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Lateral Skullbase Osteoradionecrosis: A ten-year series of 20 consecutive cases and a suggested management protocol

Running Title: Lateral Skullbase Osteoradionecrosis

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Abstract

Objective

Temporal bone (TB) osteoradionecrosis (ORN) is a rare but significant complication of radiation for head and neck malignancies. Various management techniques have been described, but no clear protocol exists.

Methods

Retrospective case review of patients with TB ORN managed over fifteen years highlighting MDT management. Comparison to published literature and a protocol derived for the management of future cases.

Results

20 patients were included, sites of ORN included external auditory canal, middle ear and lateral skullbase presenting with features including recalcitrant pain, infection, neuropathies and intracranial sepsis. Treatments included hyperbaric oxygen, antibiotics, debridement and in advanced cases lateral TB resection with vascularised tissue transfer. Post-operative and long-term outcomes discussed.

Conclusion

Early TB ORN may be managed conservatively. Refractory ORN can be life-threatening due to intracranial complications and sepsis. Such cases need an MDT approach with radical skullbase surgery for removal of necrotic foci and reconstruction using vascularised tissue transfer.

MeSH Keywords: Head and Neck Neoplasms, Temporal Bone, Radiology, Radiotherapy, Osteoradionecrosis

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Introduction

Radiation therapy, either as primary or adjuvant therapy, is a major treatment modality for head and neck cancers.[1] Although proven to be effective for the management of cancer, it is well recognised that adjacent healthy tissues are also affected by immediate and delayed side effects.[2] With the increased survival of patients treated for a head and neck malignancy there has been an increase in the incidence of post-radiation sequalae.[3-4] These include otitis media, sensorineural hearing loss, local tissue breakdown and osteoradionecrosis.[4-6]

Osteoradionecrosis (ORN), first described in 1926 by Ewing[7], involves avascular necrosis due to degeneration of the blood vessels following exposure to high dose radiation.[7] This ischaemic bone is particularly susceptible to injury and infection.[5,7] ORN of the temporal bone is a rare but potentially devastating complication of head and neck radiotherapy.[1,8] Although rarer than ORN of the mandible,[6,9] it is an important topic of discussion due to the complexity of treating this region.[1] ORN of the temporal bone may be limited to the tympanic bone or extend diffusely to involve the lateral skullbase.[10]The temporal bone is thought to be particularly susceptible due to its superficial location, limited blood supply and anatomical communication with the flora of the upper aerodigestive tract via the Eustachian tube.[1,10] Within this, the tympanic part is most commonly affected [11] due to its particularly perilous blood supply and resident flora.[5] Additionally, its compact bone is less resistant to irradiation than callous bone. This tolerance is further reduced when the bone is infected or affected by neoplasm.[10,12]

Risk factors for the development of ORN include age, diabetes, continued tobacco useage and immunosuppression.[5,13-14] When disease is localised patients often present with mild

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symptoms, particularly otalgia and otorrhoea.[9-10,15] On examination there is often bony sequestrum within the external auditory canal.[10] Patients with localised disease are managed conservatively.[5-6,9,14-16] Diffuse disease however is potentially life-threatening.[5,14] Affected patients may develop facial nerve paralysis and intracranial complications including meningitis, CSF leak, brain abscesses, and sigmoid sinus thrombosis.[5,11] Despite the potential severity of this disease process, there remains a lack of evidence for best management.[14-15,17] Medical therapy is symptomatic and helps to limit spread however surgery to remove sequestrum is often indicated and various methods have been described.[14]

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Materials and Methods

Our aim was to produce a surgical protocol for advanced cases of osteoradionecrosis of the lateral skullbase based on over a decade of experience at our tertiary centre in the UK. Advanced cases were defined as those with symptoms and disease progression necessitating surgical management. These patients had pain and discharge which could not be adequately managed with medical therapy. Patients presenting with ORN of the temporal bone between January 2006 and 2021 requiring surgery involving flap reconstruction following treatment with either primary or adjuvant radiotherapy for head and neck malignancies were included in the study. There were no exclusion criteria.

A retrospective case review was conducted from electronic records. Information including the original cancer type, location and management with primary or adjuvant radiotherapy were collected. The dates and type of radiotherapy administered were recorded where known. Any medical therapy, including hyperbaric oxygen therapy, was also noted along with details of pre-operative facial nerve function. Multidisciplinary team (MDT) recommendations were reviewed, and surgical notes and post-operative results recorded. Long-term outcomes were assessed. A protocol was developed by the skull base MDT for the management of future cases.

This retrospective case note review did not require formal ethics committee review after completing the National Decision Tool developed by the Medical Research Council Regulatory Support Centre in partnership with the Health Research Authority.

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Results and analysis

We identified 20 patients with ORN of the temporal bone who met the inclusion criteria and were managed surgically by our MDT between January 2006 and December 2021. The patients included twelve males and eight females, with a mean age of 66 years (range 24 to 82 years).

The original cancer diagnoses were variable (figure 1). The most common malignancy was squamous cell carcinoma of the ear (5), followed by the nasopharyngeal carcinoma (2), cancer of the parotid gland (2), recurrent jugulotypmanic paraganglioma (2), osteosarcoma of the ear and chondrosarcoma of the temporomandibular joint (2). Other treated malignancies included malignant melanoma of the eyelid and rhabdomyocarcoma of the ear.

Of our twenty cases, fourteen (70%) were treated with primary radiotherapy and six (30%) adjuvant radiotherapy. Eleven patients (55%) received conventional external beam radiotherapy, five (25%) hyper-fractionated radiotherapy, two (10%) proton beam therapy and two (10%) intensity-modulated radiation therapy (IMRT) (figure 2). Radiation dose ranged between 45 and 60 Gray. The mean onset of osteoradionecrosis following radiation was 2.8 years, but varied widely between 1.2 and 15 years.

The most common symptoms at diagnosis of ORN were otalgia and otorrhea. Patients also presented with sequestrum, cholesteatoma, cranial neuropathy and intracranial sepsis. Of our patients, sixteen (80%) were cancer free, two (10%) had radio-recurrent cancer as well as ORN and two (10%) were palliative (figure 3). The mean time in progression with medical therapy including hyperbaric oxygen, to curative surgery was 21 months (11-38 months).

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As per our inclusion criteria, all 20 patients underwent surgery requiring repair of defect for their advanced ORN. 70% (14/20) had small defects which were managed using a temporalis muscle (TMP) rotational flap, 20% (4/20) had moderate defects repaired using gracilis, serratus anterior or latissimus dorsi flap and the final 10% (2/20) had large defects managed with anterolateral thigh/vastus lateralis chimeric flaps. A 100% successful flap take-up rate was achieved.

There were no major operative complications and no surgery-related mortality in our population group. A 40% morbidity rate was reported with these being caused by pain, trismus, cranial neuropathy, wound sepsis, rehabilitation time, physiotherapy and prolonged hospitalisation. It is not possible to distinguish these from morbidity that would have been present without operative management.

Average follow up was for a period of 23 months (range 5 to 84 months). Ten (50%) of patients were disease free with no recurrence of ORN. Two patients (10%) were treated with palliative intent due to recurrence of their original pathology (jugulotypmanic paraganglioma and medulloblastoma). Eight (40%) of patients died during the following up period, with a mean time of death post-surgery of 15 months (range 5-32 months). Of these, three patients died due to disease recurrence whilst five died due to unrelated causes.

From our findings a management algorithm was designed by the MDT as follows (figure 4) and has now been incorporated into our skull base MDT.

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Discussion

With the increasing survival of patients following treatment including radiotherapy for head and neck malignancies,[3-4] the incidence of ORN of the temporal bone are set to increase. The hypoxic, hypovascular and hypocellular environment induced by radiotherapy leads to impaired collagen synthesis and cell production with resultant tissue breakdown and increased prevalence of chronic infection in the ischaemic bone.[5,7,18]

Whilst some risk factors such as diabetes mellitus may be modifiable,[14] many, such as patient age, are not. Ramsden et al[10] noted that the development of ORN was more frequently seen when the temporal bone was in close proximity to the focus of radiation.[10] The superficial location of the temporal bone and thin overlying soft tissue make this region particularly susceptible[10] and unfortunately when treating malignancies in this region, especially of the ear, this focus cannot be changed.[1] Rudge et al[1] found that the extent of necrosis was proportional to the dose of radiation administered.[1] However, this was not supported by Pathek et al [5] or Sharon et al [11]. In our study, patients were found on average to have received 45-60 Gy.

It has been recognised that there is a latency period between radiotherapy and the development of osteoradionecrosis.[1,5,10] Pathek et al[5] reported an average latency of eight years (range 6-11 years) from radiation to the development of diffuse ORN in their study[5] whilst Lovin et al[16] reported a mean time of 10 years.[16] Our mean time to development of ORN post-radiation was shorter at 2.8 years but ranged from 1.2 to 15 years, again showing a wide variation. Currently there does not seem to be a relationship between the latency period and the severity of ORN.[10]

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Consistent with our results, Yuhan et al[15] showed that otalgia and otorrhea are the most common initial symptoms.[15] The most commonly used classification for ORN is by Ramsden et al[10] and divides cases into localised, where bone erosion is limited to the external auditory canal, and diffuse where it affects the more of the ear and mastoid.[10,19] As reflected in our protocol (figure 4) it is widely established that limited disease associated with minimal symptoms should be managed conservatively with regular aural toilet and antibiotic therapy.[10,14] This is particularly as the goal of treatment for localised disease is directed at symptoms control[16] rather than complete removal or resolution of the necrotic bone.[15] The algorithm proposed by Sharon et al[11] also recommended initial conservative management with culture directed topical antibiotics, topical antiseptics, periodic office debridement and pain management [11] as did Kammeijer et al[19]. Yuhan et al [15] performed a systematic review on the management of osteoradionecrosis of the temporal bone and found that 89% of all cases treated conservatively adequately resolved presenting symptoms at last follow up.[15]

Pathak et al[5] found that being over 60 years of age was an indicator of those who failed conservative management within 2 years [5] and these may therefore need closer monitoring and aural toileting. These patients are more likely to progress to stage 2 management (figure 4) which we propose necessitates local debridement in the form of canalplasty, meatoplasty or mastoidectomy and consideration of hyperbaric oxygen therapy.

The systemic review performed by Yuhan et al[15] found that 21.5% received conservative management and 60.9% underwent surgical management.[15] HBO was used in conjunction with surgical treatment in 11.3% of the time.[15] Kammerijer et al[19] outlined their guidelines to

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reflect the localised and diffuse ORN described by Ramsden et al.[10] They suggest that when those with localised ORN are not symptomatically controlled they should be managed as per diffuse A ORN, defined as CT evidence supporting diffuse disease associated with little pain and infection and intact functional hearing.[19] They also suggest sequestrectomy in these cases.[19]

Hyperbaric oxygen (HBO) therapy aims to increase tissue oxygenation which in turn promotes neovascularisation and wound healing.[18] Sharon et al[11]recommended other therapies in the form of Intravenous (IV) antibiotics and HBO in patients who developed increasing pain, progressive infection and the development of cranial neuropathies despite conservative management.[11] Our algorithm includes IV antibiotics as an option in stage 1 dependent on clinical findings. There is some evidence from small randomised controlled trials to support HBO therapy in late radiation induced tissue injury.[20] Reported clinical outcomes have been variable with Sharon et al[11] finding that of their six patients who received HBO therapy, no patients achieved resolution of the necrotic bone. It was however felt to aid post-operative healing in one patient.[11]

It should be noted that although HBO is often incorporated into treatment algorithms for ORN evaluation of its benefit is currently limited by small patient cohorts, concurrent surgical management and varied treatment protocols.[14] The use of HBO affected by geographical limitations with only eight chambers across England.[21] It is also a significant undertaking for patients both physically and mentally with the most common protocol involving 40 treatments [22] each typically lasting 90 minutes[23]. We propose a more likely more manageable

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10 treatments. Risks of treatment include temporary visual problems, eustachian tube dysfunction and seizures.[24]

Whilst conservative management has been shown to be appropriate for patients with limited disease, it may not be sufficient, and refractory disease may arise. Sharon et al[11] found that 18 out of 33 patients in their study went on to require surgical management due to intractable pain, persistent infection or the development of cholesteatoma.[11] Our study showed a mean time between medical therapy and surgery with curative intent of 21 months.

Kammerijer et al[19] reserve subtotal petrosectomy (STP) for those with diffuse B disease who they define as those in whom there is severe pain and infection and/or no functional hearing due to the risk-benefits balance of the more extensive surgery.[19] Yuhan et al[15] found that less than 60% of mastoidectomies led to complete resolution but over 90% of those who had lateral temporal bone resections resolved.[15] Sharon et al[11] specified that the aim of surgery was to gain symptom control rather than complete removal of necrotis bone.[5,11] This view was justified in that it has been shown that there are increased risks of operating in radiated temporal bone including higher than expected rates of facial nerve dehiscence, oval window and lateral canal fistulae, dural exposure, CSF leak and lateral canal procedures.[20] These are thought to occur due to the poor blood supply to the EAC that is then further decreased by surgery.[5] However, it should be noted that our algorithm differs in consideration and recommendation of reconstruction in appropriate cases.

As in our advanced cases, the symptom severity and potentially life-threatening nature of diffuse disease makes more aggressive management necessary.[3,5,10] The flexibility from local

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flaps or free flaps are needed to reconstruct defects of the lateral temporal bone. With advancing techniques in reconstruction cosmesis is now of increasing focus rather than simply covering the resultant defect[3] and this is reflected in stage 3 of our algorithm. However, significant complications continue to be reported in those undergoing such surgery including persistently discharging fistulae.[11]

Free flaps can provide much better functional and aesthetic results compared to local and regional flaps.[25] However, there are a number of considerations when selecting an appropriate flap. These include the size and location of the defect, the blood supply of both the flap and recipient site and importantly the aim of the reconstruction in terms of aesthetic and functional outcomes.[25]

The Anterolateral Thigh (ALT) chimeric flap, which relies on the descending branch of the lateral circumflex femoral artery, has been described for use in reconstruction of large soft tissue defects in this region and to correct facial palsy.[25] This flap is easily obtained and offers sufficient muscle bulk to fill large defects. There is access to redundant motor nerves/motor nerve to the vastus lateralis suitable for grafting.[26] It is also possible to alter the thickness of the subcutaneous fat in the anterolateral region to achieve appropriate flap thickness at the reconstruction site.[27] This mitigates the complications of fat liquefaction and seroma associated with fat transfer and dermal grafts.[25] Lóderer et al[25] reported that there was minimal morbidity at the donor site.[25] This single stage approach is generally associated with fewer complications and better neural regeneration than in a multi-step approach.[25] Direct nerve anastomosis or cable grafting is the preferred reconstruction technique, yielding the best functional outcomes in patients undergoing facial nerve sacrifice.[25]

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Our surgically treatment patients in this report obtained good symptomatic relief and long-term control of ORN. However, our findings are based on a small cohort with heterogenicity in presentation, making it difficult to draw overall conclusions. To the best of our knowledge, no multicentre study has yet been performed, and given the rarity of this presentation it is unlikely that this will be undertaken in the near future. Additionally, consideration of the interpretation of outcomes is needed. Consensus is needed on what constitutes successful treatment, be it complete eradication of exposed bone, resolution of symptoms or reduction of symptoms to acceptable levels.[11]

ORN is a rare and difficult clinical entity needing coordinated MDT input. The key guiding principle is to restore vascularity to the dying bone and facial nerve. Outcomes are promising with 50% of cases now disease free. We advocate the enclosed surgical protocol as part of a multidisciplinary approach to this complex condition. Larger multi-centre studies may provide a better understanding of the optimum treatment strategy in any individual patient.

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Summary:

- Osteoradionecrosis is a serious potential complication of radiation for head and neck cancer.
- The temporal bone is particularly at risk due to its location, blood supply and connection to the upper aerodigestive tract.
- Presentation of ORN can be with otalgia, otorrhoea, facial palsy, CSF leak and meningitis.
- Management of ORN is difficult. Local management with regular aural toilet and antibiotics can help with early disease however in the most severe cases resection and flap reconstruction may be required to restore vascularity and function.

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Figure Legends

Initial Diagnosis	Number (%)
Squamous Cell Carcinoma Ear	5 (24%)
Nasopharyngeal Cancer	2 (9%)
Parotid Cancer	2 (9%)
Recurrent Jugulotypmanic paraganglioma	2 (9%)
Osteosarcoma Ear	2 (9%)
Chondrosarcoma TMJ	2 (9%)
Submandibular Gland Cancer	1 (5%)
Squamous Cell Carcinoma Maxilla	1 (5%)
Malignant Melanoma Eyelid	1 (5%)
Rhabdomyosarcoma Ear	1 (5%)
Medulloblastoma Cerebellum	1 (5%)

Figure 1: The original cancer diagnoses

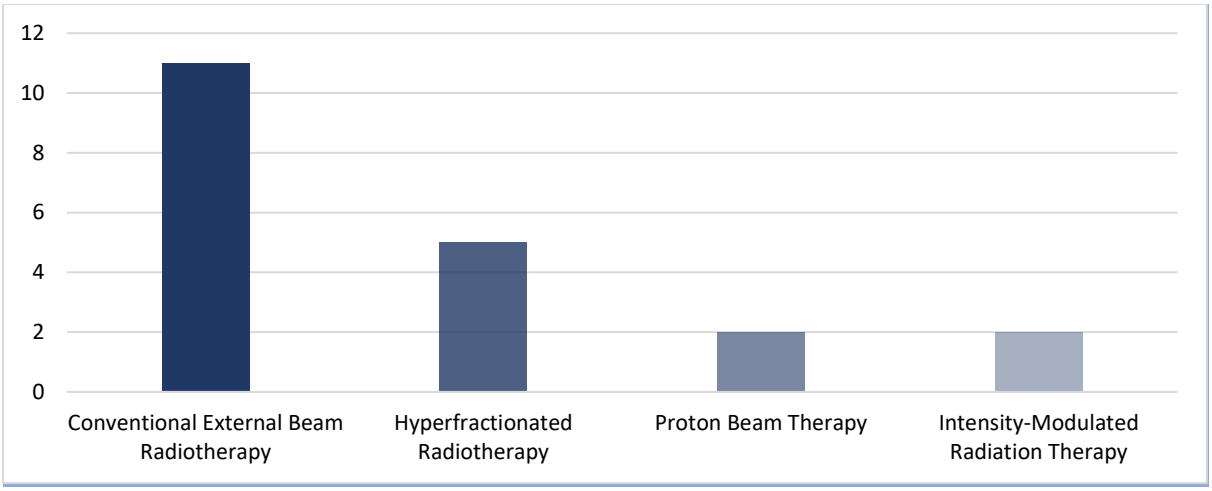

Figure 2: Type of radiation received

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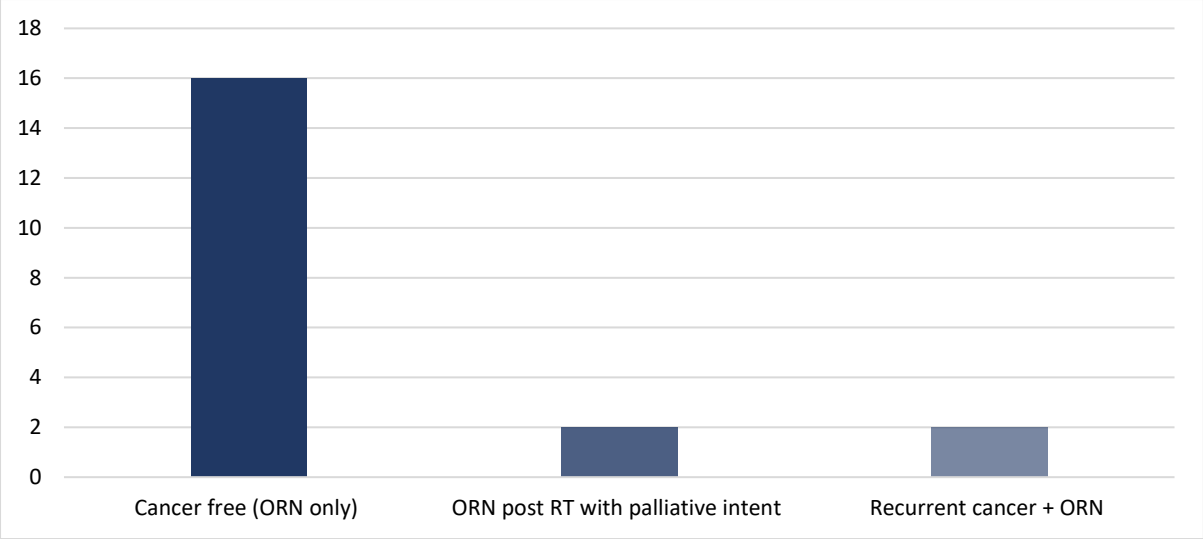

Figure 3: Cancer status of patients presenting with ORN

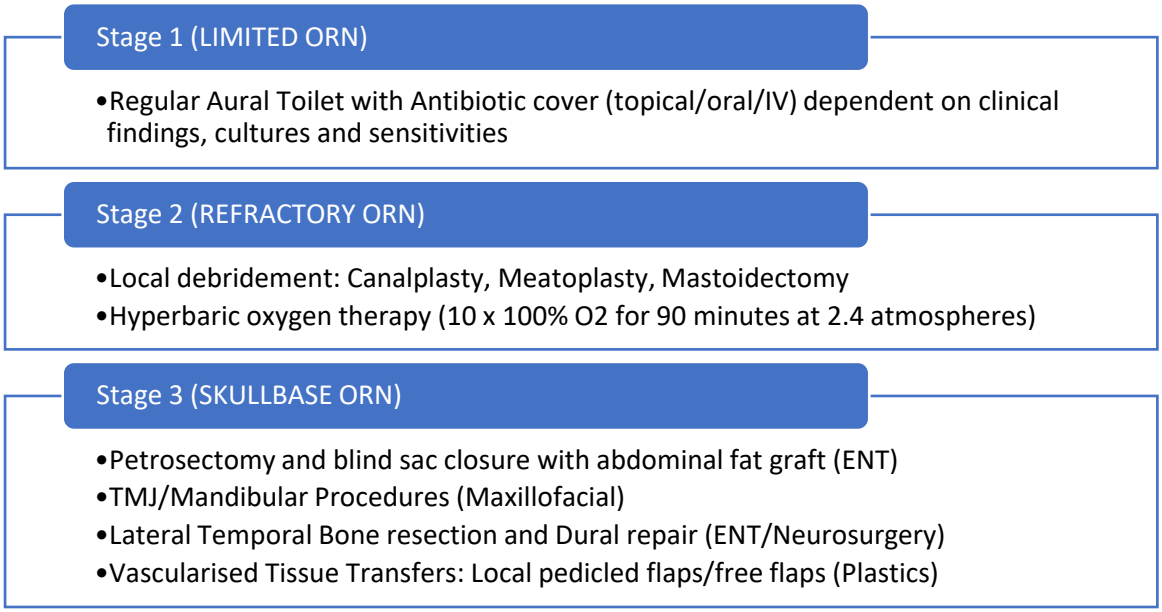

Figure 4: Management algorithm devised by the MDT

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