



Third party assessment of resection margin status in head and neck cancer



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SUMMARY

Background: Definitive assessment of primary site margin status following resection of head and neck cancer is necessary for prognostication, treatment determination and qualification for clinical trials. This retrospective analysis determined how often an independent reviewer can assess primary tumor margin status of head and neck cancer resections based on review of the pathology report, surgical operative report, and first follow-up note alone.

Methods: We extracted from the electronic medical record pathology reports, operative reports, and follow-up notes from head and neck cancer resections performed at Stanford Hospital. We classified margin status as definitive or not. We labeled any pathology report clearly indicating a positive, negative, or close (<5 mm) margin as definitive. For each non-definitive pathology report, we reviewed the operative report and then the first follow-up note in an attempt to clarify margin status. We also looked for associations between non-definitive status and surgeon, year, and primary site.

Results: 743 unique cases of head and neck cancer resection were extracted. We discarded 255 as non-head and neck cancer cases, or cases that did not involve a definitive resection of a primary tumor site. We could not definitively establish margin status in 20% of resections by independent review of the medical record. There was no correlation between margin determination and surgeon, site, or year of surgery.

Conclusion: A substantial fraction (20%) of primary site surgical margins could not be definitively determined via independent EMR review. This could have implications for subsequent patient care decisions and clinical trial options.

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Introduction

Current NCCN Clinical Practice Guidelines in Oncology for Head and Neck Cancers includes positive margins as an adverse feature for all treatment sites [1]. There remains a lack of consensus on what defines an adequate oncological surgical resection margin. The most widely accepted definition was proposed by Looser et al. [2], defining positive margins as any specimen with tumor at or within 5 mm of the cut edge, or any specimen with premalignant change or in-situ cancer in at the cut edge [2]. However, details such as how margins are sampled and assessed are not standardized. There is no consensus on how to incorporate

intraoperative frozen section into depth of invasion and margin evaluation, and how to assess margins in piecemeal resection, which is often associated with endoscopic procedures [3,4].

This lack of standardization can make it difficult to determine margin status based on chart review since the pathologist may not be able to conclusively comment on the final margin status. Many papers that have reported on margin status do not include discussions of such indeterminate margins. In the case of Eldeeb et al. [5], we contacted the first author who said that margins that were neither clearly positive nor negative according to their pathology reports were determined by a non-specific consensus opinion methodology by their multidisciplinary team, (Hany Eldeeb. Conversation with: Amy Ransohoff, 2015 May 15) which is consistent with our institutional standard of practice when discussing cases postoperatively in our multidisciplinary tumor board. However such consensus discussions and decisions are not typically auditable nor is the rationale for decisions made following such discussions.

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Because knowledge of a positive margin has implications for prognosis, trial eligibility, and subsequent treatment recommendations, it is essential to be able to verify definitively surgical margin status. Numerous studies of head and neck cancer demonstrate that positive surgical margins are independent negative prognostic variables [6]. Primary site margin status has been shown to correlate with both disease-free survival and local recurrence-free survival, even when adjusted for TNM status, perineural invasion, and subsequent radiation treatment [7]. Additionally, a positive margin may determine whether chemotherapy is used in the adjuvant setting or it may alter postoperative radiation treatment plans [8]. In order to determine eligibility for clinical trials or to review proper treatment assignment on clinical trials, it is essential to be able to determine surgical margin status from chart review [9,10].

We have noticed that definitive determination of margin status is not always possible from chart review. The goal of this retrospective analysis was to determine how often an independent reviewer can definitively assess primary tumor margin status of head and neck cancer resection based on review of the pathology report, surgical operative report, and first follow-up note alone.

Methods

Following approval by the Stanford School of Medicine Institutional Review Board, we identified patients in the Stanford Cancer Institute Research Database using specified ICD-O-3 (Appendix A) site codes combined with a resection surgery between 2009 and 2013 inclusive. We extracted from the EMR the pathology report of the resection, the surgical operative report, and the first out-patient surgical note (follow-up note) following surgery. For amended or revised reports or notes, we took the most recent version. This clinical data were then provided in a HIPPA compliant online application to assist chart review.

We removed cases which were not attempts at definitive primary site surgical resection or whose cancer site was not within the specified ICD-O-3 codes (Fig. 1). For those cases that met these criteria, we sequentially evaluated the pathology report, operative report, and first post-operative note until a final margin status was determined. If the first post-operative note did not provide any clarification on margin status for ambiguous pathology reports and operative notes, we considered that case to have non-definitive margin status.

For each pathology report, we classified margin status as definitive or not. We classified any pathology report clearly indicating a positive, negative, or close (<5 mm) margin as definitive. We categorized non-definitive pathology reports as follows: clinical correlation suggested (CC), negative frozen margin sections but with clinical correlation suggested or required (NCC), positive frozen margin sections but with clinical correlation suggested or required (PCC), or margin status cannot be determined due to the nature of the specimen, or not otherwise specified (U).

For each non-definitive pathology report, we reviewed the surgical operative report in an attempt to clarify margin status. We classified an operative report as definitive if it resolved the margin status as explicitly positive or negative. This required that the surgeon provided clinical correlation. We classified all other operative reports as non-definitive. These could be classified into two categories. The operative report reflected what was already in the pathology report without any further explanation or clarification, or there was no reference in the operative note to pathologic results.

For each non-definitive operative report, we reviewed the first follow-up note in an attempt to clarify margin status. We classified a follow-up note as definitive if it resolved the margin status as

explicitly positive or negative. This required that the surgeon provided clinical correlation. We classified all other follow-up notes as non-definitive, and these fell into the following two categories: the author of the note referred only to the status of the surgical margins' frozen sections, without addressing pathologist's desire for clinical correlation, or the margin status was not reported.

We performed statistical analysis with R (Studio Version 0.98.1091). After classifying the cancer sites (Appendix A) into five regions (Appendix B), we performed a Difference of Proportion test to determine whether the difference in rates of non-definitive margin determination by region were statistically significant ($p < .05$). We also performed a Difference of Proportion test to determine whether the difference in rates of non-definitive margin determination by year were statistically significant ($p < .05$). We performed a Linear Mixed Effect Model to determine whether the individual surgeon had a significant effect on margin status determination.

Results

We extracted pathology reports, operative reports, and follow-up notes from 743 unique cases of head and neck cancer resection; we discarded 255 as non-head and neck cancer cases, or cases that did not involve a definitive resection of a primary tumor site. Fig. 1 summarizes the findings. The margins of 382 of 488 (78%) relevant cases were definitively established in the pathology report but only an additional 3 and 5 cases were resolved upon review of the operative note and follow-up note respectively. The margin status of the remaining 98 of the 488 cases could not be definitively established after review of the pathology report, operative report, and first follow-up note. Therefore, we could not definitively establish margin status of 20% of resections by independent review of the medical record.

An ANOVA analysis did not find any significant difference ($p = 0.11$) between the rates of positive margins by cancer region. Additionally, given an ANOVA p -value of 0.28 in the Difference of Proportion Test comparing margin status determination by year in which the resection was performed, we were unable to reject the null hypothesis that all years have the same proportion of non-definitive margin determinations. In a Linear Mixed Effect Model, when controlling for the effects of the surgeon as a random effect, the effect of the surgeon proved insignificant as well. Therefore, there was no correlation between margin determination and surgeon, site, or year of surgery.

Discussion

Prior studies of surgical margin reporting have shown that margin status is not always reported. For example, in a 2014 retrospective analysis that examined 20,602 oral cavity squamous cell cancer cases, margin status was not reported in 5.2% of the cases [11]. Many of these reports, including the one cited above, use data from tumor databases rather than examination of primary medical records. Therefore, we decided to look at primary patient documentation in our study to simulate an audit-type approach as would be done in the case of a clinical trial or a postoperative assessment by an oncologist trying to determine the indications for adjuvant concurrent chemotherapy and radiation.

We found that 20% of all surgical patients were unable to have their margin status defined by the pathology report, operative report, and follow-up note. The most common reason for inconclusive margin status was the need to correlate frozen section findings with how the resection was performed and margins were sampled. Only in 8 of the 106 cases in which the pathology report was non-definitive were such ambiguities subsequently resolved and documented.

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