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## Efficacy of Hyperbaric Oxygen in the Treatment of Osteoradionecrosis of the Mandible. Results from the combined clinical trials DAHANCA-21 and NWHHT2009-1

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*Introduction:* Osteoradionecrosis (ORN) of the mandible is a severe complication of head and neck radiotherapy. This study investigates the efficacy of hyperbaric oxygen therapy (HBOT) in the treatment of osteoradionecrosis (ORN) in two combined randomized controlled clinical multicentre trials.

*Materials and Methods:* Patients with ORN and an indication for surgical treatment were randomised to either

- group 1: surgical removal of necrotic mandibular bone supplemented by 30 pre- and 10 postoperative HBO exposures
- group 2: surgical removal of necrotic mandibular bone only.

Primary outcome was healing of ORN one year after surgery evaluated by a clinically adjusted version of the Common Toxicity Criteria of Adverse Events (CTCAE) v 3.0. Secondary outcome measures were quality of life among other functional outcomes. Ninety-seven patients were enrolled and 65 were eligible for the intent-to-treat analysis. The 33% drop-out was equally distributed between both groups.

*Results:* Group 1 showed better healing compared to group 2, preliminary data showed a difference of 19%. Furthermore, in group 1 was an improvement of several of the secondary endpoints like xerostomia and dysphagia. Unfortunately, the study was underpowered due to insufficient recruitment and the results were not significant.

*Conclusions:* Hyperbaric oxygen did improve the healing outcome of osteoradionecrosis after surgical removal of necrotic bone as compared to standard care with a difference of 19% based on preliminary data. This effect is not statistically significant due to the fact that the study was underpowered but is therefore prone to type II error.

## P-257

**Cervical lymphadenopathy following COVID-19 vaccine: Clinical characteristics and implications for head and neck cancer services** Ahmad K. Abou-Foul<sup>1</sup>, Elizabeth Ross<sup>1</sup>, Mahmoud Abou-Foul<sup>2</sup>, Aiith P. George<sup>1</sup>

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*Objectives:* Lower neck lymphadenopathy usually harbour malignancy in around 75% of cases, and should warrant an urgent referral to the head and neck (H&N) cancer services. We noticed a growing number of COVID-19 vaccine-associated lymphadenopathy (CVAL) referrals at our H&N cancer clinics. The presented work is the first study to report on the incidence, clinical course, and imaging features of cervical CVAL (cCVAL), with special emphasis on the implications for the H&N cancer services.

Design: Retrospective cohort study.

Setting: Leading UK NHS trust providing tertiary H&N cancer services.

*Participants:* Patients referred to our H&N cancer clinics with cCVAL between 16 December 2020 and 12 March 2021 (12 weeks). We defined cCVAL as any unilateral and lower cervical lymphadenopathy, noticed within two weeks of COVID-19 vaccination in the ipsilateral deltoid muscle.

*Main Outcome Measures:* The proportion of patients referred with cCVAL. Secondary outcomes included the clinical and imaging characteristics and follow-up measures.

*Results:* From 88 patients referred with cervical lymphadenopathy, 13 patients (14.8%) had cCVAL with a mean age of  $54.8 \pm 16.1$  years. Pain was only reported in six patients (46.2%), but swelling was noticed by all patients within a median of four days. The average diameter of CVALs on ultrasound scans was  $5.5 \pm 1.4$  mm, and five patients (38.5%) had abnormally looking rounded node or increased vascularity on colour doppler. Seven patients (53.9%) reported full resolution of their lymphadenopathy within an average of  $3.1 \pm 2.3$  weeks, and five patients (38.5%) reported partial size reduction over an average period of  $8.4 \pm 3.1$  weeks.

*Conclusions:* Reactive cervical CVAL can mimic malignant lymphadenopathy, and therefore might prove challenging to correctly diagnose and manage. Over the next few months, primary care and H&N cancer services should be prepared for a potentially significant increase in referrals.

## P-258

## Oral leukoplakia: risk factors associated with malignancy

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*Introduction:* Leukoplakia is primarily a clinical term for a predominantly white lesion that cannot be wiped off and that cannot be characterized as any other definable white lesion of the