Treatment Outcomes of Temporal Bone Osteoradionecrosis

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Abstract

Objective. To investigate the clinical relevance of the classification systems used for temporal bone osteoradionecrosis (ORN) and to define a treatment protocol for temporal bone ORN.

Study Design. Retrospective case series.

Setting. Amsterdam, department of otorhinolaryngology and head and neck surgery.

Subjects and Methods. Classification of temporal bone ORN was performed through use of clinical data and radiologic imaging. Outcomes of conservative and surgical treatment were investigated and compared for different grades of ORN.

Results. Of the 49 ears included in this study, 35 were primarily treated conservatively. At start of conservative treatment, 23 were classified as a localized and 8 as a diffuse form of ORN; 4 could not be classified. There was a significant difference in clinical outcome between the localized and diffuse forms of ORN ($\chi^2 = 5.862, P = .015$), and mastoid air cell destruction on preoperative computed tomography scan was found to be a significant predictor for a negative outcome of conservative treatment ($\chi^2 = 4.34, P = .037$). Fourteen ears with diffuse ORN were primarily treated surgically, and 11 were secondarily treated surgically following a period of conservative treatment. Twenty-two patients were treated with subtotal petrosectomy, of which 20 were cured. Three patients were treated with canal wall down mastoidectomy, and 2 had recurrence of disease.

Conclusion. Ramsden’s classification system is clinically relevant in predicting conservative treatment outcomes. Mastoid air cell destruction on computed tomography scan differentiates between the localized and diffuse forms of ORN. Given our results and experience with treating temporal bone ORN, we propose a treatment protocol.

Keywords

osteoradionecrosis, temporal bone, radiation therapy, subtotal petrosectomy, treatment, classification

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Temporal bone osteoradionecrosis (ORN) is a difficult-to-treat complication following radiation therapy of head and neck malignancies. Depending on the extent of the disease—as classified by Ramsden et al1 into localized and diffuse—a conservative treatment strategy or surgery (subtotal petrosectomy [STP]) can be advocated. Clinical relevance of this classification remains doubtful, though, because no further series have studied the classification since. Due to the low incidence, little of what we know about ORN is based on evidence, and standardized and evidence-based treatment protocols are lacking. To increase knowledge and create standardized treatment modalities, more data and larger series are needed. Therefore, we feel that it is important to share our experience and our results of 30 years of treating temporal bone ORN. The goal of this study was to investigate the clinical relevance of classification and the role of a computed tomography (CT) scan in this classification. Based on our treatment results we defined a standardized treatment protocol for temporal bone ORN.

Like the mandible, the temporal bone has a superficial location with only little soft tissue covering the bone making it susceptible to ORN. The external ear canal is even more susceptible to ORN due to its unfavorable vasculization and thin epithelial lining of the bone.2,3 Not only are these local factors thought to contribute to the occurrence of ORN, but general factors (eg, age, diabetes mellitus, immune suppression) and radiation factors (eg, dosage, type, field) have been identified as well. ORN is a slowly progressive, aseptic, avascular necrosis of bone tissue. It is initiated by an obliterative endarteritis, resulting in a tissue that is highly susceptible to injury, fracture, and infection.4,5 The middle ear is susceptible to infection, as it is connected to the upper respiratory tract via the Eustachian tube. Such infections will accelerate the osteoradionecrotic process.

Methods

A retrospective case study was performed in the Academic Medical Centre, a tertiary referral center in Amsterdam. For
retrospective cohort analysis of regular care, no Institutional Review Board was necessary. (In the Netherlands, such research does not need ethical committee review by Dutch law, as long as the presented data are not reducible to patients.) Forty-three patients who were treated for temporal bone ORN from 1983 to 2013 were included. The medical charts were investigated, and information was gathered concerning general history (smoking, immune suppression, diabetes mellitus), age, sex, and side of affected ear. Tumor-specific data, treatment outcomes, and complications were assessed. The type of ORN was classified according to various classification systems that have been described in literature. Patients were excluded if follow-up was <6 months or if they were lost before treatment outcomes could be assessed.

**ORN Classification**

The first author classified ORN using the medical charts and the available CT reports or CT scans. Based on the classification by Ramsden et al,1 exposed bone on examination and bone erosion of only the external ear canal were considered to be a localized form of ORN. Due to the retrospective nature of this study, the presence of pain and/or otorrhea was noted, but these parameters could not be validated or used to grade ORN. Exposed bone on examination and bone erosion of the ear canal and mastoid were considered to be a diffuse form of ORN. Morrissey et al6 described another classification system, which we used to classify ORN: grade I is an erosion of the external auditory canal skin without bony involvement; grade II is an erosion of the external auditory canal skin with bony necrosis; grade III has involvement of the middle ear space and/or mastoid; grade IVa includes cranial nerve involvement; and grade IVb includes involvement of the skull base.

**Choice of Therapy**

Localized ORN was primarily treated conservatively. Diffuse ORN was treated either conservatively or surgically based on a combination of patient complaints (pain and hearing) and apparent severity of the disease. Careful regular ear canal cleaning (every 3 to 4 months), eardrops (acid or hydrogen peroxide as maintenance therapy, antibiotic with purulent discharge), and minor surgical interventions (sequestrectomies) were noted as conservative therapy. Surgical intervention included at least canal wall up/down mastoidectomy or STP.

**Evaluation of Conservative Treatment Outcomes**

We defined the following outcomes. When treatment was conservative, an ear was considered cured of ORN if pain and otorrhea were no longer present and no exposed bone was seen on examination. If slight chronic pain or exposed bone on examination persisted, an ear was considered to be persistent/stable ORN. Progression of ORN was defined as aggravation of the bony erosion and/or pain despite adequate conservative therapy. If progression of ORN was seen after a period of conservative treatment, surgical treatment was performed.

**Evaluation of Surgical Treatment Outcomes**

Outcomes of surgical treatment were defined as follows. An ear was considered cured when the operation site had healed completely and no signs of infection or ORN were present. Surgical failure was defined as a mastoid in which ORN and infection or necrosis persisted. An STP was considered to be a failure if the obliteration material became infected or necrotic and revision surgery was needed or an open nonobliterated cavity remained. The time between surgery and a cured ear was assessed as the healing time. Postoperative magnetic resonance imaging data were assessed to exclude possible cholesteatoma.

Complications of surgical management were divided into minor healing problems (wound dehiscence, blind sac granulation, fistula, wound infection), major healing problems (obliterated cavity infection), minor/major flap-related problems, and other complications (facial nerve palsy de novo postoperatively; temporary/persistent). To compare the different obliteration techniques and their complications, the obliteration techniques were divided into 3 types: fat, free flap, and locally pedicled flap. Minor complications were managed conservatively, and major complications needed revision surgery or negatively affected the patient permanently.

**Statistical Analysis**

The possible influence of symptoms (pain, otorrhea), CT signs (mastoid opacification, bone defects to middle/posterior fossa), and number of sequestrectomies on the outcome of ORN treatment was analyzed with the χ² test (significant when \( P < .05 \)).

**Results**

Information was gathered of 45 patients with temporal bone ORN: 2 were lost for follow-up because they refused surgical treatment of their diffuse ORN. Forty-three patients could be included in the study. Six had bilateral ORN; therefore, 49 ears were included. Patient and tumor characteristics are listed in Table 1. The male:female ratio of approximately 1:3 is noteworthy. More than half the patients had received radiotherapy for a parotic tumor. Eight patients had ORN following radiotherapy for nasopharyngeal carcinoma; 4 of these patients had bilateral temporal bone ORN. Two other patients had bilateral temporal bone ORN after radiotherapy for a cerebellar medulloblastoma. No patients had a suppressed immune system. Median follow-up was 12 years (range, 0.9-28). Nine patients died due to non-ORN-related causes; 1 patient died of residual nasopharyngeal carcinoma with possible signs of nasopharyngeal ORN.

**ORN Classification**

ORN was classified via the medical charts and CT findings. CT data of 4 ears were missing, making adequate classification of ORN in these ears impossible. Twenty-three ears had localized ORN, and 22 had diffuse ORN. The relation between the classifications according to Ramsden and Morrissey is outlined in Table 2.
Outcomes of Conservative Treatment

Thirty-five ears were primarily treated conservatively. At start of treatment, 23 ears were classified as localized and 8 as diffuse ORN. Four ears could not be classified (see Table 3). There was a significant difference in outcome (cured/stable vs progression of ORN) between the 2 groups ($\chi^2 = 5.862, P = .015$). Each group contained 1 ear where temporary facial nerve palsy occurred as a result of ORN progression. One ear progressed from localized/grade II ORN to diffuse/grade IVa ORN.

Mastoid air cell destruction on preoperative CT scan was the only significant predictor for a negative outcome of conservative treatment ($\chi^2 = 4.34, P = .037$). The other variables did not have a significant influence on treatment outcome: pain ($\chi^2 = 1.96, P = .16$), otorrhea ($\chi^2 = 0.75, P = .39$), mastoid opacification ($\chi^2 = 0.20, P = .66$), bone defects to middle/posterior fossa ($\chi^2 = 0.08, P = .78$), >1 sequestrectomy ($\chi^2 = 2.21, P = .14$).

Outcomes of Surgical Treatment

Fourteen ears with diffuse ORN were primarily treated surgically (13 STP, 1 canal wall down mastoidectomy). Eleven were secondarily treated surgically (ie, after primary conservative treatment: 9 STP, 2 canal wall down mastoidectomy); 4 of these ears were classified as localized and 5 as diffuse ORN at the start of conservative treatment (2 could not be classified). At the time of surgery, 10 ears had diffuse ORN, and 1 could not be classified. Of 22 ears treated with STP, 2 had a failure, and 20 were cured (Table 4). One failure followed primary surgery. The second failure followed secondary surgery after conservative treatment in an...
ear with diffuse ORN. Median healing time in the STP group was 44 days (range, 22-195). Fourteen patients had had post-operative diffusion weighted magnetic resonance imaging (median time after surgery, 5.6 years; range, 0.5-16.9), and no sign of cholesteatoma was seen.

One ear had a primary canal wall down mastoidectomy for diffuse ORN. Adequate epithelialization followed in 44 days, and no signs of ORN were seen. Two ears were secondarily treated with canal wall down mastoidectomy. One ear had primarily been treated conservatively for localized ORN; the other ear could not be classified at start of primary treatment. Both these patients needed revision surgery since ORN recurred. Adequate epithelialization occurred 314 and 1213 days, respectively (following the first surgical procedure). We believe that canal wall down is a suboptimal surgical technique with an unpredictable result. Even after epithelialization, infection can easily set in and might cause a recurrence of ORN. These ears were not included in further analysis.

**Evaluation of Types of Obliteration in STP**

The STP failures occurred in a fat obliterated ear and a free flap (musculus gracilis) obliterated ear. After multiple necrosectomies, 1 patient ended up with an open cavity that needs regular cleaning. The other was unsuccessfully treated with antibiotics and hyperbaric oxygen therapy. Revision surgery was proposed; however, the patient did not want to undergo surgery again and is currently lost for follow-up. An occlusion of the venous anastomosis in an musculus gracilis free flap occurred in another patient, and revision surgery was needed. Multiple minor complications were seen. A complete list is shown in Table 5, with complications in relation to the different obliteration techniques offered in Table 6.

**Discussion**

In our data, we found a significant difference in conservative treatment outcomes between the localized and diffuse forms of ORN, using only 1 of the parameters that Ramsden

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**Table 5. Minor and Major Complications of Surgical Treatment: Subtotal Petrosectomy.**

<table>
<thead>
<tr>
<th>Complication</th>
<th>Treatment</th>
<th>No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wound dehiscence</td>
<td>Stitches longer in place</td>
<td>3</td>
</tr>
<tr>
<td>Blind sac granulation</td>
<td>Silver nitrate application</td>
<td>2</td>
</tr>
<tr>
<td>Seroma</td>
<td>Punctures</td>
<td>2</td>
</tr>
<tr>
<td>Skin necrosis at flap donor site</td>
<td>Dressings</td>
<td>2</td>
</tr>
<tr>
<td>Cerebrospinal fluid leak</td>
<td>Lumbar drain</td>
<td>1</td>
</tr>
<tr>
<td>Fistula mastoid tip</td>
<td>Silver nitrate application</td>
<td>1</td>
</tr>
<tr>
<td>Temporary nVII palsy</td>
<td>Conservative</td>
<td>1</td>
</tr>
<tr>
<td>Wound infection</td>
<td>Antibiotics and dressings</td>
<td>1</td>
</tr>
<tr>
<td>Major</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Venous occlusion free flap</td>
<td>Revision surgery, reanastomosis</td>
<td>1</td>
</tr>
<tr>
<td>Mandibular branch of nVII paralysis</td>
<td>Conservative</td>
<td>1</td>
</tr>
<tr>
<td>Infection of cavity with temporal nVII palsy</td>
<td>Antibiotics, hyperbaric oxygen, revision surgery refused</td>
<td>1</td>
</tr>
<tr>
<td>Infection of cavity with fat and blind sac necrosis</td>
<td>Necrotectomies, gauze dressings</td>
<td>1</td>
</tr>
</tbody>
</table>

**Table 6. Complications in Different Obliteration Types.**

<table>
<thead>
<tr>
<th>Obbliteration Type</th>
<th>Healing Problems</th>
<th>Related Problems</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>None</td>
<td>Minor Wound</td>
</tr>
<tr>
<td>Fat + temporal muscle</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Free muscle flap</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rectus abdominis</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Gracilis</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Latissimus dorsi</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Local pedicled muscle flap</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Galea</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Occipital + temporal</td>
<td>9</td>
<td>7</td>
</tr>
</tbody>
</table>

*Minor wound healing problems: wound dehiscence, blind sac granulation, fistula, wound infection. Other: facial nerve palsy, free flap donor site (seroma).
described to define it—namely, ORN confined to the ear canal or concurrent erosion of the mastoid. The second parameter that Ramsden used (the severity of pain and otorrhea) was not documented in a way that we were able to use it with enough statistical power to differentiate localized and diffuse ORN. However, we do feel that this might be another parameter reflecting the severity of the disease that is relevant for the choice of treatment. A critical review of the data of the patients with diffuse ORN revealed that the severity of complaints, combined with the status of hearing, created a selection bias. Patients with more severe complaints and/or lack of hearing were excluded from conservative treatment and directly treated surgically. Patients with diffuse ORN but fewer complaints were treated conservatively, and some of them (3 of 8) gained a cured/stable ear. This group of patients has not been identified or described by Ramsden; however, this subdivision of diffuse ORN might be relevant in the choice of treatment, and we have included this group in our proposed treatment protocol (Figure 1). Yet, due to the selection criteria used in this study, we were not able to compare these groups. To substantiate our hypothesis of a third ORN group, treatment outcomes should be compared after all cases of temporal bone ORN (including the most severe) are treated conservatively—preferably in a prospective setting with a standardization method for the amount of pain and otorrhea (eg, visual analog scale score). Obviously, this might create an ethical dilemma, since progression of disease under conservative treatment in cases with severe ORN might induce serious (intracranial) complications.

Furthermore, we showed that the additional classification system as proposed by Morrissey et al is almost similar to the one proposed by Ramsden et al, since Ramsden’s localized form usually translates into Morrissey grade I/II and the diffuse form into grade III/IV. The 2 available systems are almost similar; therefore, at least 1 should be considered redundant. Four patients who had been treated for nasopharyngeal carcinoma did not follow this rule, since they were classified as localized/grade IVa and IVb. All these patients were successfully managed conservatively, which is contradictive with Morrissey’s classification wherein grade IV is supposed to reflect the most severe form of ORN with the highest need for surgical intervention. In our opinion this illustrates that using cranial nerve or skull base involvement as a parameter might be confusing, since other problems (eg, nasopharyngeal ORN) can give rise to similar signs.\(^7\) In fact, when this parameter is strictly applied, any ear with ORN that is deaf should be graded as IVa and any ear with a tympanic tegmen defect as IVb.

We agree with Morrissey that the more severe the ORN, the more likely it is that a patient will need surgery. In our experience, this severity is greatly determined by the infectious component accelerating the ORN progression. Preventing and suppressing infection and necrosis by use of eardrops, regular cleaning, and necronectomy/sequestrectomy should therefore be the cornerstone of treatment. After a stable form of ORN is created, prevention of a new infection should be the next goal. If morbidity is increasing, despite adequate conservative treatment, and if a progression of ORN is seen, surgery will most

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**Figure 1.** Temporal bone osteoradionecrosis (ORN) treatment protocol. CT, computed tomography.
likely be needed. The need for multiple sequestrectomies might be an indication that conservative treatment is not successful.

In some cases, surgery might be the primary treatment of choice. The presence of functional hearing is an important factor to advocate conservative treatment, since surgery will most likely create a severe air-bone gap. However, in the absence of functional hearing, the choice of treatment is based on risks and benefits of both treatment modalities. Conservative treatment may take months or years with regular outpatient clinic visits for aural cleaning and continuous use of eardrops. Surgical treatment has a relatively short healing time and needs little follow-up. Complications might occur in surgical treatment, while conservative treatment has no real complications. However, fast progression of disease might induce (temporary) facial nerve palsy or intracranial complications. Our advice for treatment, as summarized in our treatment protocol (Figure 1), is to start conservative treatment with adequate analgesics and diagnostic workup with a CT scan. If mastoid air cell destruction is seen but there is functional hearing and there are few complaints of pain and otorrhea (diffuse ORN type A), conservative treatment can be continued. When the ORN stabilizes, conservative treatment is continued. Progression from diffuse type A to type B is marked by aggravation of pain and otorrhea or loss of hearing and should be managed surgically. Patients primarily presenting with these complaints—with or without (intracranial) complications (diffuse type B on presentation)—should also be treated surgically. Of course, patient counseling is of great importance in this decision-making process.

In our opinion, surgical treatment should be STP with vascularized flap obliteration. In the ears, we have treated with canal wall down mastoidectomy alone, and ORN returned after a period of time, increasing the total healing time. STP for ORN is based on 3 steps: removal of necrotic bone and all mastoid air cells and mucosa, prevention of new infection (closing ear canal and Eustachian tube), and promotion of revascularization (vascularized flap obliteration). Minor complications are to be expected, but they can be managed easily. Major cavity infection is more troublesome and likely needs revision surgery. Obliteration can be accomplished in many ways. We have seen the best results (least complications) with the combined occipital-temporal flap obliteration. The galea flap might induce skin necrosis at the donor site, and free flaps have the disadvantage that a donor site complication and occlusion of the anastomosis can occur. However, based on the small groups of different obliteration types in this database, strong conclusions cannot be made on this topic.

**Conclusion**

Ramsden’s classification system is clinically relevant in predicting conservative treatment outcomes. Mastoid air cell destruction on CT differentiates between the localized and diffuse forms of ORN. However, there seems to be a gray area between these 2 groups. Given our results and the experience of treating temporal bone ORN, we have defined a third ORN group and included this in our proposed treatment protocol.

**Author Contributions**

Quinten Kammeijer, study design, data analysis, drafting, final approval, accountability for all aspects of the work; Erik van Spronsen, study design, data analysis, drafting, final approval, accountability for all aspects of the work; Piet G. B. Mirck, study design, data analysis, drafting, final approval, accountability for all aspects of the work; Wouter A. Dreschler, study design, data analysis, drafting, final approval, accountability for all aspects of the work.

**Disclosures**

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**References**