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Patient-reported outcome measures following surgeries in implant dentistry and associated factors: a cross-sectional study

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ABSTRACT

Objectives We aimed to evaluate the patient-reported outcome measures (PROMs) of dental implant surgeries and analyse the associated indicators.

Design A cross-sectional study design was used.

Setting Department of Oral Implantology, Hospital of Stomatology, Wuhan University (May 2020–April 2021).

Participants Participants with missing teeth in need of implant-supported rehabilitation.

Interventions Dental implant placement and/or bone augmentation procedures.

Primary and secondary outcome measures The primary outcome was discomfort on postoperative day 1, measured using a numerical rating scale (NRS). Secondary outcomes included pain and anxiety during surgery; discomfort on postoperative days 3, 7 and 14; and post-surgical complications.

Results A total of 366 participants were included, of which 288 (78.7%) and 328 (89.7%) reported no to mild pain and anxiety (NRS 0–3) during surgery, respectively. The proportion of patients reporting discomfort decreased from postoperative day 1 (57.7%) to day 3 (36.1%) and day 7 (17.5%). The most frequent postoperative adverse events were pain and swelling. Patient-related factors (age, sex, smoking, alcohol consumption, history of periodontitis, and pain and anxiety during surgery) and surgery-related factors (type and extent of surgical procedure) were analysed. The factors associated with the severity of discomfort after surgery included alcohol consumption, pain perception during surgery, bone augmentation procedures and age ($p<0.05$). Similarly, the factors associated with the duration of discomfort included alcohol consumption, pain perception during surgery and age ($p<0.05$).

Conclusions PROMs related to dental implant surgeries can be predicted using certain risk indicators. Alcohol consumption, pain during surgery and age were associated with discomfort following dental implant surgery.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study comprehensively evaluated patient-reported outcome measures, including pain, anxiety and discomfort during dental implant surgery.
⇒ Patient-reported discomfort and complications during the first postoperative week were carefully evaluated.
⇒ Patient-related and surgery-related factors were listed as risk indicators and were comprehensively explored.

INTRODUCTION

Dental implant placement has been regarded as a widely accepted surgical approach to replace missing teeth with a high early survival rate.[1] Post-surgical infection or early wound failure may influence the early survival rate of implants.[2] Thus, a successful early healing process is essential to optimise the outcomes of dental implant therapies. The early healing procedure of dental implant placement has been investigated histologically,[3] clinically[4] and under inflammatory conditions.[5]

In implant dentistry, patient-reported outcome measures (PROMs) such as patient anticipation of treatment outcomes,[6] quality of life[7] and discomfort due to dental implant surgery[8] have received increasing research interest. With an understanding of PROMs, clinicians can ensure patients' own perception of need, involve patient preference in clinical decision-making, and improve clinician–patient trust and subsequent patient oral hygiene maintenance.[9–11] Furthermore, postoperative PROMs might reflect the early healing process and inflammatory conditions after dental implant placement.

For dental implant surgeries, different aspects of PROMs have been assessed separately, including pain, swelling and bleeding. Previous studies have reported that surgeries in implant dentistry provoked mild-to-moderate pain.[12–16] Potential predictors of the severity of post-surgical pain include patient-related factors (age, sex, history of smoking)[12–14 17 18] and surgery-related factors (flap design, use of surgical guide, extension of surgery, bone augmentation procedures and patient anxiety).[12 15–17] However, there is

currently limited evidence on PROMs following different types of dental implant surgeries.

Another type of PROM which has been rarely assessed is discomfort. According to the dental literature, discomfort can be summarised as a subjective perception derived from oral or facial symptoms (pain, swelling, bleeding and infection),[19] functional disability (chewing, speech and oral hygiene maintenance)[20] or general conditions (palpation, vomiting and dizziness)[21] following dental treatment. Severe or persistent discomfort might affect daily life and make patients apprehensive of their treatment. It has been reported that the peak discomfort occurs at 4–6 hours[16 18] to 1 day[12 17] after dental implant surgery. However, discomfort has not been comprehensively evaluated as an independent variable following dental implant surgery, and its associated factors remain unclear.

Thus, the aim of this study was to (1) evaluate the PROMs of dental implant surgeries, including pain, discomfort and anxiety, and (2) analyse the factors associated with the severity and duration of discomfort after surgery.

Table 1 Patient information (N=366)

Characteristics	No of patients (%)
Gender	
Male	146 (39.9)
Female	220 (60.1)
Age	
<40	173 (47.3)
≥40–<60	147 (40.1)
≥60	46 (12.6)
Smoking	
Yes	28 (7.7)
No	338 (92.3)
Alcohol drinking	
Yes	74 (20.2)
No	292 (79.8)
Periodontitis	
Yes	150 (41.0)
No	216 (59.0)
Type of surgery	
Implant placement	219 (59.8)
Bone augmentation	40 (10.9)
Bone augmentation with implant placement	107 (29.1)
Number of surgery sites	
Single site	253 (69.1)
Two sites	93 (25.4)
≥Three sites	20 (5.5)

MATERIALS AND METHODS

Study design

This study was designed as a cross-sectional study and has been reported according to the Reporting of Observational Studies in Epidemiology statement for cross-sectional studies.

Patient selection

Patients visiting the Department of Oral Implantology, School and Hospital of Stomatology, Wuhan University, in need of dental implant-supported rehabilitation from May 2020 to April 2021, were recruited. Inclusion criteria were as follows: (1) missing teeth; (2) in need of dental implant placement or bone augmentation procedures, or both; (3) older than 18 years; (4) with basic communication, reading and writing skills; and (5) willingness to sign an informed consent form. Exclusion criteria were: (1) patients receiving second-stage surgeries; (2) previously augmented sites; (3) sites with previous implant failure; (4) relative contraindications to dental implant therapy; (5) systematic diseases and psychological or medical disorders that might influence pain threshold; (6) use of pain medication within 1 year[8]; (7) acute intraoral pain (periodontal or endodontic pain); and (8) acute infections in which oral sensitivity was affected.

Clinical procedures

Before surgery, the patients were advised to rinse with 0.2% chlorhexidine solution for 1 min. All surgeries were performed by an experienced oral implantology clinician under local anaesthesia (4% articaine hydrochloride with epinephrine 1:100 000). A full-thickness mucoperiosteal flap was elevated for implant placement without bone augmentation. Implant socket preparation and placement were performed according to the manufacturer's instructions. The bone augmentation procedures included guided bone regeneration, sinus floor augmentation (through an osteotome or lateral window approach) and onlay bone grafting. Surgical details for these procedures have been described previously.[22–25] Autogenous bone blocks were harvested from the mandibular symphysis for onlay bone grafting. Bone substitute materials included Bio-Oss, Bio-Oss collagen and Bio-Gide (all from Geistlich Pharma, Wolhusen, Switzerland).

During the postoperative phase, the patients were administered antibiotics (500 mg amoxicillin every 8 hours, or for patients allergic to penicillin, 150 mg clindamycin every 6 hours) orally or intravenously (if bone augmentation procedures were performed). In addition, post-surgery oral hygiene instructions were delivered, including (1) tooth brushing 24 hours after surgery; (2) rinsing with 0.12% chlorhexidine mouthwash after eating, 24 hours after surgery, for 1 week; (3) using an ultra-soft toothbrush soaked in chlorhexidine over the treated area starting on postoperative day 3 and continued for 6 weeks; and (4) avoiding chewing or trauma to the surgery sites for the first 6 weeks.[26 27] According to previous studies, the majority of patients reported no or mild pain after

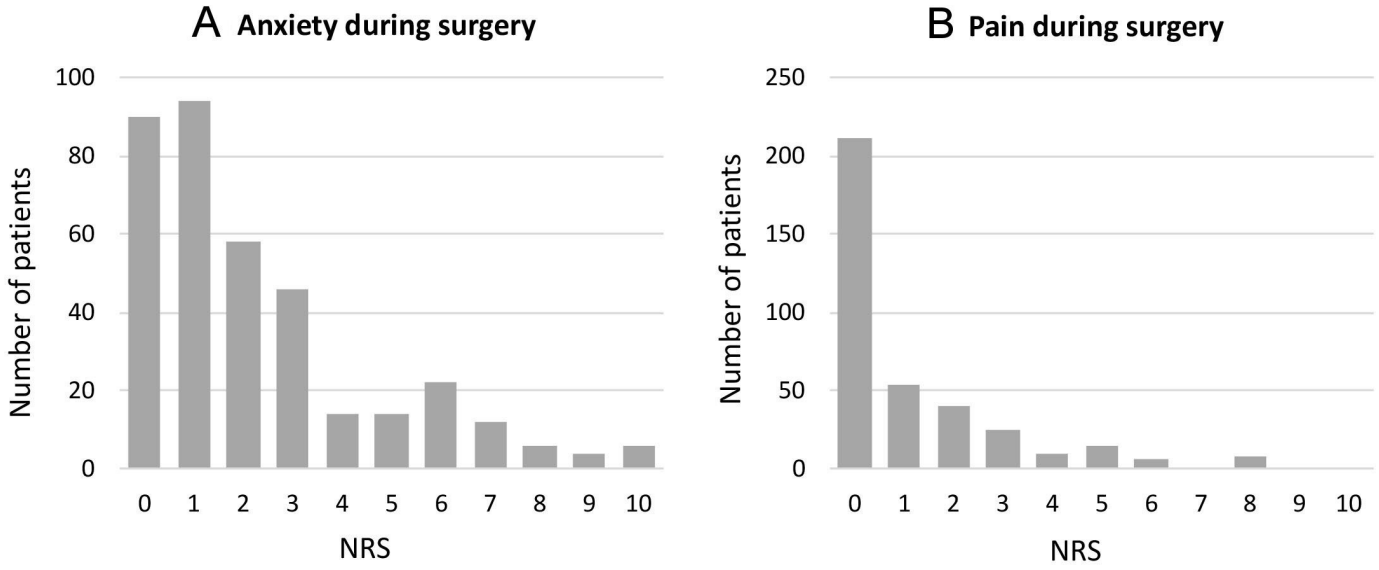

Figure 1 Patient-reported (A) anxiety and (B) pain during surgery. NRS, numerical rating scale.

implant surgeries.[15 16] Thus, analgesics were not routinely prescribed. Patients could choose to take analgesics (diclofenac sodium 50 mg two times per day).

Data collection

Relevant clinical information was collected for all patients, including patient-related information (age, sex, smoking, alcohol drinking and presence of periodontitis) and surgery-related information (number of implant sites and the type of surgical procedure performed).

- Patients who smoked at least one cigarette per day were defined as current smokers.[15]
- Patients who consecutively drank at least half a litre of alcoholic beverages per day for at least 1 year were defined as alcoholics.[28]
- Periodontitis was defined as the presence of clinical attachment loss, periodontal pocketing, gingival bleeding and radiological evidence of alveolar bone loss.[29]
- The types of surgical procedure performed were categorised as implant placement alone, bone augmentation procedures alone or bone augmentation procedures with simultaneous implant placement.

Before surgery, two trained researchers (MY and JS) who were not aware of the treatment plan interviewed the patients, recorded patient-related information and performed clinical assessments. Patient-reported baseline conditions (age, sex, smoking and drinking habits) were assessed using a questionnaire at their first visit. The assessment of periodontitis was calibrated by measuring the same subject twice, with each round containing 20 subjects. Any disagreement was resolved by discussion with senior doctors (HX and BS) until the assessment by the two researchers was the same in a round. Surgery-related information was recorded by two researchers (MY and JS) postoperatively.

Assessment of PROMs

Three trained researchers (XW, MY and JS) assessed patient-reported outcomes. Immediately after surgery, the patients were asked to rate their perception of pain and anxiety during surgery. On postoperative days 1, 3, 7 and 14, patients were contacted telephonically and asked to rate their perception of discomfort and report any adverse events. Patients were also requested to report

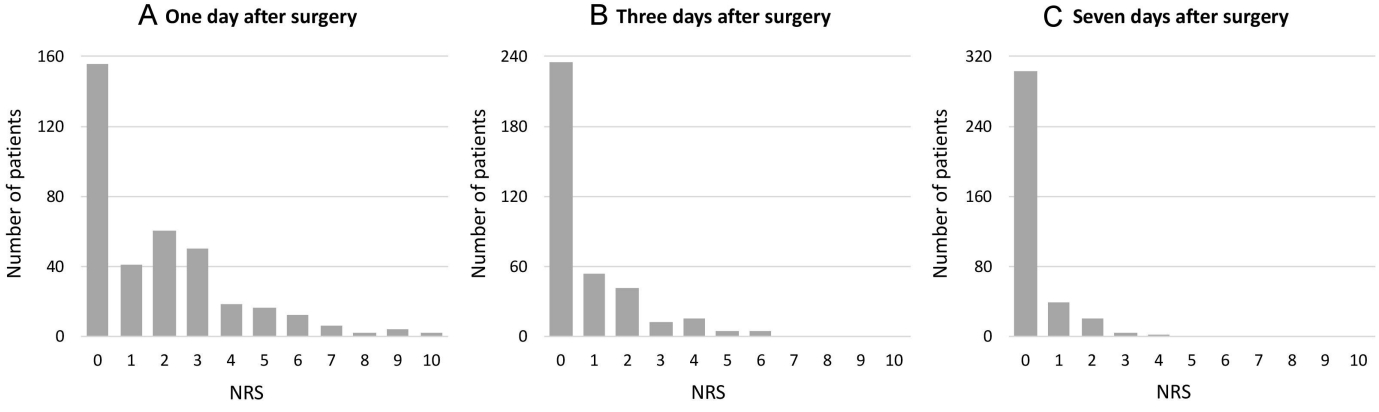

Figure 2 Severity of discomfort at (A) 1, (B) 3 and (C) 7 days after surgery. NRS, numerical rating scale.

Table 2 Adverse events after implant surgery (N=366)

Adverse events	No of patients (%)
One day after surgery	
No adverse event	143 (39.1)
Pain	179 (48.9)
Swelling	179 (48.9)
Bleeding	21 (5.7)
Foreign body feeling	19 (5.2)
Sleep disturbance	9 (2.5)
Feeling dizzy	6 (1.6)
Fever	4 (1.1)
Three days after surgery	
No adverse event	238 (65.0)
Swelling	98 (26.8)
Pain	67 (18.3)
Foreign body feeling	14 (3.8)
Ulcer	6 (1.6)
Bleeding	3 (0.8)
Bruising	2 (0.5)
Seven days after surgery	
No adverse event	331 (90.4)
Pain	32 (8.7)
Swelling	21 (5.7)
Foreign body feeling	4 (1.1)

whether they required postoperative analgesics and their respective dosages.

Perception of anxiety, pain and discomfort was evaluated using the numerical rating scale (NRS),[15 16] with scores ranging from 0 to 10. To grade the severity of perception, scores 1–3 represent 'mild perception', scores 4–6 represent 'moderate perception' and scores 7–10 represent 'severe perception'.

Statistical analysis

SPSS (V.25.0) was used for the statistical analysis. Percentages were calculated to describe basic patient information and NRS distribution. Factors associated with the severity of discomfort 1 day after dental implant surgery and the duration of discomfort were investigated using ordinary logistic regression analyses. To explore the factors associated with the severity of discomfort, the dependent variable was the NRS value of discomfort on day 1 after surgery. The NRS value of discomfort was graded into 'no' (NRS=0), 'mild' (1–3), 'moderate' (4–6) and 'severe' (7–10). To explore factors associated with the duration of discomfort after surgery, the duration was set as dependent variable, graded into '<1 day', '>1 but <3 days', '>3 days but <7 days', and '>7 days'. Candidate factors for both regression analyses included patient age, sex, smoking, alcohol consumption, periodontal status, number of implant sites, types of surgical procedures, pain perception during surgery and anxiety during surgery. Initially, all candidate factors were included in the univariate ordinary regression model. The factors with $p<0.1$ were further put into a multivariable ordinary regression model. Results were calculated as ORs and 95% CIs. Collinearity diagnostics and parallelism tests were performed. Statistical significance was defined as a two-sided $p<0.05$.

Patient and public involvement

Neither the patients nor the public were involved in the design, conduct, reporting or dissemination plans of the present study.

RESULTS

Patient information

In total, 366 patients were included in this study. The demographic information of the included patients is listed in table 1. Briefly, 28 (7.7%) patients were smokers and 74 (20.2%) were alcoholics. Of all patients, 219 (59.8%) underwent only implant placement and 253 (69.1%) underwent single-site surgeries.

Patient-reported outcome measures

During the surgery, 90 patients (24.6 %) reported no anxiety. A total of 198 (54.1%), 50 (13.7%), and 28 (7.7%) patients reported mild, moderate, and severe anxiety, respectively (figure 1A). Regarding pain during surgery, 211 (57.7%), 117 (32.0%), 30 (8.2%), and 8 (2.2%) patients reported no, mild, moderate, and severe pain, respectively (figure 1B).

Seventy-three patients (19.9%) required analgesics the day after surgery. The severity of discomfort on postoperative days 1, 3 and 7 is shown in figure 2. On postoperative day 14, no discomfort was reported. The severity of discomfort decreased from day 1 to day 14. In addition, 151 (41.3%), 248 (67.8%), 314 (85.8%), and 366 (100%) patients reported that the duration of discomfort was <1 day, <3 days, <7 days, and <14 days, respectively.

The adverse events are listed in table 2. On postoperative day 1, the incidence of pain and swelling was the same (179 patients, 48.9%) and the highest among all adverse events. On postoperative day 3, the incidence of swelling was the highest (98 patients, 26.8%). On postoperative day 7, the incidence of pain was the highest (32 patients, 8.7%). The incidence of adverse events decreased from postoperative day 1 to day 7. Fourteen days after the surgery, no adverse events were reported.

Factors associated with the severity of discomfort

In univariate ordinary logistic analyses, the p values of age, alcohol consumption, number of surgery sites, types of surgical procedures and pain perception during surgery were less than 0.1. These factors were incorporated into a multivariate ordinary logistic model. Finally, the severity of discomfort on postoperative day 1 was significantly associated with alcohol consumption (OR=2.61, 95% CI:

Table 3 Significant predictors for the severity of discomfort 1 day after surgery in multivariable logistic regression model (N=366)

Predictors	Univariate analyses		Multivariable analyses	
	OR (95% CI)	P value	OR (95% CI)	P value
Age	1.02 (1.00 to 1.03)	0.016	1.02 (1.01 to 1.04)	0.009
Gender				
Male	Reference			
Female	1.08 (0.73 to 1.60)	0.706		
Smoking				
No	Reference			
Yes	1.22 (0.59 to 2.50)	0.592		
Alcohol drinking				
No	Reference		Reference	
Yes	2.43 (1.47 to 4.03)	0.001	2.61 (1.55 to 4.38)	<0.001
Periodontitis				
No	Reference			
Yes	0.46 (0.75 to 1.87)	0.463		
Number of surgery sites	1.47 (1.06 to 2.05)	0.022	1.08 (0.75 to 1.55)	0.678
Type of surgery				
Implant placement	Reference		Reference	
Bone augmentation	1.63 (1.06 to 2.53)	0.027	1.71 (1.08 to 2.70)	0.021
Bone augmentation with simultaneous implant placement	0.90 (0.46 to 1.78)	0.764	1.31 (0.65 to 2.62)	0.450
Pain during surgery	1.40 (1.23 to 1.60)	<0.001	1.35 (1.18 to 1.56)	<0.001
Anxiety during surgery	1.07 (0.98 to 1.16)	0.129		

1.55 to 4.38, p<0.001), pain perception during surgery (OR=1.35, 95% CI: 1.18 to 1.56, p<0.001), performing bone augmentation procedure without implant placement (OR=1.71, 95% CI: 1.08 to 2.70, p=0.021) and age (OR=1.02, 95% CI: 1.01 to 1.04, p=0.009) (table 3).

Factors associated with the duration of discomfort

In univariate ordinary logistic analyses, the p values of age, alcohol consumption, number of surgery sites, pain perception and anxiety during surgery were less than 0.1. These factors were incorporated into a multivariate ordinary logistic model. Finally, the duration of discomfort was significantly associated with alcohol consumption (OR=1.92, 95% CI: 1.17 to 3.15, p=0.010), pain perception during surgery (OR=1.47, 95% CI: 1.26 to 1.70, p<0.001) and age (OR=1.02, 95% CI: 1.00 to 1.03, p=0.046) (table 4).

DISCUSSION

The present study comprehensively assessed discomfort associated with dental implant surgeries at different time points. In addition, the factors associated with the severity and duration of discomfort were analysed. The severity of discomfort decreased from postoperative day 1 to day 14. Approximately half of the patients reported no to mild discomfort on postoperative day 1. The most frequent adverse events after dental implant surgery were pain and swelling, both occurring in 48.9% of patients on postoperative day 1. Factors associated with both the severity and duration of surgery were alcohol consumption, pain perception during surgery and age, among which the OR of alcohol consumption was the highest. The results of this study provide guidance for clinicians in preventing or alleviating discomfort after dental implant surgery. In addition, the clinical symptoms of early healing after dental implant placement may indicate a trend of peri-implant post-surgical wound healing.

PROMs for dental implant surgeries have been reported. A previous study reported that implant placement surgery had an impact on post-surgery oral health-related quality of life and dental anxiety.[30] Another study reported a significant time effect of post-surgery discomfort (including pain, swelling and bruising) with the most severe pain and bleeding on the first day after surgery and the most severe swelling on the second day after surgery.[31] The results of the present study showed a similar trend with swelling and pain most frequently reported on postoperative day 1 and swelling most frequently reported on postoperative day 3. The time effect of post-surgery discomfort might be attributed to the wound-healing process after implant placement with flap elevation.[32] In previous studies, the peak proportion of patients reporting pain ranged from 90.3% to 100%.[13 15 16] The differences observed among the studies might result from

Table 4 Predictors for duration of discomfort after surgery in multivariable logistic regression model (N=366)

Predictors	Univariate analyses		Multivariable analyses	
	OR (95% CI)	P value	OR (95% CI)	P value
Age	1.02 (1.00 to 1.03)	0.021	1.02 (1.00 to 1.03)	0.046
Gender				
Male	Reference			
Female	1.03 (0.70 to 1.50)	0.891		
Smoking				
No	Reference			
Yes	1.37 (0.68 to 2.75)	0.374		
Alcohol drinking				
No	Reference		Reference	
Yes	2.01 (1.24 to 3.27)	0.005	1.92 (1.17 to 3.15)	0.010
Periodontitis				
No	Reference			
Yes	0.93 (0.60 to 1.44)	0.738		
Number of surgery sites	1.48 (1.08 to 2.04)	0.016	1.20 (0.84 to 1.72)	0.306
Type of surgery				
Implant placement	Reference			
Bone augmentation	1.17 (0.77 to 1.78)	0.474		
Bone augmentation with simultaneous implant placement	0.72 (0.37 to 1.39)	0.325		
Pain during surgery	1.51 (1.32 to 1.73)	<0.001	1.47 (1.26 to 1.70)	<0.001
Anxiety during surgery	1.09 (1.00 to 1.78)	0.051	1.02 (0.93 to 1.12)	0.666

the differences in patients evaluated, surgeons, surgical tools, manufacture and dosage of anaesthetics, and use of analgesics. In this study, all surgeries were performed by an experienced oral implantologist and completed over short duration, which alleviated the pain and discomfort of patients during and after surgery.[12 33]

In the present study, alcohol consumption was significantly associated with the severity (OR=2.61, 95% CI: 1.55 to 4.38) and duration (OR=1.92, 95% CI: 1.17 to 3.15) of discomfort after dental implant surgery. The OR for alcohol consumption was the highest among all candidate factors, indicating that alcohol consumption was a major factor. Alcohol consumption has been reported to influence systemic inflammatory cytokine levels[34 35] and bone metabolism[36–38] and inhibit wound healing following procedures.[39] Previous studies reported that alcohol consumption increased dental pain.[40 41] Clinicians usually experience reduced efficacy of local anaesthetics in alcoholics.[42] It was difficult to achieve satisfactory pain control with local anaesthetics in patients with a history of habitual drinking.[43 44] The results of the current study suggest that patients should be advised to cease or decrease the frequency of alcohol consumption to shorten the healing time and reduce discomfort after dental implant surgery. For alcoholics with a high risk of discomfort during and after surgery, it is recommended that patients be comforted before surgery, to minimise flap opening and place fewer implants at one time when multiple implants are needed. In addition, for alcoholics who have multiple missing teeth, pre-surgical analgesics[45 46] or a combination of other therapies (such as low-level laser therapy)[47] is recommended.

Stronger pain perception during dental implant surgery was associated with higher severity (OR=1.35, 95% CI: 1.18 to 1.56) and longer duration of discomfort (OR=1.47, 95% CI: 1.26 to 1.70) after surgery. According to previous studies on dental implant surgery, pain during surgery is related to larger surgical trauma, such as performance of the bone augmentation procedure, duration of surgery and flap opening.[12 13 15] Larger surgical trauma usually requires a longer healing time. In addition, placement of bone substitute materials may trigger more severe inflammatory responses, leading to stronger swelling after surgery.[48 49]

The results of the present study indicated that advanced age was associated with higher severity (OR=1.02, 95% CI: 1.01 to 1.04) and longer duration (OR=1.20, 95% CI: 1.00 to 1.03) of discomfort. The literature reports contradictory results regarding the influence of age on PROMs in dental implant surgery. Beaudette *et al*[17] reported that older patients experienced less severe pain 1 day after dental implant surgery. However, others[12 50] have reported that age is not a significant predictor of pain or discomfort in dental implant surgery. For older people, cells and mediators involved in wound healing are usually negatively influenced, resulting in stronger inflammatory

reactions, reduced new bone/soft tissue formation and remodelling, and a prolonged healing phase.[51–55] In addition, older people usually have compromised systemic conditions and received certain medications or treatments (such as bisphosphonates or radiotherapy). However, in the present study, all patients were systemically healthy and did not receive medication or treatment that contradicted dental implant surgery.

The current study comprehensively investigated the factors associated with the severity and duration of discomfort after dental implant surgery. The results of the present study can be used to identify risk indicators for PROMs, which should be considered during dental implant placement. Future prospective studies and randomised trials with larger sample sizes are needed to demonstrate the association between PROMs and risk indicators. One limitation of the present study was that the influence of site-specific factors (bone quality and implant sites) was not investigated because approximately 30% of patients received multiple implants. Moreover, owing to the nature of the cross-sectional observational study, the present study failed to determine the association between alcohol consumption and the post-surgery healing process. Further studies are needed to explore site-specific factors associated with discomfort caused by dental implant surgery to provide more detailed information for clinicians. In addition, proper prevention methods should be explored for patients at risk of severe postoperative pain. Furthermore, the biological rationale for the healing patterns of different patients and surgical procedures should be investigated.

CONCLUSIONS

Most patients experienced no to mild discomfort after dental implant surgery. Alcohol consumption, pain during surgery and age are risk indicators of postoperative discomfort. Future studies should explore the association between PROMs and inflammatory conditions to improve the early healing and survival of dental implants.

Contributors Study conception—QY, BS and HX. Study design—XW, MY, JS, QY, BS and HX. Literature search—XW, MY and JS. Data collection—XW, MY and JS. Data analysis—XW and MY. Data interpretation—XW, QY, BS and HX. Manuscript drafting—XW and MY. Critical revision of the manuscript—JS, QY, BS and HX. The guarantor responsible for the content—HX. Approval of the final version—all authors.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Obtained.

Ethics approval This study was performed in accordance with the Helsinki Declaration of 1975 and the 2013 revised version. The study protocol was approved by the Ethics Committee of the School and Hospital of Stomatology, Wuhan University (No. 2020(B21)). Written informed consent was obtained from all patients.

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Data availability statement Data are available upon reasonable request. The data sets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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