**Critically Appraised Topic (CAT)**

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| **Project Team:** |
| **9A-2** |
| **Project Team Participants:** |
| **Klea Rota (D3), Lauren Preston (D4), Joshua Rodriguez (D2), Adam Fraeyman (D1)** |
| **Clinical Question:** |
| **How can the risk of osteoradionecrosis (ORN) be reduced in patients who require extractions after head and neck radiation?** |
| **PICO Format:** |
| **P:** |
| **Patients with previous head and neck radiation** |
| **I:** |
| **Extractions with conjunctive treatments (i.e. HBO, ABX)** |
| **C:** |
| **Extractions alone** |
| **O:** |
| **Reduce the risk of ORN** |
| **PICO Formatted Question:** |
| **In patients with prior H&N radiation, do extractions with conjunctive treatments as compared to extractions alone, reduce the risk of ORN?** |
| **Clinical Bottom Line:** |
| **There is weak evidence to support the use of hyperbaric oxygen (HBO) therapy and/or prophylactic antibiotics in prevention of osteoradionecrosis (ORN) associated with dental extractions post-radiation therapy. HBO is indicated for patients that are deemed at most risk, meanwhile, antibiotic and chlorhexidine mouthwashes may be considered for extensive surgical procedures post-radiation. There are also widely accepted intraoperative efforts that can be made to prevent ORN after post-radiation extractions. These include performing the extractions with minimal trauma or with limited mucoperiosteal disruption.** |
| **Date(s) of Search:** |
| **9/13/20, 9/14/20** |
| **Database(s) Used:** |
| **PubMed** |
| **Search Strategy/Keywords:** |
| **Radiation, caries, extractions, osteoradionecrosis, hyperbaric oxygen therapy, antibiotics** |
| **MESH terms used:** |
| **Radiation, dental caries, tooth extraction, osteoradionecrosis, hyperbaric oxygen therapy** |
| **Article(s) Cited:** |
| **1. Nabil S, Samman N. Incidence and prevention of osteoradionecrosis after ental extraction in irradiated patients: a systematic review. Int J Oral Maillofac Surg. 2011; 40(3): 229-243.**  **doi: 10.1016/j.ijom.2010.10.005**  **2. Shaw RJ, et al. HOPON: A RCT of Hyperbaric Oxygen to Prevent Osteoradionecrosis of the Irradiated Mandible After Dentoalveolar Surgery. Int J Radiat Oncol Biol Phys. 2019; 104(3):530-539. doi:10.1016/j.ijrobp.2019.02.044**  **3. Al-Bazie SA, et al. Antibiotic protocol for the prevention of osteoradionecrosis following dental extractions in irradiated head and neck cancer patients: A 10 years prospective study. J Can Res Ther. 2016; 12:565-70** |
| **Study Design(s):** |
| **(Article 1): Systematic Review of Cohort Studies (2a)**  **(Article 2): Randomized Controlled Phase 3 Trial (1b)**  **(Article 3): Prospectice Cohort Study (2b)** |
| **Reason for Article Selection:** |
| **Each article addressed the PICO question, provided high level of evidence, and was a relatively recent publication which demonstrates the current trend in treating patients with previous head and neck radiation who require dental extractions.** |
| **Article(s) Synopsis:** |
| **Article 1 Synopsis:**   * A systematic review of Medline, Pubmed, Ovid, Embase and The Cochrane Library databases was performed from 1950 through April 2010, and 19 articles on post-irradiation extractions were analyzed by two independent reviewers after meeting all of the eligibility criteria. The radiation had to include the maxilla and/or the mandible. Studies with and without intervention to prevent the occurrence of ORN after extractions in post-irradiated patients were accepted. The primary outcome measure was the occurrence of ORN at the extraction socket, which was defined as “an area of devitalized irradiated bone that failed to heal over 3 months with no evidence of recurrence of local neoplastic disease.” The total incidence of ORN after tooth extraction post-radiation was 7%. When extractions were performed with prophylactic HBO, the incidence was 4%, and the extractions were in conjunction with antibiotics the incidence was 6%. The risk of ORN was 3x higher in the mandible (3%) versus the maxilla (1%). Extraction of teeth outside of the radiation field resulted in no ORN in any socket, suggesting that any extractions outside the radiation field could be performed safely. Patients with a radiation dose less than 60 Gy also did not develop ORN, whereas greater than 60 Gy had a 12% incidence of ORN after post-radiation extraction. This study also concluded that the period 2-5 years after radiation had the highest incidence of ORN after post-radiation extractions. Overall, the risk of ORN after post-radiation extractions is relatively low and based on weak evidence, prophylactic HBO can be effective in reducing the risk of developing ORN in patients with the most risk. The highest risk is considered to be extraction of mandibular teeth within the radiation field after receiving more than 60 Gy radiation dose). The limitations of this study include a limited sample size and the nature of retrospective studies introduces bias.   **Article 2 Synopsis:**   * A randomized controlled phase 3 trial was performed by recruiting patients who required dental extractions or implant placement in the mandible with prior radiotherapy that was greater than 50 Gy radiation dose. Patients who met the criteria were randomly assigned to receive, or not receive HBO. All patients did receive pre and post-op CHX mouthwash and ABX (amoxicillin 3g 1-hour pre-op, and 250 mg 3x/day for 5 days post-op). For the HBO group, oxygen was administered in 30 daily dives (20 pre-treatment and 10 post-treatment). The primary outcome measure of this study was diagnosis of ORN 6 months after surgery done via a blinded assessment. A total of 100 patients was analyzed, and the incidence of ORN at 6 months was 6.4% for the HBO group and 5.7% for the control group (non-HBO group). None of the patients with ORN at 6 months had healed by 12 months, and no new cases of ORN developed between 6 and 12 months. Overall, the low incidence of ORN makes it unnecessary to recommend HBO for dental extractions or implant placement in the irradiated mandible. The limitations of this study include a higher drop-out in the HBO group, a limited sample size, and a lack of control for no antibiotic/CHX administration.   **Article 3 Synopsis:**   * Irradiated head and neck cancer patients reporting for dental extractions between January 2002 and December 2009 were recruited for this 10-year prospective cohort study. A total of 89 participants were recruited and had non-restorable teeth in the field of radiation, a radiation dose greater than 60 Gy and at least a 6-month latency period post-radiotherapy. They had no history of ORN, ulcers or bone exposures at the extraction site. All patients were prescribed Amoxicillin 50 mg orally every 8 hours starting 10 days pre-extraction and continued through 7 days post-extraction. All patients were also given 10 mL of undiluted CHX Gluconate 0.2% solution to use as a mouthwash for 1 minute every 12 hours starting 10 days pre-extraction and continued through 7 days post-extraction. All extractions were done with local anesthetic and as atraumatically as possible. Follow-up visits were conducted weekly for the first month, and monthly up to 6 months, after which the patients were seen 1x/3 months for 2 years. A total of 232 teeth were extracted from the field of radiation exposure, 78 in the maxilla and 154 in the mandible. This study reported no ORN after a mean follow up perio of 63 months. The study concluded that perioperative oral antibiotic in combination with antibacterial mouthwashes are effective in preventing ORN following dental extractions in irradiated patients. However, this study was limited by its lack of a suitable control group for comparison. |
| **Levels of Evidence:** (For Therapy/Prevention, Etiology/Harm)  See <http://www.cebm.net/index.aspx?o=1025>  **1a** – Clinical Practice Guideline, Meta-Analysis, Systematic Review of Randomized Control Trials (RCTs)  **1b** – Individual RCT  **2a** – Systematic Review of Cohort Studies  **2b** – Individual Cohort Study  **3** – Cross-sectional Studies, Ecologic Studies, “Outcomes” Research  **4a** – Systematic Review of Case Control Studies  **4b** – Individual Case Control Study  **5** – Case Series, Case Reports  **6** – Expert Opinion without explicit critical appraisal, Narrative Review  **7** – Animal Research  **8** – In Vitro Research |
| **Strength of Recommendation Taxonomy (SORT) For Guidelines and Systematic Reviews**  See article **J Evid Base Dent Pract 2007;147-150**  **A** – Consistent, good quality patient oriented evidence  **B** – Inconsistent or limited quality patient oriented evidence  **C** – Consensus, disease oriented evidence, usual practice, expert opinion, or case series for studies of diagnosis, treatment, prevention, or screening |
| **Conclusion(s):** |
| **Our patient is at a relatively low risk for developing osteoradionecrosis post-extractions. This is due to his last radiation dose being more than eight years ago, and it not including the maxilla, nor the mandible, in the field of radiation. If the patient requires surgical extractions, or if all teeth are extracted on the same day, prophylactic antibiotics in conjunction with a chlorhexidine mouthwash may be indicated. The use of hyperbaric oxygen therapy remains controversial and is not recommended for our patient due to its weak evidence, lengthy process, and high costs. Furthermore, there are intraoperative efforts that can be made to reduce the risk of ORN, these include performing the extractions with minimal trauma or limited mucoperiosteal disruption.** |