Review

Patient-reported outcome measures in third molar surgery: A scoping review

Laura O’Sullivan a,†, Rícheal Ní Ríordáin a,b

a Cork University Dental School and Hospital, University College Cork, Ireland
b University College London, London Eastman Dental Institute, UK

Accepted 30 May 2022

Abstract

Despite a surge of interest in patient-centred outcomes (PROMs) in healthcare settings, they remain an underutilised resource in third molar surgery. Clinicians and researchers in the field of oral surgery who are interested in incorporating PROMs into their clinical practice may face challenges in instrument selection with as yet no consensus registry available. PROMs have undoubtedly transcended their original brief as research instruments, with the collection of PROMs data now a routine undertaking in many healthcare systems. Quality improvement, appropriate resource allocation, and measurement of effectiveness of interventions are but a few of their advantages. This review article presents a scoping overview of the instruments most relevant to the third molar surgery population.

© 2022 The Author(s). Published by Elsevier Ltd on behalf of The British Association of Oral and Maxillofacial Surgeons. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/).

Keywords: Patient reported outcome measures; Quality of life; Third molar; Wisdom tooth; Oral surgery

Introduction

The role of the patient in establishing disease chronology and meaningful outcomes of surgical and pharmacological interventions is now widely considered crucial when evaluating the quality of healthcare services, and should be seen as complementary to objective clinical outcome measures. In healthcare provision, this shift away from the traditional disease-centred approach towards a more patient-centred ethos has been lauded by some as transformative to healthcare services, and has prompted the widespread implementation of patient-reported outcome measures (PROMs) in Sweden, England, and the United States.1

A PROM is a standardised instrument, typically a questionnaire, that enables patients to self-evaluate one or more aspects of their health,2 such as functional status and health-related quality of life (QoL).3 PROMs were originally developed for use in research, but have since been adopted by medical professionals to aid clinical decision-making and assess the outcomes of treatment provision.4 Policymakers may also look to PROMs data to inform funding decisions that prioritise patient groups deemed most in need of resources. PROMs are distinct from patient-reported experience measures (PREMs), which focus more on qualitative aspects of the humanity of care.1,3

Mandatory collection and analysis of PROMs data was introduced by NHS England in April 2009 for a number of elective surgical procedures (including hip replacement, knee replacement, inguinal hernia repair, and varicose vein surgery) with four key aims in mind:4

- Assessment of individual provider performance
- Research on effectiveness rather than efficacy of treatments
- Establishment of a baseline preoperative health status of patients
- Reduction of health inequalities.

The Royal College of Surgeons of England (RCS Eng) also asks all providers of cosmetic surgery to routinely collect baseline and postoperative PROMs data for patients undergoing abdominoplasty, rhinoplasty, blepharoplasty, augmentation mammoplasty, liposuction, and rhytidectomy. Collection of such data for this patient cohort is essential to truly appreciate the risk-benefit analysis of cosmetic surgery.
PROMs in oral surgery

The use of PROMs in oral surgery is not a novel concept. The first preliminary reports into the impact of third molar surgery on QoL date back over 20 years, when researchers collected data from 29 patients on days one and seven postoperatively.5 The results of this study helped inform the design of a disease-specific third molar QoL instrument, the Postoperative Symptom Severity (PoSSe) scale,6 which to this day remains the only disease-specific PROM of its kind with proven validity and reliability.

Researchers have demonstrated the discriminative validity of oral health-specific instruments such as the 14-item oral health impact profile (OHIP-14) and the 16-item UK oral health-related QoL measure (OHQoL-UK©) in identifying patients most likely to benefit from third molar surgery.7 This is particularly relevant in the current climate where National Health Service (NHS) operating lists are at an all-time high as a result of the Covid-19 pandemic. The “Clinical Guide to Surgical Prioritisation of Patients on Oral Surgery Waiting Lists” document published jointly by the British Association of Oral Surgeons (BAOS) and the British Association of Oral and Maxillofacial Surgeons (BAOMS) suggests that surgical prioritisation may be a reality for up to three years.8

The core oral surgery PROMs outlined in the NHS Commissioning Guide are reportedly based on NHS classifications OPSC-4 and the WHO ICD-10 classification of disease, since superseded by ICD-11.9 To date, only two studies have investigated the use of these core PROMs in an oral surgery patient cohort, one each in primary3 and secondary care.10 In both cases, authors collected data for benchmarking purposes, generally garnering positive feedback from patients undergoing dental extractions at their respective institutions. While these core PROMs may play a role in crude service evaluation, they have no proven validity and reliability, and are therefore of limited value in the broader context of patient outcomes in oral surgery. There is currently no agreed consensus on a core set of oral surgery PROMs, but a need to expand the available repertoire of specialty and procedure-specific PROMs has been identified by the profession.10

PROM development is far from straightforward, and requires a robust analysis of psychometric properties in the relevant patient population.11,12

- Validity: does the instrument measure what it is intended to measure?
- Reliability: does the instrument consistently generate reproducible scores?
- Responsiveness (sensitivity): does the measure detect clinically meaningful changes over time?
- Acceptability: is the measure suitable for its intended purpose?
- Interpretability: are the results measurable and clinically relevant?

This can be achieved by using checklists such as SAC-MOT13 or the COmmision-based Standards for the selection of health Measurement INstruments (COSMIN). The latter defines nine measurement properties clustered within three domains. The evaluation process is essential to ensure that available PROMs are robust and fit for purpose.

Third molar surgery remains one of the most commonly performed surgical procedures worldwide,14 with a significant impact on QoL during the postoperative period.15 Such is the predictability of the associated sequelae that third molar surgery is one of the most popular research models for interventional studies. With ever more third molar studies appearing in the scientific literature, where does the aspiring researcher begin with respect to outcome measure selection? It goes without saying that outcome measures should be measurable, reproducible, and meaningful for the target population. We have previously explored trends in clinical outcomes reporting (ClinRO) in third molar surgery, and found that swelling and mouth opening/trismus were the two most frequently reported clinical outcomes by researchers.16 It is not unreasonable to suggest that these numerical values are less meaningful than the impact they will have on patient function during the postoperative period (chewing ability, speech and so on), which is where the role of PROMs in third molar surgery outcomes reporting comes into play.

A systematic review published in 2010 summarised the most commonly used QoL PROMs in the broader context of oral and maxillofacial surgery.17 However, to our knowledge, no authors to date have published a summary of PROMs that are pertinent to third molar surgery. With this in mind, we aimed to present the PROMs most widely reported in the third molar literature (Table 1), and hope that this article will act as a useful aide-mémoire for interested clinicians and aspiring researchers.

Measurement of pain

Pain is one of the most common complaints among patients following third molar surgery, and remains the most likely reason for patients to seek help postoperatively.18 Pain has a protective function in the postoperative period by promoting undisturbed healing. For patients, pain will restrict mouth opening thereby limiting function at the site of surgery and encouraging rest. A reduction in pain after oral surgery, rather than total elimination, is desirable to prevent a premature return to normal function, which might otherwise lead to wound damage and ultimately to delayed healing.18

Measurement of a patient’s pain intensity is crucial to effective postoperative pain management. The numerical rating scale (NRS), first described by Downie in 1978, consists of a linear 11-point scale with a vertical or horizontal orientation (Fig. 1). Patients are asked to rate their pain anywhere from 0 ‘no pain’ to 10 ‘worst pain imaginable’. Advantages are its simplicity, suitability for written and verbal administration, as well as its usefulness among patients whose native language is not English, overcoming any potential language barriers to pain measurement.19 In its original application, the assessment of pain in a cohort of 100 rheumatoid arthritis patients, it was found to out-perform the visual analogue.
scale (VAS) and ordinal descriptor scales. Other studies have corroborated the superior responsiveness of the NRS compared to other uni-dimensional pain measuring instruments, and it is recommended as one of the best choices of instrument where sensitive measures of pain intensity are indicated. The NRS has also demonstrated superior construct validity to the VAS in patients with oral lichen planus.

The VAS is a 100 mm linear scale that has been in use for over 80 years, and is administered in a horizontal or vertical format (Fig. 2). It has verbal anchors at either end, ‘no pain’ and ‘worst pain imaginable’, which represent a continuum of pain intensity. Patients are asked to draw a single mark on the line to indicate their current level of pain. The distance from the ‘no pain’ anchor to this mark is measured using a ruler, which corresponds to the pain score (ranging from 0 to 100). Although the horizontal VAS orientation is the preferred format, the vertical format tends to yield superior sensitivity. VAS is by far the most commonly cited pain measurement instrument used in third molar surgery. Its disadvantages compared to NRS are the need to instruct patients on how to use it to ensure accurate pain rating, and the potential for error when converting the marking to a numerical score. Furthermore, it must be used in a written format if it is to be applied correctly, thus making it unsuitable for verbal administration.

The McGill pain questionnaire (MPQ) and its short-form equivalent (SF-MPQ) document the intensity of pain as well as its sensory and affective dimensions by using a series of verbal descriptors such as ‘throbbing’, ‘shooting’, ‘stabbing’, ‘sharp’ and ‘cramping’. It is one of the few instruments that can truly capture the multi-dimensionality of pain, but the level of respondent burden renders it an unlikely choice in third molar surgery cohorts where more transient, inflammatory-type pain can be suitably captured using a simpler uni-dimensional instrument such as a NRS or VAS.

Measurement of quality of life

QoL assessment encompasses a triad of physical, social, and psychological parameters that must be documented preoperatively and postoperatively to give a true appreciation of the impact of third molar surgery on a patient’s QoL. A lack of baseline data is identified as a weakness in many QoL studies (Duarte-Rodrigues et al.), as it is impossible to distinguish a positive from a negative impact if baseline QoL data are not collected.

The evaluation of QoL in the third molar surgery population has transcended its original application in research stud-
gies such as randomised controlled trials (RCTs) and cohort studies; it has helped shape what and how we communicate with patients who are considering third molar surgery. It should be borne in mind that ‘cure’ is often worse than ‘disease’ in the case of third molar surgery, and it is imperative that patients are appropriately and adequately informed during the decision-making process.15

A plethora of QoL instruments is currently available for use in third molar surgery and these can be broadly categorised into three distinct groups: generic, for example, SF-12, EQ-5D-3L; oral health-related, for example OHIP-14, OHQoL-UK®; and disease-specific, for example, PoSSe.

Disease-specific PROMs have the advantage of demonstrating greater face validity and credibility, while generic PROMs allow for comparisons across conditions. Oral health-related PROMs meanwhile compare oral operations with other oral healthcare on QoL.7

Generic

The EuroQol-5D-3L instrument was introduced in 1990 and is one of the most widely used instruments for the measurement of health-related QoL.26 It comprises a descriptive system of five dimensions and a vertical VAS denoting a patient’s self-rated health score at a particular point in time. Each of the five dimensions is scored on a three-point scale (no problems, some problems, and extreme problems). The EQ-5D-5L, with a novel five-response level, was subsequently developed to address the potential for ceiling effects, and concerns about the sensitivity of the 3L version to detect clinically important differences in health-related QoL.27

Authors of a 2017 study sought to evaluate QoL outcomes in patients undergoing third molar surgery under general anaesthesia.28 With a response rate of 72% among their 50 patients, they reported good responsiveness of the EQ-5D-3L instrument, but no baseline QoL data were captured and there were no objective outcome comparators to substantiate their findings. Based on this study alone, it is difficult to ascertain the suitability of the EQ-5D-3L in this population.

The validity and sensitivity of the SF-12 in the context of third molar surgery have previously been investigated.7 In their cohort of 100 patients awaiting removal of a single mandibular third molar under local anaesthesia, the authors found that the generic SF-12 instrument was unable to distinguish high-need patients from those who were asymptomatic. They concluded that the SF-12 was not a valid measure of preoperative or postoperative health status in an oral surgery population. It did, however, demonstrate acceptable sensitivity in the immediate postoperative period, and correlated well with oral health-related instruments.

Oral health-related

The Oral Health Impact Profile (OHIP) is the most widely used oral health measure in use today. It was originally developed as a 49-item (OHIP-49) instrument capturing seven conceptually formulated dimensions based on Locker’s theoretical model of oral health.29 OHIP-49 has since been largely superseded by the short-form OHIP-14, designed to improve usability without compromising on psychometric properties. Compared to SF-12, OHIP-14 shows superior discriminative validity in determining the patients most likely to benefit from third molar surgery.7 The preoperative use of oral health measures such as OHIP-14 has been advocated as a screening mechanism to help identify patients most in need of third molar surgery.7 Use of the OHQoL-UK® in third molar research lags behind that of the OHIP-14, and tends to be favoured as complementary to OHIP-14 rather than preference in third molar studies.15 The former (based on an updated WHO model of ‘structure-function-ability-participation’) measures both positive and negative aspects of oral health across 16 domains of life quality.15 Higher levels of dental anxiety have been shown to exert a negative impact on oral health-related QoL. In a random cohort of 1800 British patients aged 16 years and older, 1 in 10 experienced high levels of dental anxiety that were associated with lower (worse) OHQoL-UK® scores.30

Currently only one QoL instrument is specific to third molar surgery with proven validity, reliability, and sensitivity – the Postoperative Symptom Severity (PoSSe) scale,6 which has seven subscales (eating, speech, sensation, appearance, pain, sickness, and interference with daily activities). While Ruta et al acknowledged earlier work by another source in designing an instrument to specifically measure patients’ perceptions after third molar removal,31 limitations in sample size (n = 19) and an absence of psychometric testing failed to qualify the instrument as a valid measure of oral health-related QoL. Numerous researchers have demonstrated the responsiveness of the PoSSe questionnaire, as well as a positive association between PoSSe scores and postoperative trismus and pain.22,32 Its superior responsiveness over the long-established SF-36 in the context of third molar surgery, together with its rigorous development protocol and psychometric testing, favour its selection as the first choice of instrument with which to evaluate the impact of third molar removal on a patient’s perceived health.9 While one would expect greater face validity and credibility with a disease-specific PROM,1 these qualities are further enhanced by the reproducibility of the PoSSe when used in third molar studies.

Psychosocial-specific

The Hospital Anxiety and Depression Scale (HADS) was developed to assess anxiety and depression in patients with illness, and in the general population.33 It comprises 14 questions divided equally between two subscales: HADS-A (anxiety) and HADS-D (depression). It was recommended in the 2015 NHS Commissioning Guide for use as a routine oral medicine PROM, yet has never been validated for this purpose11 or for use in a third molar surgery context. There are reports of the HADS being used in oral cancer patients undergoing tumour resection and reconstructive surgery to fully evaluate depression and anxiety levels.34 In this
context, the scores can help determine whether patients are in need of additional psychological support during what can be an incredibly challenging time. It would seem reasonable to extrapolate that the HADS is best suited to patients with chronic illness, or those on a protracted surgical journey.

Conclusion

Oral surgery lags far behind other dental specialties with respect to standardisation of outcome measures, despite a plethora of research in the field of third molar surgery in particular. While equivalent dental specialties such as oral medicine and restorative dentistry continue to develop recommended core outcome sets (COS), as outlined on the publicly available COMET (Core Outcome Measures in Effectiveness Trials) database, no such guidance yet exists for oral surgery. Considering the substantial contribution of third molar surgery to the oral surgeon’s workload and the long established implications of third molar disease and surgery on QoL, it would appear that this is a missed opportunity for relevant stakeholders to fall into step beside other dental specialties.

As it stands, considerable heterogeneity in the methods of data collection in third molar cohort studies and clinical trials can be attributed largely to a lack of standardisation of the outcome measures available. Standardisation of clinical and patient-centred outcomes in the third molar population would facilitate the collection of high-quality data that could be merged for meta-analysis and, in turn, inform future clinical practice.

We hope that this review will go some way towards providing a source of reference for clinicians and researchers who are looking to incorporate PROMs into their clinical practice and clinical trials.

Conflict of Interest

We have no conflicts of interest.

References


