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# Longitudinal evaluation of health-related quality of life after osteoradionecrosis of the mandible

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### Abstract

There is a lack of longitudinal data on the effect of osteoradionecrosis (ORN) on health-related quality of life (HRQoL). We report data on HRQoL across groups of patients with ORN at different stages of disease and reconstruction. We identified 71 patients treated for ORN of the mandible, and cross-referenced the data with their medical records. They were divided into 4 groups according to the Notani classification and patients who did not have ORN were used for comparison. Patients with ORN reported the most pain, and rates were relatively high for problems concerning appearance, activity, recreation, swallowing, and chewing. There were significant differences for pain, appearance, swallowing, and chewing between patients who had ORN and those who did not and had not had radiotherapy. On the University of Washington quality of life questionnaire (UWQoL), patients with ORN reported similar levels of morbidity to those who had had radiotherapy but did not have ORN, particularly on the physical and social-emotional subscales. Those with grade III ORN were particularly affected, and the UWQoL scores after mandibular resection and reconstruction were disappointing. HRQoL after composite resection for Notani grade III disease is relatively poor. In patients whose symptoms can be managed without an operation, it seems appropriate to defer resection and reconstruction until there is an appreciable drop in the quality of life, and pain is difficult to control.

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## Introduction

Despite advances in the dosage and fractionation of radiation used to treat cancer of the head and neck, osteoradionecrosis (ORN) remains difficult to manage,<sup>1</sup> and patients who are free from cancer have physical, psychological, and social problems because of the effects of radiation on their normal tissues.<sup>1</sup> The prevalence of ORN in those with cancer of the

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head and neck is around 7.4% after conventional radiotherapy, 5.1% after intensity-modulated radiotherapy (IMRT), and 6.8% after chemoradiotherapy.<sup>2</sup> Although IMRT is becoming more readily available, the incidence of ORN will increase over time as more patients are treated with primary or adjuvant radiotherapy or chemoradiotherapy. We regularly see patients who have severe side effects that include pain, infection, fistulas, and bony destruction after chemoradiation for cancer of the head and neck.

Outcome data on patients with ORN, including patientreported health-related quality of life (HRQoL), can help inform discussions with patients and their families about the expected outcomes of treatment. In a previous 8-year study,

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we reported on the influence of hyperbaric oxygen (HBO) on outcomes in patients treated for ORN,<sup>3</sup> and more recently, we reported a reduction in the use of free tissue transfer in patients with ORN from 51% to 25% after the introduction of medical management with pentoxifylline, tocopherol, and doxycycline.<sup>4</sup> Although free tissue transfer is a viable option for patients with advanced ORN (Marx stage III), segmental resection and microvascular free tissue reconstruction is not without complications.<sup>5</sup> Baumann et al reported 32% surgical complications overall, and total loss of the flap in 5%. Chang et al reported a 37% complication rate that included infection and non-union of bone.<sup>6</sup> In their series of 21 patients who had operations for Marx stage III mandibular ORN, Hirsch et al reported 86% survival of flaps, and 50% overall complications, which included necrosis of the skin, wound infection, salivary fistula, partial loss of flap, and carotid blowout. Treatment for cancer of the head and neck, and ORN, and the complications of surgical management, all have an impact on HRQoL, and to our knowledge, relatively few studies report HRQoL that is specific to patients with ORN.<sup>3,6</sup> In those that do, 5-10 the factors of greatest concern include appearance, swallowing, chewing, and speech. They reflect a lack of improvement in HRQoL after radiotherapy as well as practical aspects such as a continuing need for feeding with a tube.

We know of 3 studies that report HRQoL data specific to the use of HBO.<sup>11–13</sup> Only 2 of them report on patients before and after treatment,<sup>11,12</sup> and in both it is difficult to tease out the effect of operation in combination with HBO. Potential improvements were seen in emotional function, insomnia, social eating, xerostomia, and "teeth". In a randomised trial, Delanian et al provided treatment protocols for the medical management of ORN that were supported by clinicians, but did not report any HRQoL data.<sup>14</sup>

To our knowledge, there are few outcome studies that attempt to establish how various treatments for ORN affect HRQoL, and they include small numbers of patients. Outcome data on patients with ORN that include HRQoL are essential for use in discussions between clinicians and patients about management strategies. The aim of this work was to compare HRQoL between 4 groups of patients at different stages of ORN and reconstruction, and to compare them with a group of patients with cancer of the head and neck who did not have ORN. This can provide a reference point and guide for clinicians, and could affect the planning of treatment.

# Method

Since 1992, the details of all patients diagnosed with cancer of the head and neck at the Regional Maxillofacial Unit, University Hospital Aintree, have been entered on to a computerised head and neck database. The database was used to identify those treated for mandibular ORN, and the data were cross-referenced with their medical records. Data on presentation, radiotherapy, HBO therapy, operations, medical management, outcomes, and survival, were extracted. Patients were graded according to the Notani classification:<sup>15</sup> grade I: ORN confined to the alveolar bone; grade II: ORN limited to the alveolar bone or mandible, or both, above the level of the inferior alveolar canal; 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. The main treatments were minimal surgical debridement, HBO, or medical management (tocopherol and pentoxyphylline). The response to treatment was defined as complete healing, stable disease as shown by the control of symptoms, and a halt in the progression of disease and progressive disease. Patients who did not respond to initial conservative management were eligible for reconstruction with a free flap.

The University of Washington quality of life scale (UWQoL) has been used by the unit, notably version 4, in annual postal surveys since 2000. It is well established for use in patients with cancer of the head and neck, and has been extensively validated with other QoL assessment tools.<sup>16</sup> The 12 domains are each scaled from 0 (worst) to 100 (best) according to the hierarchy of response. In this study we analysed 2 subscale composite scores: physical function and social-emotional function, as well as the single question 6point overall QoL scale. Physical function is the simple mean of the scores for the swallowing, chewing, speech, saliva, taste, and appearance domains, whilst social-emotional function is the simple mean of the activity, recreation, pain, mood, anxiety, and shoulder domains. We also used criteria derived from earlier work to establish the domains in which patients had a serious problem.<sup>17</sup> The criteria derive from the 12 domain scores and from the choice of 3 domains (at most) that were important to the patient during the previous week. In regard to the single-item overall QoL scale, patients were asked to consider not only their physical and mental health, but also other factors, such as family, friends, spirituality, and personal leisure activities that were important to their enjoyment of life. Patients in this study have completed the questionnaires at different times, and some have done more than others depending on specific ongoing studies.

#### Statistical method

ORN results were analysed within 4 subgroups of patients: grade I/II patients who had, and had not had, free flaps, and grade III patients who had, and had not had, free flaps. For a reasonable group match to the follow-up status of patients with ORN, we selected patients who did not have ORN from the 1992-2009 group that had UWQoL data at least 36 months after initial primary diagnosis or operation, and then selected their records closest to 84 months from baseline. As all patients with ORN had radiotherapy during primary treatment, 2 main comparison groups of patients who did not have ORN were formed: those who had radiotherapy and those who had not. The former were further split into early-stage oral, late-stage oral, and pharyngeal groups.

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