



An Analysis of the National Surgical Quality Improvement Program and Surgery for Osteoradionecrosis of the Head and Neck: Overview, Complications, & Readmissions

William W. Thomas¹, Jason A. Brant M.D.¹, Jason G. Newman M.D.¹, Ara A. Chalian M.D.¹, Steven B. Cannady M.D.¹

¹Department of Otorhinolaryngology: Head and Neck Surgery, University of Pennsylvania Health System, Philadelphia, PA

Abstract

Objectives: Osteoradionecrosis (ORN) is a debilitating post-treatment sequela with a range of treatment options. There is little data concerning complications and readmissions following free tissue transfer as management from a national database.

Methods: Retrospective review of a national database

The American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP), 2005-2014 was queried for patients being admitted from home for surgery with the ICD-9 corresponding to ORN.

Results: The NSQIP database identified 222 patients who underwent surgery for ORN with 75 patients undergoing free tissue transfer. Sixty of these free flaps included bony reconstruction while 15 were soft tissue alone. 83/222 patients had a complication and 53/220 had a serious complication. The presence of a wound infection, decade of life and length of index operation were significantly associated with having a post-operative complication: Odds-ratios 3.58 (1.62 - 8.28), 1.46 (1.05 - 2.07) and 1.25 (1.13-1.38) respectively. Readmission within 30 days was predicted by underweight BMI. (ORs: 17.66 (1.93-389.08) In an analysis of 3335 patients who underwent free tissue transfer of the head and neck, an ORN diagnosis did not increase risk of complication on multivariate regression analysis.

Conclusion: In this database analysis of ORN patients, there is significant risk for post-operative complications, reoperations and readmissions. However, in comparison to free tissue transfer as treatment modality using anecdotal evidence and case series data, the risk of ORN reconstruction are not shown to be significantly elevated.

Introduction

Survivors of head and neck cancer are often left with significant functional and psychological sequela due to their primary treatment modality. A post-treatment complication of considerable morbidity following radiation therapy is the development of osteoradionecrosis (ORN) of the mandible.¹ To date the literature supports the surgical treatment of ORN for reestablishment of mastication with bone and soft tissue free flaps. Additionally, large case series of previously irradiated patients have illustrated that these patients are at significantly higher risk for complications than treatment naive head and neck reconstruction patients.² Additionally, the exact pathophysiology of ORN is unknown. It manifests as the development of a non-healing oral wound due to radiation induced fibroatrophy with hypoxia, hypovascularity and hypocellularity.³ In a prior analysis of the NSQIP database regarding microvascular reconstruction of the head and neck, the reoperation rate was found to be 18.04% with 28.97% of those involving further microsurgery. In summation of the difficulty of free tissue transfer in the head and neck and in conjunction with the post-radiation treatment changes associated with ORN, the NSQIP database was queried to assess for risk factors for complications specific to free tissue transfer for ORN.

NSQIP Analysis

- American College of Surgeons – National Surgical Quality Improvement Program
 - Validated, risk-adjusted, outcomes capturing database as an outgrowth of the VA – NSQIP program
- 1st Assessment
 - Assessed from 2005 – 2014 to capture the outcomes of all patients admitted from home for surgery for osteoradionecrosis
 - ICD-9 codes to identify patients: 526.89 (disease of jaw, not otherwise specified) & 733.45 (aseptic necrosis of the jaw)
 - Procedure CPT codes for free tissue transfer: 15756, 15757, 15758, 15842, 20969, 20955, 20962
 - Bidirectional step-wise Regression model to assess for contributing factors for Complications
 - Univariate analysis 1st performed to filter all variables w/ ≥ 0.2 or $> 10\%$ missing data
 - Multivariate analysis w/ variables reaching $p < 0.05$ considered significant
- 2nd Assessment
 - Same inclusion criteria except new data available regarding readmission rates available from 2012
 - NSQIP evaluated from 2012-2014 for assessment of readmission rates and factors associated
 - From 2012 onward – Additional NSQIP data
 - # of reoperations – 1, 2 or 3+
 - # Days from Index OR to Return to OR
 - CPT code for Return to OR & ICD-9 Code for Return to OR if related to Index OR
- 3rd Assessment
 - NSQIP evaluated from 2005-2014 by CPT codes for Free Tissue Transfer or ORN
 - CPT codes as above – 3335 cases found
 - Case descriptor “ORN.CASE” assessed in conjunction with multiple other characteristics for multivariate regression:
 - age (decade), sex, race, BMI, pre-operative lab values, operative time (hrs), diabetes, renal failure, CHF, COPD, smoking, dyspnea, functional status, steroid use, hypertension requiring medication, bleeding disorder, wound class, ASA class, flap type, separate operative team for flap
 - “ORN.CASE” assessed as independent risk factor for complication, reoperation or readmission

Results

Analysis 1:

- 2005 – 2014: 222 patients underwent surgery for ORN
- 75 Cases requiring Free Tissue Transfer, 60 requiring Bone 2005 - 2009 - 32 cases reported
- 2010 – 2014 - 190 cases reported
- 83/222, 37.4%, patients had a complication
 - 40 - Intraop or Postop transfusions, Minor Complication

Reoperations: avg. 9.73 days

- 15 - 1st reoperations – 12 prior to initial discharge, all related to initial operation, 11.4% of cohort
 - 2, 2nd reoperations, 1- 3rd reoperation

CPT Codes for 15 Initial Reoperations

Neck Exploration, 35800 - 3	Drainage of Neck, 21500 - 2
Closure of wound dehiscence, 12020 - 2	Debridement, 11042 - 2
1 Incidence Per:	
Island Pedicle Flap, 15740	Close Nasal Fistula, 30580
Repair wound, 13132	Flap from Trunk, 15734
Wound drainage, 10180	EGD and G-tube, 43246

- 79 Major Complications in 51 patients
 - 26 Return to OR (11.7% of Cohort)
 - 12 Requiring Mechanical ventilation for > 48 hours
 - 10 Wound disruptions
 - 8 Sepsis, 5 Septic Shock
 - 7 Organ/Deep Space Infections
 - 5 Unplanned Intubation
 - 2 Myocardial Infarctions, 2 Stroke/CVA
 - 1 CPR, 1 Death

For All Complications: Factors associated

- Wound Infection - 3.58 (1.62 - 8.28)
- Age (Decade) - 1.46 (1.05 - 2.07)
- Length of Index Operation - 1.25 (1.13-1.38)

Major Complication:

- Wound Infection - 3.03 (1.42 - 6.50)
- HTN requiring medication – 2.39 (1.15 - 5.02)
- Length of Index Operation – 1.15 (1.05-1.27)

Analysis 2:

Analysis of 2012-2014 Data with Updated Readmission and Reoperation Data

- 131 Cases, 48 requiring Free Tissue Transfer

Risk Factors for Prolonged Hospitalization:

- Return to OR – 11.26 (2.67 - 61.22)
- Age (Decade) – 2.02 (1.17 - 3.74)

Readmissions: #8

- Mean 19.75 days from OR
- BMI Underweight associated - 17.66 (1.93 - 389.09)

Analysis 3:

- ORN.CASE was not associated with Complications, Prolonged Hospitalization, Reoperation or Readmission on Multivariate analysis of 3335 Free Tissue Transfer cases

Discussion / Conclusions

Patients suffering from osteoradionecrosis of the head and neck are a unique cohort due to their prior radiation therapy; the psychosocial impact of subsequent surgical treatment is complicated by their altered physiology and pathology. The NSQIP dataset allows for an analysis of care for this disease across academic and community providers. Free tissue transfer offers the best restoration of function with the possibility of dental implantation. However, it is also associated with significant risk of complication, 20-40%, as well as institutional studies suggesting a higher rate of free flap failure in this population.⁵

With regards to complications, this assessment of the NSQIP dataset agrees that patients are at high risk of suffering significant morbidity and possible mortality. Given the significant increased odds-ratio for complication with wound infections pre-operatively any infection superimposed with the ORN should be controlled prior to definitive surgical repair. ORN itself is not an infectious state but rather a hypoxic and hypovascular wound that is easily infected from the oral cavity. Older patients, many of whom require blood pressure regulation, are also at increased risk for complication and a thorough exhaustion of conservative measures should be attempted prior to a large operation such as free tissue transfer. Conversely, as reported by Cannady et al complications were increased as the duration of ORN disease progressed and a larger resection was required thus lending evidence for aggressive upfront surgical measures.⁵ Longer duration procedures have been associated with complications in head and neck microvascular cases and the ORN cohort is no exception.⁶ Measures to increase operative speed and safety, such as independent ablative and reconstructive teams and dedicated operative nursing staff familiar with microvascular cases has been shown to improve operative duration.⁷

An assessment of the indications for reoperations illustrates that proper initial wound debridement and closure techniques as well as excellent wound care post-operatively can make large gains in limiting reoperations. Readmissions are very few in number and this may be related to the large number of bone containing flaps. Bone containing flaps were protective against readmission relative to soft tissue alone though patient's with bone containing flaps were hospitalized for a longer duration (unpublished NSQIP data).

Although this assessment of the NSQIP is unable to present ORN as an independent risk factor for complication, reoperation or readmission within the context of head and neck reconstruction, this patients require attentive care and a high suspicion for complications. Prior radiation therapy is a known risk for poor wound healing and wound complications² which will translate into prolonged hospitalizations, reoperations and readmission. This is a challenging cohort of patients who deserve the best functionality possible as they progress through survivorship; however, the desire to improve function in the setting of ORN must be tempered with the risk of complications and worsened morbidity post-operatively. Free tissue transfer for ORN will continue to be a challenging arena of microvascular head and neck surgery and great outcomes can be achieved by experienced treatment teams.^{5,8}

Contact

William W. Thomas, MD
Department of Otorhinolaryngology, University of Pennsylvania Health Systems
Email: William.Thomas@uphs.upenn.edu

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