to be performed utilising minimally invasive techniques, promising shorter recovery times and a theoretically improved patient experience; however, there is limited evidence in the literature that confirm the latter impression in particular. Many IR procedures are performed to address QoL issues, examples of which include symptom improvement and decreased disability, and the provision of palliative comfort measures to end-of-life patients. Assessment of treatment effectiveness in these situations requires a holistic view of the patient's care, with improvement of their subjective experience paramount.

There are several studies that utilise PROs and detail the development of PROMs in the fields of Uterine Artery Embolisation (UAE) [9–11], Transarterial Chemoembolisation (TACE) of Hepatocellular Carcinoma (HCC) [12, 13], and venous insufficiency [3, 14, 15], among others; however, reports detailing PROM use in other conditions relevant to IR are currently lacking [5].

Spies et al. demonstrated an improvement in QoL among 50 women who underwent UAE using preoperative questionnaires repeated at 3 & 6 months of follow-up [9] and subsequently developed a validated PROM assessing symptom severity and symptom impact on health-related QoL in women with uterine leiomyomata and their responsiveness to intervention, called the Uterine Fibroid Symptom and Quality of Life (UFS-QOL) [10]. We have included this PROM and its scoring manual in the attached appendices (Online Appendix 1) [10]. UFS-QOL was subsequently utilised in the FIBROID study by Goodwin et al. [11], a multi-centre prospective longitudinal registry of over 2000 women undergoing intervention for fibroids. This large data set showed "a durable improvement in quality of life" and significant symptom improvement in women undergoing UAE versus other surgical treatments such as hysterectomy or myomectomy.

Many publications have compared TACE vs yttrium-90 radioembolisation (TARE) of HCC in terms of treatment efficacy and tumour response [16, 17]; however, the evidence is limited in relation to the subjective patient experience. The FACT-Hep (Functional Assessment of Cancer Therapy—Hepatobiliary) is a validated disease-specific PROM (Online Appendices 2 & 3) used to assess patient's QoL after these treatments [18]. This instrument has been utilised in two small studies [12, 13] which demonstrated an increased QoL in patients post-TARE in comparison with TACE. Results such as these can add a dimension to the decision-making between treatment options, particularly relevant in the palliative setting.

Despite the substantial amount of work studying QoL improvement with regard to oncological practice in general, disease-specific research such as the aforementioned is scarce in IR [5]. European radiation oncologists use PROMs frequently in treatment evaluation [19–23]. Of the trials currently recruiting, we found only one incorporating an IR procedure, namely MR-guided high-intensity focused ultrasound for palliating painful osseous metastases, which will be compared to external beam radiotherapy using the following generic and disease-specific PROMs: EORTC QLQ BM22, C15-PAL, EQ-5D-5L and PGIC [19].

In patients with lower limb ischaemia, PAD-QOL [24] and Vascu-QOL Questionnaires [25] are used, the latter facilitating evaluation in the SUPER trial, [26] which compared the cost-effectiveness of endovascular revascularisation and supervised exercise therapy.

Future Directions

The authors encourage IRs to familiarise themselves with existing PROMs in their domains, incorporate them into their practice and report their results in order to contribute to the currently limited evidence. By extension, where PROMs do not exist for a particular treatment or group of treatments, there is an opportunity for IRs to play a leading role in the design and development of appropriate treatment/disease-specific PROMs. IRs are ideally placed to do this work given their knowledge of their procedures' desired outcomes, potential complications and perceived benefits of IR procedures over open alternatives. Patient advocate groups can be invaluable collaborators in identifying the issues most important to patients. By pursuing this route, the IR community can accrue meaningful evidence confirming our perceptions of the benefits of our procedures to our patients.

For those who remain sceptical, we would highlight the increasing weight that governing bodies ascribe to PROMS. Some, such as NICE (National Institute for Health and Care Excellence) in the UK have begun requesting PRO data to support the wider adoption of procedures such as genicular artery embolisation for osteoarthritis [27], high-intensity focused ultrasound for symptomatic breast fibroadenoma [28] and superior capsular augmentation for massive rotator cuff tears [29]. It appears inevitable that PRO data will form an important part of the evidence used to influence which procedures are supported and which are not. Taking the lead in this sphere will give IR an important voice in addition to bolstering the existing evidence and contributing new validated methods of evaluating procedures' outcomes. The European Medicines Agency and the FDA have published guidance for the use of PROMs as part of clinical research in Oncology [30] and to support labelling claims for medications or medical products [1]. Recognising the importance of PROs in clinical practice and research, the Society of Interventional Radiology convened an expert group in 2017 to develop a strategy to increase PROs use in practice [5]; however, a recent systematic review has shown that the use of PROMs has plateaued [31].

It should be acknowledged that the required data collection comes with an administrative cost. With ever-mounting pressures on healthcare resources and costs, any additional workload needs to be efficacious and time efficient if it is to be widely adopted. Electronic methods such as online surveys and in-person tablet-based questionnaires have the benefit of more streamlined data collection. Paper questionnaires are more cumbersome but they do have the advantage of better response rates [32], likely reflecting the current older age-group requiring health care. This pattern is expected to change as "digital natives" become a greater proportion of patient populations.

Conclusion

The minimally invasive techniques employed by IR can offer patients more than just shorter recovery times. PROs offer an invaluable insight into the patient experience and are becoming more widely recognised as a key measure of an intervention's utility, both post-procedure and at follow-up, and can be used as validated methods of service assessment, to monitor the success of any changes implemented and facilitate comparison of service quality between different providers. Positive results from a PRO database will prove useful in negotiations with healthcare bodies for increased funding, especially if the IR approach is proven to be of greater benefit and more acceptable to patients than non-IR alternatives vying for limited resources.

We believe this topic should be once again highlighted to encourage IRs to routinely use recognised PROMs in their treatment domains, and where a PROM does not exist, to cooperate with others to produce a valid, reliable assessment tool. It is anticipated that greater incorporation of PROMs into practice in combination with appropriate evaluation and reporting will support IRs position in comparison with other providers.

Funding This study was not supported by any funding.

Declarations

Conflict of interest The authors declare that they have no conflict of interest.

Formal Consent For this type of study, formal consent is not required.

Informed Consent For this type of study, informed consent is not required.

Consent for Publication For this type of study, consent for publication is not required.

References

1. U.S. Department of Health and Human Services FDA Center for Drug Evaluation and Research. Guidance for industry: patient-reported outcome measures: use in medical product development to support labeling claims: draft guidance. Health Quality Life Outcomes. 2006;4:79. https://doi.org/10.1186/1477-7525-4-79.
2. Black N. Patient reported outcome measures could help transform healthcare. BMJ (Clinical research ed). 2013;346(f167):28. https://doi.org/10.1136/bmj.f167.

3. Vedantham S, et al. Pharmacomechanical catheter-directed thrombolysis for deep-vein thrombosis. New England J Med. 2017;377(23):2240–52. https://doi.org/10.1056/NEJMoa1615066.
4. Weldring T, Smith SMS. Patient-reported outcomes (PROs) and patient-reported outcome measures (PROMs). Health Serv Insights. 2013;6:61–8. https://doi.org/10.4137/HSI.S11093.
5. Kwan SW, et al. Development of national research and clinical agendas for patient-reported outcomes in IR: proceedings from a multidisciplinary consensus panel. J Vasc Interventional Radiol: JVIR. 2018;29(1):1–8. https://doi.org/10.1016/j.jvir.2017.08.027.
6. Devlin NJ, Brooks R. EQ-5D and the EuroQol Group: Past, Present and Future. Appl Health Econ Health Policy. 2017;15(2):127–37. https://doi.org/10.1007/s40258-017-0310-5.
7. Adam DJ, et al. Bypass versus angioplasty in severe ischaemia of the leg (BASIL): multicentre, randomised controlled trial. Lancet (London, England). 2005;366(9501):1925–34. https://doi.org/10.1016/S0140-6736(05)67704-5.
8. Fry BT, et al. Using patient-reported outcomes to enhance appropriateness in low-risk elective general surgery. Ann Surgery. 2019;269(1):41–2. https://doi.org/10.1097/SLA.0000000000002864.
9. Spies JB, et al. Uterine fibroid embolization: measurement of health-related quality of life before and after therapy. J Vasc Interventional Radiol: JVIR. 1999;10(10):1293–303. https://doi.org/10.1016/s1051-0443(99)70235-6.
10. Spies JB, et al. The UFS-QOL, a new disease-specific symptom and health-related quality of life questionnaire for leiomyomata. Obstet Gynecol. 2002;99(2):290–300. https://doi.org/10.1016/s0029-7844(01)01702-1.
11. Goodwin SC, et al. Uterine artery embolization for treatment of leiomyomata: long-term outcomes from the FIBROID Registry. Obstet Gynecol. 2008;111(1):22–33. https://doi.org/10.1097/01.AOG.0000296526.71749.c9.
12. Toro A, et al. Health-related quality of life in patients with hepatocellular carcinoma after hepatic resection, transcatheter arterial chemoembolization, radiofrequency ablation or no treatment. Surg Oncol. 2012;21(1):e23-30. https://doi.org/10.1016/j.suronc.2011.10.005.
13. Salem R, et al. Increased quality of life among hepatocellular carcinoma patients treated with radioembolization, compared with chemoembolization. Clin Gastroenterol Hepatol: Off Clin Pract J Am Gastroenterol Assoc. 2013;11(10):1358-1365.e1. https://doi.org/10.1016/j.cgh.2013.04.028.
14. Lamping DL, et al. Evaluation of outcomes in chronic venous disorders of the leg: development of a scientifically rigorous, patient-reported measure of symptoms and quality of life. J Vasc Surgery. 2003;37(2):410–9. https://doi.org/10.1067/mva.2003.152.
15. Kahn SR, et al. VEINES-QOL/Sym questionnaire was a reliable and valid disease-specific quality of life measure for deep venous thrombosis. J Clin Epidemiol. 2006;59(10):1049–56. https://doi.org/10.1016/j.jclinepi.2005.10.016.
16. Dhondt E, et al. ^{90}Y Radioembolization versus drug-eluting bead chemoembolization for unresectable hepatocellular carcinoma: results from the TRACE phase II randomized controlled trial. Radiology. 2022;303(3):699–710. https://doi.org/10.1148/radiol.211806.
17. Chow R, et al. Radiofrequency ablation vs radiation therapy vs transarterial chemoembolization vs yttrium 90 for local treatment of liver cancer—a systematic review and network meta-analysis of survival data. Acta Oncologica (Stockholm, Sweden). 2022;61(4):484–94. https://doi.org/10.1080/0284186X.2021.2009563.
18. Heffernan N, et al. Measuring health-related quality of life in patients with hepatobiliary cancers: the functional assessment of cancer therapy-hepatobiliary questionnaire. J Clin Oncol: Off J Am Soc Clin Oncol. 2002;20(9):2229–39. https://doi.org/10.1200/JCO.2002.07.093.
19. Slotman DJ, et al. Focused Ultrasound and RadioTHERapy for non-invasive palliative pain treatment in patients with bone metastasis: a study protocol for the three armed randomized controlled FURTHER trial. Trials. 2022;23(1):1061. https://doi.org/10.1186/s13063-022-06942-1.
20. Huele EH, et al. Stereotactic Body radiotherapy and pedicLE screw fixatioN During one hospital visit for patients with symptomatic unstable spinal metastases: a randomized trial (BLEND RCT) using the Trials within Cohorts (TwiCs) design. Trials. 2023;24(1):307. https://doi.org/10.1186/s13063-023-07315-y.
21. Doppenberg D, et al. Stereotactic ablative radiotherapy or best supportive care in patients with localized pancreatic cancer not receiving chemotherapy and surgery (PANCOSAR): a nationwide multicenter randomized controlled trial according to a TwiCs design. BMC Cancer. 2022;22(1):1363. https://doi.org/10.1186/s12885-022-10419-4.
22. Verweij ME, et al. Impact of dose-escalated chemoradiation on quality of life in patients with locally advanced rectal cancer: 2-year follow-up of the randomized RECTAL-BOOST trial. Int J Radiat Oncol, Biol, Phys. 2022;112(3):694–703. https://doi.org/10.1016/j.ijrobp.2021.09.052.
23. Pielkenrood BJ, et al. Quality of life after stereotactic body radiation therapy versus conventional radiation therapy in patients with bone metastases. Int J Radiat Oncol, Biol, Phys. 2022;112(5):1203–15. https://doi.org/10.1016/j.ijrobp.2021.12.163.
24. Treat-Jacobson D, et al. The PADQOL: development and validation of a PAD-specific quality of life questionnaire. Vasc Med (London, England). 2012;17(6):405–15. https://doi.org/10.1177/1358863X12466708.
25. Morgan MB, et al. Developing the vascular quality of life questionnaire: a new disease-specific quality of life measure for use in lower limb ischemia. J Vasc Surg. 2001;33(4):679–87. https://doi.org/10.1067/mva.2001.112326.
26. van Reijen NS, et al. Cost Effectiveness of Endovascular Revascularisation vs. Exercise Therapy for Intermittent Claudication Due to Iliac Artery Obstruction. Eur J Vasc Endovasc Surg: Off J Eur Soc Vasc Surg. 2022;63(3):430–7. https://doi.org/10.1016/j.ejvs.2021.10.048.
27. 1 Recommendations: Genicular Artery Embolisation for Pain from Knee Osteoarthritis: Guidance. *NICE*. 2021. https://www.nice.org.uk/guidance/ipg708/chapter/1-Recommendations.
28. 1 Recommendations: High-Intensity Focused Ultrasound for Symptomatic Breast Fibroadenoma: Guidance. *NICE*. 2017. https://www.nice.org.uk/guidance/ipg592/chapter/1-Recommendations.
29. "1 Recommendations: Superior Capsular Augmentation for Massive Rotator Cuff Tears: Guidance." *NICE*. 2018. https://www.nice.org.uk/guidance/ipg619/chapter/1-Recommendations.
30. Reflection Paper on the Use of Patient Reported Outcome (PRO) Measures in Oncology Studies. *European Medicines Agency*. 2014. www.ema.europa.eu/en/documents/scientific-guideline/draft-reflection-paper-use-patient-reported-outcome-pro-measures-oncology-studies_en.pdf.

31. Datta S, et al. Systematic review of use of patient-reported outcomes in interventional radiology. J Am Coll Radiol: JACR. 2023;S1546–1440(23):00416-7. https://doi.org/10.1016/j.jacr.2023.05.009.

32. Lagha E, et al. Patient reported experience measures (PREMs) in chronic heart failure. J R Coll Physicians Edinb. 2012;42(4):301–5. https://doi.org/10.4997/JRCPE.2012.404.