

## SYSTEMATIC REVIEW OF USE OF PATIENT REPORTED OUTCOME IN INTERVENTIONAL RADIOLOGY

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### ABSTRACT

**Introduction:** At present, the implementation of patient-reported outcomes in interventional radiology is not widespread. However, they are capable of significantly impacting the manner in which we deliver healthcare. Patient-reported outcomes provide an avenue for evaluating the perceived advantages that patients encounter subsequent to a medical procedure. Furthermore, they facilitate a comparison of these results with those of open procedures that are more invasive, as perceived by the patient.

**The aim:** This study review of use of patient reported outcome in interventional radiology.

**Methods:** For this systematic review, publications that were published from 2012 to 2023 were taken into account during the search process. This was achieved through the utilization of numerous online reference sources, such as Pubmed and SagePub. The decision was made to exclude review articles, previously published works, and incomplete works.

**Result:** We obtained 94 articles from Pubmed and 110 from SagePub. The therapies we extracted were 1 article from Pubmed and 3 articles from SagePub.

**Conclusion:** Quality of life and patient perception must be respected as one of the parameters of successful therapy. Previous research shows that PRO can be used with good validity and reliability as a therapeutic outcome parameter in many cases, including interventional radiology.

**Keyword:** Interventional radiology; Patient reported outcome; Quality of Life

## INTRODUCTION

Interventional radiology (IR) uses medical imaging like x-ray fluoroscopy, computed tomography, magnetic resonance imaging, and ultrasound to conduct minimally invasive operations. IR uses tiny incisions or bodily orifices to diagnose and treat. Diagnostic IR methods include image-guided tumor biopsy or imaging contrast agent injection into a hollow structure like a blood artery or duct. Therapeutic IR techniques, including as catheter-based medicine distribution, stent implantation, and narrowed structure angioplasty, treat directly.<sup>1</sup>

The primary purpose of interventional radiology is to access internal biological systems using small needles and cables, either through a body opening or a small surgical cut. Compared to open operations, it diminishes the likelihood of dangers, discomfort, and the need for a lengthy recovery period.<sup>2</sup> The utilization of real-time visualization aids in precisely identifying anomalies, hence enhancing the precision of operations or diagnoses. The advantages of this approach are assessed in comparison to the risks of radiation exposure, cataracts, and cancer, as well as the potential loss of immediate access to internal structures in the case of bleeding or perforation.<sup>3</sup>

The discipline of interventional radiology is seeing fast growth, providing a wider array of options as alternatives to traditional open surgical treatments. This method, which utilizes imaging guidance and involves little invasion, is expected to result in quicker recovery periods and may enhance the patient experience.<sup>4</sup> However, there is insufficient evidence to support the actual fulfillment of these anticipated benefits. Patient-reported outcomes are a method of gathering information on the patient's experience, which is becoming more common in clinical trials and the delivery of surgical services.<sup>5,6</sup>

A patient-reported outcome (PRO) is any self-reported account of the condition of a patient regarding the status of their health, as defined by the Food and Drug Administration (FDA).<sup>7</sup> It comprises a documentation of the patient's encounter with an intervention that is relevant to the patient's health-related quality of life, functional status, and symptoms. PROs provide information on subjective outcomes such as disabilities, symptoms, and quality of life in clinical trials. They frequently serve as secondary outcomes in clinical trials, as this information is not reliably obtainable through other means.<sup>6,8</sup>

When adequate objective outcome measures are lacking, as is the case with disease biomarkers or morbidity, PROs are especially valuable and can be utilized as primary endpoints. It helps guide clinical practice for various elective operations. Currently, patient-reported outcomes are not widely used in interventional radiology.<sup>6,8</sup> However, they have the potential to greatly influence the way we provide care. Patient-reported outcomes allow us to assess the perceived benefits experienced by patients after undergoing a procedure. They also enable us to compare these outcomes with those of more invasive open procedures, from the patient's point of view.<sup>5,9</sup>

Examining the utilization of patient-reported outcomes in interventional radiology is the focus of this study.

## METHODS

The data acquisition, processing, and reporting requirements of PRISMA 2020 were duly adhered to. The decision to enact additional restrictions was impacted by a multitude of variables. An examination of the application of patient-reported outcomes in interventional radiology. All written materials pertaining to patient-reported outcomes in interventional radiology must be composed in English, according to the study's main findings. This systematic review assessed scholarly articles that were published subsequent to 2012 and fulfilled the inclusion criteria of the study. Editorials, entries lacking a DOI, book reviews that have been previously published, and unduly lengthy duplicate journal articles will be excluded from the compilation.

The search for studies to be included in the systematic review was carried out from December, 5<sup>th</sup> 2023 using the PubMed and SagePub databases by inputting the words: "patient reported"; "outcome"; and "interventional radiology". Where (*"patient reported outcome measures"[MeSH Terms] OR ("patient"[All Fields] AND "reported"[All Fields] AND "outcome"[All Fields] AND "measures"[All Fields]) OR "patient reported outcome measures"[All Fields] OR ("patient"[All Fields] AND "reported"[All Fields] AND "outcome"[All Fields]) OR "patient reported outcome"[All Fields]) AND ("radiology, interventional"[MeSH Terms] OR ("radiology"[All Fields] AND "interventional"[All Fields]) OR "interventional radiology"[All Fields] OR ("interventional"[All Fields] AND "radiology"[All Fields])) AND (clinicaltrial[Filter] OR meta-analysis[Filter] OR randomizedcontrolledtrial[Filter] OR systematicreview[Filter]) is used as search keywords.*

The titles and abstracts of the studies had an equivalent effect on their acceptability. They must thus place their trust in historical archives. As a result of the consistent nature of research findings, it is mandatory to submit unpublished English papers. The inclusion criteria were strictly adhered to in order to select studies for inclusion in the systematic review. By doing so, the search is restricted to outcomes that exclusively satisfy the given criteria. The subsequent sections delineate the evaluation procedure. Authors, publication dates, geographic locations, activities, and motivations were all taken into account in the study.

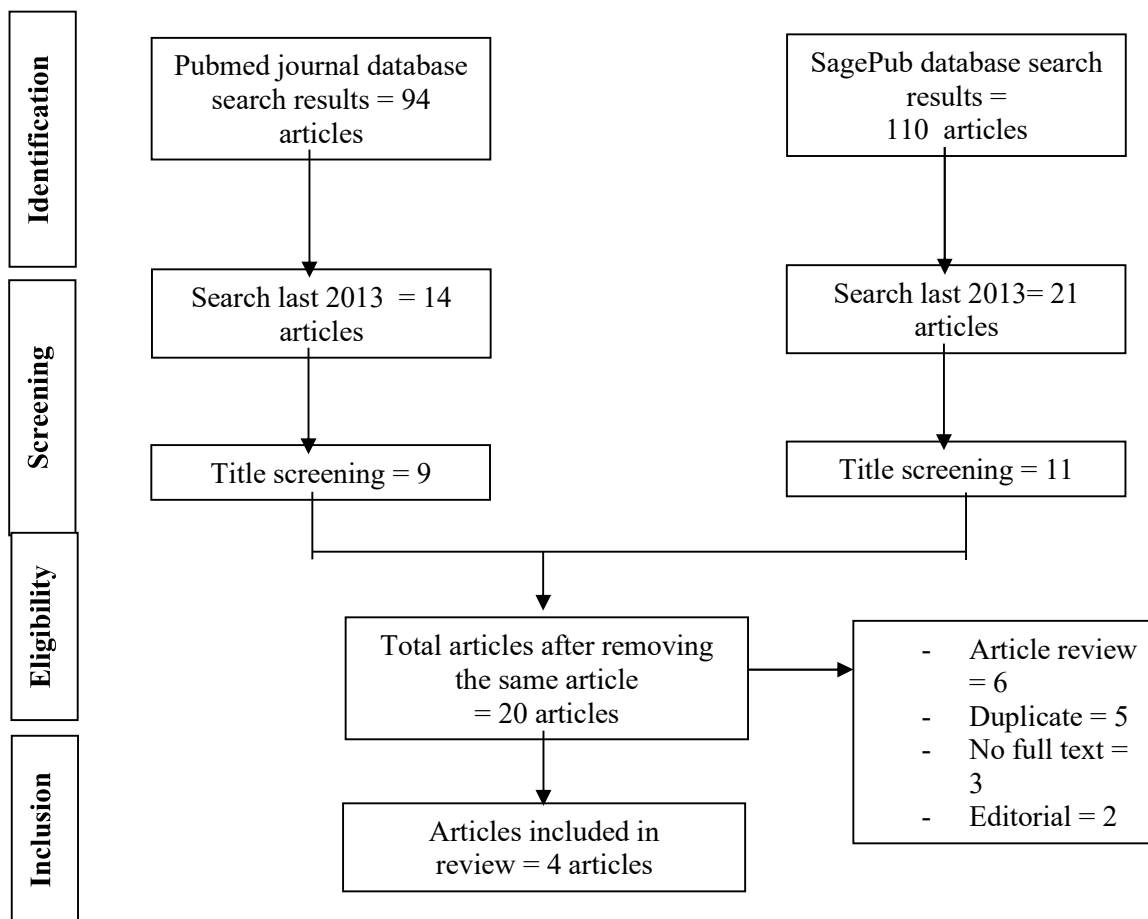


Figure 1. Article search flowchart

Following the recording of search results by EndNote, the database proceeded to identify and eliminate duplicate articles. The titles and abstracts of every paper were assessed by two individuals in preparation for this article. Prior to making coverage decisions, every author thoroughly evaluates relevant abstracts and article titles. Every paper that meets the specified criteria for review will undergo a thorough and rigorous analysis. After the investigation has been completed, we will reexamine any relevant scientific publications that we may have failed to consider during our initial examination. Irrespective research was omitted in favor of pertinent research.

**RESULT**

Ring, et al (2023)<sup>10</sup> showed PROVAM score exhibited exceptional discriminatory power in identifying symptom improvement, as evidenced by its area under the receiver operating characteristic (ROC) curve of 0.856. The correlation between the change in the total PROVAM score and the change in patient symptoms as assessed during clinical visits was moderately positive and statistically significant (Spearman correlation coefficient [rs] = 0.67, P <0.001). Following treatment, the overall PROVAM score and all subdomain scores improved substantially (all P <0.05). Cohen d effect size (ESp) and standard response mean difference (SRM) were, respectively, 0.80 and 0.83. As it is sensitive to improvement following treatment, PROVAM could be utilized to evaluate the health-related quality of life of vascular malformations (VMs) patients.

England, et al (2021)<sup>11</sup> showed instrument responsiveness, as judged by the total score, decreased significantly in the subgroup analysis of 13 patients who completed PROVAM before and after treatment (median, -10 points; interquartile range [IQR], -3 to -16; P =.04). The questions were straightforward for participants to grasp (median, 5 points; IQR, 4-5 on a 5-point scale) and relevant (median score, 4; IQR, 3-5). Preliminary findings confirm PROVAM's reliability and validity in assessing health-related quality of life in patients with vascular malformations.

Horbach, et al (2018) showed a study with 77 individuals were enrolled, with a median follow-up of 22 months. About half of respondents (49.3%) reported health improvements. Most improved were ‘pain’ (54.5%) and ‘overall intensity of symptoms’ (57.1%). No variables substantially predicted patient-perceived vascular malformation health improvement. Pre-sclerotherapy impairment in work or study activities significantly impacted physical QoL at follow-up (p = 0.03). After bleomycin sclerotherapy, 50% of low-flow vascular malformation patients report improved pain and symptom severity. Most patients saw minimal to moderate health improvement and wanted more therapy.<sup>12</sup>

**Table 1. The litelature include in this study**

Author	Origin	Method	Sample	Instrument	Conclusion
Ring, 2023 <sup>10</sup>	United State of America	Prospective cohort study	56 patients with venous and lymphatic VMs	Patient-Reported Outcome Measure for Vascular Malformation (PROVAM) questionnaire	With an area under the ROC curve of 0.856, the overall PROVAM score discriminated symptom improvement well. A statistically significant, moderate positive connection existed between overall PROVAM score change and clinical visit symptoms (Spearman correlation coefficient [rs] = 0.67, P < .001).
England, 2021 <sup>11</sup>	United State of America	Prospective cohort study	108 consecutive patients	Patient-Reported Outcome Measure for Vascular Malformation	Primary domain structure was confirmed by factor analysis (P <0.001) and convergent construct validity for all but 1 Likert scale item. Instrument responsiveness , as measured by the total score, decreased significantly in the subgroup analysis of thirteen participants who completed the PROVAM before and after treatment (median, -10 points; interquartile range [IQR], -3 to -16; P = 0.04). On a 5-point Likert scale, participants

					rated the queries as pertinent (median score: 4; IQR: 3-5) and simple to comprehend (median and interquartile range: 4-5).
Horbach, 2018 <sup>12</sup>	Dutch	Prospective cohort study	Seventy-seven patients	Questionnaire evaluating disease symptoms, QoL (Short Form 36)	The health aspects that exhibited the greatest frequency of improvement were "pain" (54.5%) and "overall severity of symptoms" (57.1%). There were no significant predictive factors in terms of patient-perceived health improvement in relation to the vascular malformation. Prior to sclerotherapy, impairment in work or academic activities was found to have a deleterious effect on physical quality of life at follow-up (p = 0.03).
Diane, 2012 <sup>13</sup>	United State of America	Prospective cohort study	297 symptomatic PAD patients	PAD Quality of Life Questionnaire (PADQOL)	Social relationships and interactions, Self-concept and feelings, Symptoms and limitations in physical functioning, Fear and uncertainty, and Positive adaptation ( $\alpha = 0.92-0.73$ ) and items related to sexual function,

intimate relationships and employment. Between-instrument correlations established construct validity. In conclusion, PADQOL is a validated measure to assess the disease-specific physical, psychosocial and emotional effects of PAD for research and practice.

Diane, et al (2012)<sup>13</sup> conducted study with PADQOL. PADQOL is a questionnaire consisting of 38 items was developed based on the analysis of data collected from 297 patients who were experiencing symptoms of PAD. The questionnaire was comprised of five factors: social relationships and interactions, self-concept and feelings, symptoms and limitations in physical functioning, fear and uncertainty, and positive adaptation ( $\alpha = 0.92-0.73$ ). Additionally, the questionnaire included items that were related to sexual function, intimate relationships, and employment. Construct validity was proven through the use of between-instrument correlations. PADQOL is a validated measure that may be used for research and treatment to evaluate the disease-specific physical, psychosocial, and emotional impacts of PAD with regard to the patient.

**DISCUSSION**

Quality of life according to the World Health Organization Quality of Life (WHOQOL) Group is defined as an individual's perception of an individual's position in life in the context of the culture and value system in which the individual lives and its relationship to a person's goals, expectations, established standards and concerns. Quality of life is defined as an individual's perception of their position in life in the context of the culture and value system in which they live and in relation to their goals, expectations, standards and concerns. Quality of life can be one of the goals assessed in treatment. Quality of life is an individual's subjective perception of the physical, psychological, social and environmental conditions they experience in their daily life.<sup>14,15</sup>

According to the concept of quality of life in relation to health, also known as health-related quality of life, quality of life refers to a spectrum that encompasses both objective circumstances and subjective impressions of those situations. The term "quality of life" refers to a collection of components that are associated with an individual's physical, functional, psychological, and social health, according to professionals. Within the scope of this discussion, it frequently refers to the quality of life that ultimately results in health. There are five components that make up health-related quality of life. These components are identified as opportunity, perceived health, functional status, sickness, and mortality.<sup>16</sup>

According to the Food and Drug Administration (FDA), a patient-reported outcome (PRO) is any self-reported account of the condition of a patient about the status of their health. This definition holds true regardless of the kind of patient.<sup>7</sup> It consists of a record of the patient's interaction with an intervention that is important to the patient's health-related quality of life, functional status, and symptoms. In clinical studies, PROs give information on subjective outcomes such as impairments, symptoms, and quality of life. They are commonly used as secondary outcomes in clinical studies since this information cannot be obtained consistently through other techniques.<sup>6,8</sup>

In order to construct a health-related quality of life (QOL) measure for patients who have received radiological intervention, a patient-centered method was developed. When it comes to the reliability of the PRO questionnaire, the results of the study provide preliminary evidence. Every single one of the key domains, which included pain, emotional and social well-being, and functional effect, exhibited factorial and construct validity, as well as internal consistency. Research using PROVAM's shows that the instrument has reliability and validity in assessing health-related quality of life in patients with vascular malformations.<sup>11</sup>

Other study that makes use of PADQOL demonstrates that PADQOL is a validated measure that may be utilized for research and therapy purposes in order to analyze the disease-specific physical, psychological, and emotional affects that PAD has on the patient.<sup>13</sup> Patient-centered, precise, straightforward, and efficacious quality of life questionnaires tailored to peripheral arterial disease (PAD) offer the greatest benefit in terms of evaluating the disease's effects, identifying efficacious treatment alternatives, and customizing interventions. These measurement instruments should assess the patient's perceived social, emotional, and physical well-being as well as the burden of living with PAD.<sup>17</sup>

Study identified one Likert scale item in the pilot instrument that lacked both reliability and validity while assessing the use of cosmetics in our patients. Consequently, we decided to exclude this item from the emotional/social well-being subscale. The secondary measure of response was seen in a subset of patients who filled out the questionnaire both prior to and following the therapy. While broad questionnaires and patient-reported outcome measures (PROMs) are widely used and validated, disease-specific PROMs provide the benefits of increased responsiveness and sensitivity within a specific patient group.<sup>18,19</sup>

Kwan et al. provide a description of the ideal characteristics of a research protocol PROM, which are as follows: "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." It is possible for PROMs to be either disease-specific or general.<sup>20</sup> The EuroQol-5D, a generic QoL questionnaire, measures mobility and self-care and makes comparisons easier.<sup>18,19</sup>

## CONCLUSION

Quality of life and patient perception must be respected as one of the parameters of successful therapy. Previous research shows that PRO can be used with good validity and reliability as a therapeutic outcome parameter in many cases, including interventional radiology.

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