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Health related quality of life and patient concerns in patients with osteoradionecrosis

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Keywords; head and neck cancer; osteoradionecrosis; health related quality of life; Patient Concerns Inventory; UW-QOL

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Abstract

The number of patients presenting with osteoradionecrosis (ORN) is likely to increase in future and health related quality of life (HRQOL) is a key outcome.

This study aimed to report patient concerns and HRQOL in an osteoradionecrosis cohort over 12 years. Patients attended routine follow-up clinics between 2008 to 2020, where patient reported outcome (PRO) assessment was used before consultations as standard practice. The two PROs were the Patient Concerns Inventory (PCI) and the University of Washington quality of life questionnaire (UW-QOL v4).

The study sample comprised 109 patients with ORN seen in 445 clinics when PCI and UW-QOL were used. At clinic, patients were in one of six ORN states: before ORN (26 with data), at diagnosis (12), and following treatment either improved (27), progressed (46), stable (63) or resolved (37). Worst HRQOL outcomes were reported in the progressive group with 50% reporting overall QOL as less than good. Pain was a major dysfunction (63%) as was physical and social-emotional functioning and this group reported many PCI issues, median (IQR) 7 (4-11). Kaplan-Meier estimates of survival with 95% CI after diagnosis with ORN were 96% (90-99%) at 12 months, 89% (81-94%) at 24 months and 73% (61-82%) at 60 months.

This study indicates that ORN is a chronic condition with long-term survivorship consequences. More data through cohort studies and trials is needed to assist in decision making for individual patients.

Introduction

Osteoradionecrosis (ORN) is one of the most debilitating side effects following radiotherapy for head and neck cancer (HNC). The reported incidence of ORN ranges between 10 and 15%.⁽¹⁾ Although modern radiotherapy techniques might reduce the risk, the number of ORN patients is expected to rise as more patients are treated with primary or adjuvant radiotherapy or chemoradiotherapy and with increasing life expectancy. The number of papers reporting health-related quality of life (HRQOL) following ORN are relatively few,⁽²⁻⁹⁾ however they highlight the detrimental impact on HRQOL.

Surgical management of ORN is complex.⁽¹⁰⁾ and there are various approaches to managing ORN.⁽¹¹⁾ Previously we reported our experience of hyperbaric oxygen⁽¹²⁾ but generally our current practice is initial non-surgical management using combinations of tocopherol, pentoxifylline, chlorhexidine mouthwash, doxycycline and clodronate.⁽¹³⁾ Patients with advanced ORN disease will have radical surgery if their symptoms are uncontrolled with medications.

Study data was possible due to the integration of patient reported outcomes measures (PROM) into routine out-patient consultations with one of the authors (SNR) since 2007. The aim of this study was to report patient concerns and HRQOL in an osteoradionecrosis cohort spanning a twelve-year period. This information serves to highlight the impact of ORN on patients and to reflect on possible clinical interventions to help patients cope with the sequelae of HNC treatment.

Methods

HNC patients of one consultant () attending outpatient clinics from 4th June 2008 to 11th March 2020 completed PCI and UWQOL data directly onto a computerised system on the Aintree-Hospital secure server. Patients were disease-free and under routine follow-up at least 6 weeks after completing treatment. Exclusions were pre-treatment, palliative, review for other post-operative wound management or if in an outcomes study in clinic. Patients completed the PCI/UW-QOL immediately before their planned routine outpatient clinic consultation. When approached in the routine clinic setting virtually all patients participated. The consultant used a print-out of PCI responses in real-time during the consultation. Study data were extracted from electronic case notes on SIGMA (System C) and outpatient clinical letters. Data included patient demographics, head and neck staging (American Joint Committee on Cancer AJCC 7), HNC site, diagnosis date and treatment modality of HNC,

diagnosis date and treatment of ORN, ORN site, treatment modality, ORN status, date of last follow-up, survival, and (for each clinic) PCI and UW-QOL.

Patients were graded using the NOTANI score for the mandible: grade I: ORN confined to alveolar bone, grade II: ORN limited to the alveolar bone and/or mandible above the level of the inferior alveolar canal and grade III: ORN involving the mandible below the level of the inferior alveolar canal, and ORN with a skin fistula or pathological fracture or both.⁽¹⁴⁾ The main treatments were surgical debridement, hyperbaric oxygen (HBO) or medical management (tocopherol, pentoxifylline and antibiotics). Patients were classified into six ORN states; before ORN, at diagnosis, and four responses to treatment- improved, progressed, stable, resolved. Response was an overall impression based on patients' symptoms, clinical examination, and radiographical changes. Comments about patient response to treatment (status) was included in the correspondence following each out-patient consultation.

Instruments

The PROMs used were the Patient Concerns Inventory (PCI)⁽¹⁵⁾ and the University of Washington quality of life questionnaire (UW-QOL v4).⁽¹⁶⁾ The PCI is a condition-specific item prompt list of 56 items, selected by patients to help guide their outpatient consultations. A recent systematic review and content comparison of unmet needs self-report measures favoured the PCI over 13 other PROMs tools.⁽¹⁷⁾ Patients appreciate the opportunity to raise their issues, and inclusion of the PCI is a low-cost intervention which in a randomised trial setting has indicated improvements in QOL and socio-emotional dysfunction.⁽¹⁸⁾

The UW-QOL version 4 consists of 12 domains scaled from 0 (worst) to 100 (best) according to response hierarchy.⁽¹⁶⁾ UW-QOL domains are presented within two subscales, physical function and social-emotional function with each subscale score being the mean of six domain scores.⁽¹⁹⁾ Criteria derived from earlier work can highlight domains in which patients have a significant problem or dysfunction;⁽¹⁵⁾ **these criteria involve domain scores and whether patients select the domain as one of three most important to them in the previous week.** From 2008 to 2011, the PCI-HN had 54 items, before 'dry mouth' and 'sore mouth' were added in 2012.

Statistics

Survival after ORN diagnosis, with 95% Confidence interval, was estimated using life table methods within SPSS version 25. The amount of clinic data varied considerably between patients, both overall and within each ORN state. PCI/UW-QOL clinic-based data was difficult to summarise longitudinally over ORN states because one-quarter of the patient sample only had one clinic record while one-sixth of patients had 40% of clinic records. To gain a representative sample within each ORN state and avoiding the issue of multiple clinics per patient within each ORN state, one clinic per patient per state was selected. For example, one patient had 6 clinics overall, 2 stable, 1 progression, 3 resolved; 3 clinics were selected, 1 stable (at random, 1 from 2), 1 progression, 1 resolution (at random, 1 from 3). This was intended to maximise the number of patients within each state. However, because some patients were represented in more than one state, this overlap of patients meant that the independence assumption of data was not met and hence it was not possible to perform statistical testing with P values to compare the states.

This study was approved by [redacted] Hospital NHS Foundation Trust Audit Department and used data as collected in routine care (Reference 7448).

Results

The study sample comprised 109 patients with ORN seen in 445 routine oncology clinics for which PCI and UW-QOL data were available. Median (IQR) age at primary tumour diagnosis was 56 (50-64) years and 75% (82) were male. The primary tumour site was oropharyngeal cancer for 65 patients, with 31 treated by surgery plus radiotherapy and 34 non-surgically by radiotherapy or chemoradiotherapy. The location was oral cavity for 36 patients, 35 treated by surgery plus radiotherapy and 1 treated non-surgically. There were 8 with other locations, 3 treated with surgery plus radiotherapy and 5 non-surgically.

Time from diagnosis of primary tumour to diagnosis of ORN was a median (IQR) of 38 (16-81) months. Median (IQR) age at diagnosis was 61 (55-68) years. ORN site was the mandible for 87% (95), maxilla for 6% (6), mandible and maxilla for 5% (5), and 3 others (orbit, temporal bone, external auditory canal). Of 100 cases involving the mandible the NOTANI classification on initial presentation to the clinic was known for 98, with 42 being grade I ORN, 15 grade II and 33 grade III; 8 could not be classified because the ORN occurred in the free-flap. Initial treatment was medication in 66 cases, a combination of medication and surgical debridement for 11, surgery alone for 18 (10 debridement, 8 free

tissue transfer), HBO for 5, while 9 were managed conservatively. Forty-one patients had medical management alone throughout. Another 41 patients had medical management followed by further treatment; 12 had surgical debridement, 24 had free-flap reconstruction and 5 had further medical management. Another 2 patients had surgical debridement followed by free-flap reconstruction. These 26 later free-flap reconstructions occurred a median (IQR) of 17 (9-32) months after initial treatment. The 5 HBO cases all received further treatment, 3 with free flaps and 2 with medications. Of those initially managed conservatively, one went on to have debridement. In total, 37 free flaps were performed, all for mandibular reconstruction, and comprised of composite radial 13, soft radial 6, fibula 12, DCIA 3, ALT 2 and scapula 1. Surgery was a median (IQR) of 16 (8-28) months after ORN diagnosis, range 8-28 months. In terms of follow-up status for the 37 free flap cases: 17 were discharged, 12 were under follow-up and 8 had died (median 10 months after the free-flap surgery).

Overall, the last follow-up clinic was a median (IQR) 41 (20-63) months after ORN diagnosis, with patient status being ongoing for 52, discharged for 36 and deceased for 21. Of those with ongoing management, the ORN resolved for 19, was stable for 30 while 3 were progressive. Of those discharged, the ORN resolved for 22, while 10 were stable, 3 were progressive and 1 was unknown. Of those deceased, the ORN had resolved for 8, while 7 were stable, 2 were progressive, 1 died in hospital and 3 were unknown. Kaplan-Meier estimates of survival with 95% CI after diagnosis with ORN were 96% (90-99%) at 12 months, 89% (81-94%) at 24 months and 73% (61-82%) at 60 months.

PCI and UW-QOL data were collected at 445 clinics, median (IQR) 4 (1-6) survey completions per patient, range 1-16. There were 82 clinics (26 patients) before ORN was diagnosed, 12 clinics (12 patients) with data at the time of ORN diagnosis, 31 clinics (27 patients) at a time of improvement in ORN, 69 clinics (46 patients) at a time of ORN progression, 159 clinics (63 patients) when the ORN was stable and 92 clinics (37 patients) after the ORN had resolved. One clinic per patient per state was selected for analysis (Tables 1 and 2) as described in methods. Patients in the progressive phase of the disease (Table 1) were observed to have experienced problems particularly with pain (63% dysfunction) and low levels of both physical function (median 56) and social-emotional function (median 61) subscale scores. There was dysfunction for 28% of these patients with mood and for 30% with anxiety and 50% with overall QOL that was less than good. Patients before ORN

developed, at the time of diagnosis and in the progressive phases tended to select more PCI items for discussion in their consultations (Table 2) while patients in the stable and improved states selected fewer and patients with ORN resolution selected fewest. The PCI items most frequently selected (by at least 25% of patients per group) reflected issues typically associated with patients experiencing ORN.

Discussion

Controversy remains regarding the most appropriate management of ORN. In future, it is hoped that a trial based on NICE guidelines is conducted.⁽¹¹⁾ HRQOL is a very important outcome after ORN but as yet there is no long-term trial data to evaluate success of various treatments. This current study gives a unique opportunity to reflect on outcomes in routine care. Having the PROM integrated into standard follow-up means that few patients are missed and there is opportunity for repeated measures with longitudinal assessment spanning 12 years. Furthermore, we had the opportunity to report HRQOL and PCI of patients before their ORN diagnosis. However, as most ORN patients were referred from ENT colleagues there is not a true longitudinal cohort of every patient with data before ORN and followed through ORN diagnosis and then beyond. Analysis was challenging as some patients had multiple sets of data at the same state – the analysis was limited in that we had to focus separately on each state and to randomly select only one clinic per patient as being representative for that state. This meant that comparison of states was compromised by some patients straddling between different combinations of states (Table 1). The resulting lack of statistical independence of data ruled out formal statistical testing between states in Table 1. Comparison was based solely on observation. The findings reflect one consultant's clinic and although giving an insight into the PRO, might not reflect the experience of other centres. The six ORN status groups allowed for a useful means of comparison but it is accepted that the status has no clear objective measurement and is the inference of the clinician following each patient. Only one consultant was involved so hopefully there is consistency here. Also, there were relatively small numbers in some groups.

Patients with ORN report various problems such as dysphagia, dentition, and activity limitations,⁽⁷⁾ also trismus and a range of symptom distress including problems with teeth/gums, dry mouth, oral malodour, tinnitus/ear obstruction/difficulty hearing.⁽⁹⁾ Previous papers reporting HRQOL following reconstructive surgery for ORN, although with small patient numbers, tend to support the benefit of surgical intervention on QOL.^(2, 3, 5, 8)

However, in an earlier series, HRQOL was relatively poor after composite resection for NOTANI grade III disease; the long-term side effects of radiotherapy affects many different domains that are not improved by radical surgery such as speech, swallowing, appearance, chewing, shoulder.⁽⁶⁾ For all ORN groups in this current sample the physical subscale of the UW-QOL was in keeping with poor outcomes following HNC treatment, reflecting the major detrimental impact of radiotherapy and ORN on HRQOL. Pain was a major influence on the relatively low socio-emotional subscale scores. In terms of the PCI, patients at diagnosis and with ORN progression were reporting nine issues on average. This number is twice that seen in typical HNC follow up consultations and an increasing number of PCI concerns is strongly correlated to poor HRQOL outcomes.⁽¹⁸⁾

Further detailed cohort studies or trials reporting different treatment strategies are needed as there is still uncertainty as to when to undertake radical surgery and reconstruction based on HRQOL and PCI outcomes. There are various potential factors influencing the decision-making process such as ORN stage, symptoms, physiological age, comorbidity, and previous management. Earlier consideration should be contemplated for patients with more advanced disease or those showing little response to medication.

Furthermore, the complex needs of ORN patients might benefit from designated clinics where multi-professional support is available, including clinical nurse specialist, dietician, emotional support therapist, oncologist, physiotherapist, speech and language therapist, and surgeon. It is important to reconcile patient and carer expectations of treatment outcomes as many side-effects of radiotherapy are long-term, potentially progressive, and very challenging to manage.

In conclusion, although medical management and radical surgery both have clear roles in managing ORN, it is a chronic condition with long-term survivorship consequences and a relatively poor HRQOL and concerns profile.

Conflict of interest statement

We have no conflicts of interest.

Ethics Statement / Confirmation of Patient's Permission

The data was collected for service evaluation and approved by the local Clinical Governance Department.

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Table 1. UW-QOL for 109 ORN patients, with one clinic HRQOL record selected per patient within each ORN state

	ORN state											
	Before ORN		At diagnosis of ORN		Improved		Progressive		Stable		Resolved	
	26		12		27		46		63		37	
Number of patients												
Median (IQR) months from ORN diagnosis	-19 (-9, -43)		0 (0-0)		9 (4-21)		14 (6-24)		22 (7-36)		24 (15, 62)	
Overall QOL life: Less than good	%	N	%	N	%	No	%	No	%	No	%	N
	39	10	42	5	33	9	50	23	43	27	31	11/36
Social-emotional Dysfunction:												
• Pain	27	7	42	5	22	6	63	29	29	18	27	10
• Activity	12	3	25	3	15	4	26	12	14	9	19	7
• Recreation	8	2	8	1	15	4	20	9	11	7	19	7
• Shoulder	8	2	17	2	7	2	11	5	10	6	11	4
• Mood	15	4	8	1	19	5	28	13	14	9	14	5
• Anxiety	19	5	17	2	22	6	30	14	13	8	19	7
Physical function Dysfunction:												
• Appearance	8	2	8	1	26	7	11	5	10	6	19	7
• Swallowing	31	8	33	4	15	4	33	15	29	18	24	9
• Chewing	35	9	25	3	7	2	24	11	19	12	19	7
• Speech	12	3	8	1	4	1	17	8	5	3	11	4
• Taste	38	10	8	1	22	6	15	7	21	13	22	8
• Saliva	35	9	33	4	19	5	33	15	33	21	24	9
Social-emotional scale: Median (IQR)	70 (56-87)		83 (57-98)		70 (53-87)		61 (48-74)		73 (59-91)		72 (60-92)	
Physical function scale: Median (IQR)	54 (41-59)		68 (43-84)		62 (52-83)		56 (44-68)		63 (48-75)		65 (49-77)	

Table 2. Patients concerns inventory (PCI) items most often selected by 109 ORN patients, with one clinic HRQOL record selected per patient within each ORN state

	ORN state					
	Before ORN	At diagnosis of ORN	Improved	Progressive	Stable	Resolved
Number of patients	26	12	27	46	63	37
Mean, Median (IQR) total number of PCI items selected	8.2, 6 (3-14)	9.0, 7 (4-15)	5.8, 5 (2-9)	8.8, 7 (4-11)	6.3, 5 (2-9)	4.8, 2 (1-8)
PCI items selected by more than 25% of patients	Chewing/eating 54 Fear of recurrence 54 Dry mouth 50 Sore mouth 41 Salivation 38 Dental Health/teeth 35 Mouth opening 35 Taste 31 Pain in head/neck 27 Swallowing 27 Swelling 27	Dry mouth 60 Dental Health/teeth 58 Fear of recurrence 50 Sore mouth 50 Wound healing 50 Mouth opening 42 Salivation 42 Chewing/eating 33 Pain in head/neck 33 Pain elsewhere 33 Swelling 33	Mouth opening 44 Dental Health/teeth 37 Pain in head/neck 30 Fatigue/tiredness 26	Sore mouth 50 Mouth opening 46 Chewing/eating 41 Fatigue/tiredness 39 Pain in head/neck 37 Salivation 37 Dental Health/teeth 35 Fear of recurrence 35 Swallowing 33 Depression 28 Mood 28 Sleeping 28 Anxiety 26 Dry mouth 26 Mucus 26	Dental Health/teeth 38 Dry mouth 37 Mouth opening 30 Pain in head/neck 29 Swallowing 29 Fear of recurrence 27	Dental Health/teeth 38 Swallowing 27

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CONFIRMATION OF AUTHORSHIP

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We confirm that all the authors have had material input into the submission.

We confirm that, to our knowledge, all the claims, statements and conclusions are true and are our jointly held opinions.

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