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Review

Patient-reported outcome measures in third molar surgery

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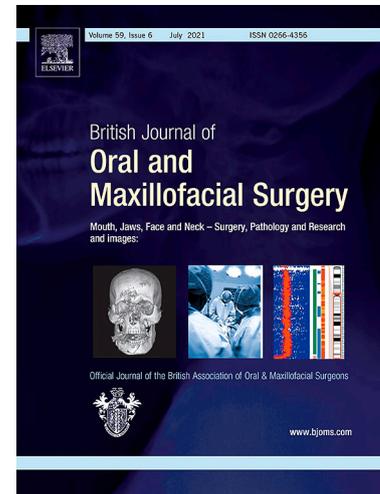
Patient-reported outcome measures in third molar surgery

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Declaration

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

Abstract

Despite a surge in 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 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 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 the advantages of PROMs data collection. This review article presents a scoping overview of those instruments most relevant to the third molar surgery population.

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 in evaluating the quality of healthcare services, and should be seen as complementary to objective clinical outcome measures. This shift away from the traditional disease-centred approach to

healthcare provision towards a more patient-centred ethos, has been lauded by some as transformative to healthcare services, and has prompted 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.[3] PROMs were originally developed for use in research, but have since been adopted by medical professionals to aid clinical decision-making, and to assess outcomes of treatment provision.[1] Policymakers may also look to PROMs data to inform funding decisions, prioritising 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 baseline pre-operative health status of patients
- Reduction of health inequalities

The Royal College of Surgeons in 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

Use of PROMs in oral surgery is not a novel concept. The first preliminary reports into the impact of third molar surgery on quality of life date back over twenty years, where researchers collected data from 29 patients on days 1 and 7 postoperatively.[5] The results of this study helped inform the design of a disease-specific third molar quality of life 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 16-item UK Oral Health-related Quality of Life 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 British Association of Oral and Maxillofacial Surgeons (BAOMS) suggests that surgical prioritisation may be a reality for up to 3 years.[8]

The core oral surgery PROMs outlined in the NHS Commissioning Guide are reportedly based on NHS Classifications OPSC-4 and the WHO ICD10 Classification of Disease, since superseded by ICD11.[9] To date, only two studies have investigated the use of these core

PROMs in an oral surgery patient cohort, one each in primary[3] 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, yet 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-MOT[13] or the COnensus-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 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 previously explored trends in clinical outcomes (ClinRO) reporting in third molar surgery, and found that swelling and mouth opening/trismus are 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 e.g. chewing ability, speech etc. 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 pertinent to third molar surgery. With this in mind, we aim to present those PROMs most widely reported in the third molar literature (Table 1), and hope this article will act as a useful aide memoire for interested clinicians and aspiring researchers.

Measurement of pain

Pain is among 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 undergoing third molar surgery, the pain experience will restrict mouth opening

thereby limiting function at the site of surgery and encouraging rest. Reduction of 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 delayed healing.[18]

Crucial to effective postoperative pain management is measurement of a patient's pain intensity. The numerical rating scale (NRS), first described by Downie in 1978, consists of a linear 11-point scale with either a vertical or horizontal orientation (Fig 1). Patients are asked to rate their pain anywhere from 0 'no pain' to 10 'worst pain imaginable'. Its advanatages 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] Its original application was in the assessment of pain in a cohort of 100 rheumatoid arthritis patients, where it was found to outperform the visual analogue scale (VAS) and ordinal descriptor scales.[20] Other studies have corroborated the superior responsiveness of the NRS compared to other unidimensional pain measuring instruments, and it is recommended as one of the best choices of instrument where sensitive measures of pain intensity are indicated.[21] The NRS has also demonstrated superior construct validity to the VAS in patients with oral lichen planus.[11]

The VAS is a 100mm 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.[19] 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 instrument format, its vertical counterpart tends to yield superior sensitivity.[19] VAS is by far the most

commonly cited pain measurement instrument used in third molar surgery studies.[22, 23] Its disadvantages compared to NRS are the need to instruct patients on how to use the instrument to ensure accurate pain rating, and the potential for error when converting the marking to a numeric score. Furthermore, it must be administered 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 pain intensity as well as the sensory and affective dimensions of pain by using a series of verbal descriptors such as "throbbing", "shooting", "stabbing", "sharp" and "cramping".[19] The MPQ is one of the few instruments that can truly capture the multidimensionality of pain, but the level of respondent burden renders it an unlikely choice in third molar surgery cohorts where the more transient, inflammatory-type pain can be suitably captured using a simpler unidimensional instrument such as NRS or VAS.[24]

Measurement of quality of life

Quality of life assessment encompasses a triad of physical, social and psychological parameters that must be documented preoperatively and postoperatively to be able to truly appreciate the impact of third molar surgery on patients' QoL. A lack of baseline data is identified as a weakness of many QoL studies (Duarte-Rodrigues et al);[25] it is impossible to distinguish a positive impact from a negative one if baseline QoL data are not collected.

Evaluation of QoL in the third molar surgery population has transcended its original brief of application in research studies such as RCTs and cohort studies; it has helped shape what and how we communicate with patients 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.[26]

There is a plethora of QoL instruments currently available for use in third molar surgery that can be broadly categorised into three distinct groups:

- Generic (e.g. SF-12, EQ-5D-3L)
- Oral health-related (e.g. OHIP-14, OHQoL-UK©)
- Disease-specific (e.g. PoSSe)

Disease-specific PROMs have the advantage of demonstrating greater face validity and credibility, while generic PROMs allow for comparisons across conditions.[1] Oral health-related PROMs meanwhile compare oral operations with other oral healthcare on quality of life.[7]

Generic

The EuroQol-5D-3L instrument was introduced in 1990 and is one of the most widely used instruments for measurement of health-related quality of life.[27] 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, representing 'no problems', 'some problems' and 'extreme problems'. Subsequently EQ-5D-5L, with a novel five response level, was developed to address the potential for ceiling effects and concerns about the sensitivity of the 3L version for detecting clinically important differences in health-related quality of life.[28] Authors of a 2017 study sought to evaluate QoL

outcomes in patients undergoing third molar surgery under general anaesthesia.[29] With a response rate of 72% among their 50 patients, they reported good responsiveness of the EQ-5D-3L instrument. However, 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 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 the generic SF-12 instrument was unable to distinguish high-need patients from those who were asymptomatic. They concluded that the SF-12 is 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, correlating well with oral health-related instruments.

<u>Oral Health-Related</u>

The Oral Health Impact Profile (OHIP) is by far 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.[30] OHIP-49 has since been largely superseded by the short-form OHIP-14 designed to improve usability without compromising on psychometric properties. OHIP-14 shows superior discriminative validity compared to SF-12 in determining those patients most likely to benefit from third molar surgery.[7] 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 OHQoL-UK© in third molar research lags behind that of OHIP-14,

and it tends to be favoured as complementary to OHIP-14 rather than preferential in third molar studies.[26] The former is based on an updated WHO model of 'structure-function-ability-participation', and measures both positive and negative aspects of oral health across 16 domains of life quality.[26] Higher levels of dental anxiety have been shown to exert a negative impact on oral health-related quality of life. In a random cohort of 1800 British patients aged 16 years and older, 1 in 10 experienced high levels of dental anxiety, which was associated with lower (worse) OHQoL-UK© scores.[31]

There currently exists only one QoL instrument specific to third molar surgery with proven validity, reliability and sensitivity – the Postoperative Symptom Severity (PoSSe) Scale[32] which has seven subscales: eating, speech, sensation, appearance, pain, sickness and interference with daily activities. While Ruta et al (2000) acknowledge earlier work by another source in designing an instrument to specifically measure patients' perceptions after third molar removal,[33] limitations in sample size (n=19) and an absence of psychometric testing fail to qualify the instrument as a valid measure of oral health-related QoL. The responsiveness of the PoSSe questionnaire has been demonstrated by numerous researchers, as well as a positive association between PoSSe scores and postoperative trismus and pain experience.[22, 34] The superior responsiveness of the PoSSe instrument over the long-established SF-36 in the context of third molar surgery, together with its rigorous development protocol and psychometric testing, lend favour to its selection as the first choice of instrument for evaluation of the impact of third molar removal on a patient's perceived health.[32] 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.[35] It comprises 14 questions divided equally between two subscales: HADS-A (anxiety) and HADS-D (depression). It is recommended in the 2015 NHS Commissioning Guide for use as a routine oral medicine PROM, yet has never been validated for this purpose.[11] Nor has it been validated for use in a third molar surgery context. There are reports of HADS use in oral cancer patients undergoing tumour resection and reconstructive surgery, to fully evaluate depression and anxiety levels during the patient journey.[36] In this context, HADS 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 HADS is best suited to patients with chronic illness, or for those with 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 year on year. 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[37] (Core Outcome Measures in Effectiveness Trials) database, no such guidance yet exists for the oral surgery community. 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 quality of life, it would appear this is a missed opportunity for relevant stakeholders to fall into step beside other dental specialties.

As it stands, there is considerable heterogeneity in the methods of data collection in third molar cohort studies and clinical trials which can be attributed largely to a lack of standardisation of 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.

It is hoped this review article will go some way towards providing a source of reference for clinicians and researchers looking to incorporate PROMs into their clinical practice and clinical trials.

Conflict of interest

The authors confirm there are no conflicts of interest to declare.

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Table 1 Summary of commonly used PROMs in third molar surgery

PROM	Items (n)	Rating scale	Dimensions	References
Symptom-specific				
NRS	1	0-10	pain	O'Sullivan et al 2022[34]
VAS	1	0-100mm	pain	Bello et al 2011[38]
VRS	1	4-point scale	pain	-
MPQ	78	6-point scale	Sensory, affective, evaluative, miscellaneous, pain	High et al 1988[39]
SF-MPQ	15	4-point scale	Sensory, affective, pain	McCarthy et al 2017[40]
QoL-specific				
Generic				
EQ-5D-3L	6	3-point scale; 0-100mm	general QoL	Beech et al 2017[29]
SF-36	36	2- to 6- point scale	general QoL	-
SF-12	12	2- to 6- point scale	general QoL	McGrath et al 2003
Oral health-related				
OHIP-14	14	5-point scale	OHRQoL	McGrath et al 2003
OHQol-UK®	16	5-point scale	OHRQoL	McGrath et al 2003
Disease-specific				
PoSSe	15	3- to 5- point scale	Postoperative QoL specific to third molar surgery	O'Sullivan et al 2022, Grossi et al 2007
Psychosocial-specific				
HADS	14	4-point scale	anxiety, depression	McCarthy et al 2017

Figure 1. Vertical format of the numerical rating scale (NRS)

10
9
8
7
6
5
4
3
2
1
0

Figure 2. Visual analogue scale

No pain   Worst pain imaginable