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National And Institutional Outcomes Data In Head And Neck Cancers, And Functional And Patient Reported Outcomes In Patients With Oropharyngeal Cancers

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National and
Institutional Outcomes
Data in Head and Neck
Cancers, and
Functional and Patient
Reported Outcomes in
Patients with
Oropharyngeal
Cancers

Abstract

Background and Purpose: To determine the availability of outcomes data to head and neck cancer patients. To create a database of comprehensive information including demographics, process metrics, and outcomes for head and neck cancer patients who were diagnosed or treated at a Yale New Haven Hospital affiliate. To examine factors affecting functional and patient reported outcomes in patients with oropharyngeal cancers.

Materials and Methods: The websites of all NCI-designated Cancer Centers and all affiliated institutions were examined for publicly available data regarding head and neck cancer patients. For Yale data, IRB approval was obtained to use tumor registry data, as well as chart review, to create a comprehensive database for all new head and neck cancer patients at Yale in 2013 and 2014. The patients with oropharyngeal cancers were then isolated and all living patients were called to survey them about long term treatment effects, using a standardized survey. The data gathered was then analyzed using univariate and multivariate analysis.

Results: Only 6 institutions across the country had any publicly available data regarding head and neck patients, and only three of them had information beyond the number of patients seen. The database of head and neck cancer patients at Yale was created successfully, and compiled into outcomes books for each year that presented the relevant data. Analysis of oropharyngeal patients focused on HPV status, insurance type, academic vs. non-academic centers, and distance from radiation treatment site for patients treated with that modality. Many factors were found to be significant on univariate analysis. On multivariate analysis, it was found that HPV positive patients had better outcomes in various functional and patient reported outcomes. It was also found that private practice patients had improved outcomes compared to Medicare patients. Finally, it was also found that recurrence rates were higher for patients that lived over 15 miles away from their treatment site.

Conclusions: There is a paucity of publicly available data regarding head and neck cancer outcomes at NCI designated cancer centers around the country. At Yale, the data showed that standard metrics are in line with national outcomes. The institution can improve significantly in terms of various process metrics, most specifically in terms of having various ancillary staff work with patients who are diagnosed or treated for a head or neck cancer. Analysis of oropharyngeal patients demonstrated that patients with HPV negative cancers need closer monitoring for various functional and patient reported outcomes. It also demonstrated that patients on Medicare need monitoring for various other functional and patient reported metrics. Patients who live further from their treatment sites have higher recurrence rates, indicating that patients who have to travel further might be at higher risk for missing treatment or for receiving adequate follow-up.

Acknowledgements

I would like to thank my mentor and thesis advisor, Saral Mehra, MD, for his encouragement, mentorship, and leadership during this project and throughout medical school. Additionally, I would like to thank our collaborators on this project for their valuable contributions—the Yale Smilow Tumor Registry, especially Teresita Vega, and my fellow medical student, Elliot Morse.

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Introduction

Background

Head and Neck (H&N) cancers account for approximately 3 percent of cancers annually.

This translates to over 50,000 new diagnoses annually. When patients receive a diagnosis of head or neck cancer, many of them want more comprehensive data about their diagnosis, but are unable to obtain specific data about the prognosis of their specific pathology, both in terms of morbidity and mortality. For most patients, local referral patterns and Internet searches are the most common ways to seek further evaluation and treatment. However, despite the frequency of these cancers, there is relatively little data available to patients pertaining to the outcomes they can expect.

National Data

Many of these patients are seen and treated at NCI-designated cancer centers, of which there are currently 62 sites that provide patient care including 45 NCI-designated Comprehensive Cancer Centers and 17 NCI-designated Cancer Centers. All of these centers have programs dedicated to H&N cancers; however, the public availability of information on quality of care, including basic structural, process, and outcome metrics amongst these centers has never been systematically analyzed. We hypothesized that there was almost no data available for each cancer center on their individual metrics.

Yale Database

At Yale, approximately 200 head and neck cancer patients are diagnosed or treated at Yale New Haven Hospital or an affiliated hospital annually. This includes cancers found in the oral cavity, salivary glands, larynx, and pharynx (including nasopharynx,

oropharynx, and hypopharynx). In addition, while there is some national data available broadly, treatment center specific data at Yale is unavailable.

This project aimed to analyze the feasibility of providing comprehensive outcomes data to providers and patients about how our program performed. The data analyzed was based on the American Association of Head and Neck Surgery guidelines. This is based on evidence based reviews showing optimal outcomes for patients diagnosed with head and neck cancers. The analysis was broken into three main categories, with a number of subcategories. The three main categories were structural, process, and outcome metrics.

Oropharyngeal Patients

In recent years, it has become apparent that in order to maximize value to the patient, health care providers must work to provide care that minimizes morbidity and mortality, while also attempting to maximize patient quality of life. Traditionally, quality was measured through functional outcomes that could be quantified. However, in recent years, the use of patient reported surveys has become more common, and has been shown to be strongly correlated with patient quality of life. There have been many studies that report morbidity and mortality outcomes for head and neck cancer patients.¹⁻³ Other studies have focused on differences in outcomes based on a variety of patient, tumor, and treatment variables. One recent area of focus has been HPV positive cancers. There have been numerous studies that show that HPV positive cancers have significantly improved survival⁴⁻⁷, as well as decreased rates of progression⁸ and improved responses to treatment⁹⁻¹² compared to HPV negative ones. However, there

have only been three studies¹³⁻¹⁵, to our knowledge, that have analyzed differences in patient reported quality of life based on HPV status. There has been only one study that analyzed age, gender, and stage differences in quality of life outcomes in oral cavity and oropharyngeal cancers¹⁶, though others have analyzed survival and treatment response^{10,17}. No studies, to our knowledge, have analyzed both objective quality of life outcomes as well as patient reported outcomes in oropharyngeal cancers based on a variety of patient, tumor and treatment factors, which was one of the goals of this study.

Patient Reported Outcomes

Patients with head and neck cancers have traditionally had a wide variety of functional problems, such as problems with speech and/or swallowing, pain management, and social burden. Many of these problems have not been measured in traditional studies, but has been measured more recently through patient surveys. A validated head and neck patient reported outcomes measurement tool, the EORTC-35, has been used to examine patient quality of life during and after treatment for head and neck cancers. One major goal of this study was to assess the long-term quality of life for patients with oropharyngeal cancers.

Statement of Purpose

1. To analyze the data available to patients at NCI-designated Cancer Centers across the country

2. To create a comprehensive database of all analytic patients in 2013 and 2014 treated at a Yale New Haven Hospital
3. To compile oropharyngeal patient data for functional outcomes, and analyze that data for key metrics that may affect outcomes
4. To gather patient reported outcomes for oropharyngeal patients, and analyze it for key metrics that affect outcomes.

Materials and Methods

National Data

In order to analyze the data that is available to patients, the websites of the NCI designated 45 Comprehensive Cancer Centers, as well as the 17 Cancer Centers across the US were searched for any outcomes data that would be accessible to patients. The affiliated universities and hospitals were searched for the same information. That data was then compiled all the data into structural, process, and outcome metrics. PubMed was not used, as the articles in it are not easily accessible to patients.

Yale Database

For the second part of this study, functional outcomes were examined for oropharyngeal patients at Yale. IRB approval was obtained to conduct a study examining all oropharyngeal patients in 2013 and 2014, which would involve analyzing data about them, as well as contacting them to obtain patient reported outcomes data. In order to analyze the vast amount of data to present comprehensive data to our patients and providers, the tumor registry data was used as a starting point. The registry was able to provide all head and neck cancer patients who had been seen at a Yale affiliated

hospital broken down by year. Thyroid cancer cases were specifically excluded for this analysis, as many thyroid cases at Yale are treated by the endocrine surgery department. In order to verify that the data gathered by the tumor registry was accurate, a manual analysis of every patient seen by a head and neck cancer surgeon in 2014 was done. This involved looking at the four head and neck cancer surgeons in 2014, and cataloguing every new patient that they saw. All patients who were subsequently diagnosed with cancer were then compared to the data the tumor registry had on file. It was found that the data matched up, so all patients provided by the tumor registry were used. Only analytic patients (those diagnosed and/or treated at a Yale facility) were included in the analysis. The following data was gathered for each patient:

Structural metrics are defined as information that assesses the basic characteristics of the patient, the pathology, and the treatment received.

- Patient factors
 - Age
 - Gender
 - insurance status
 - geographic location
- Tumor factors
 - site of tumor
 - type of tumor
 - stage
 - HPV status

- Treatment factors
 - types of treatment
 - Hospital where patient received treatment
 - Type of chemotherapy
 - Academic vs Non-academic treatment site
 - Distance from Radiation treatment site

Process metrics measure whether the care provided is consistent with routine clinical care.

- pre-treatment
 - physical exam
 - head or neck CT or MRI
 - chest imaging
 - audiogram
 - speech and swallow evaluation
 - dental evaluation
 - nutrition consult
 - staged before treatment
 - clinically staged
 - pathology was reviewed at a Cancer Center
 - reviewed by the multidisciplinary tumor board.
- Treatment
 - number of lymph nodes removed (if they underwent surgery)

- positive margins
- times to treatment
 - diagnosis to treatment
 - surgery to adjuvant therapy
 - radiation therapy
 - total treatment
- post-treatment
 - 1 year follow-up
 - CT/MRI 3-6 months after treatment
 - TSH 1 year after treatment
 - Dental follow-up

Outcomes metrics involved morbidity and mortality assessments, as well as how effective Yale physicians were at stopping detrimental habits such as smoking and drinking.

- Mortality
 - 1 year overall survival (OS)
 - 1 year disease specific survival (DSS)
 - 1 year disease free survival (DFS)
- Surgical complications
 - Surgical Site Infection
 - Flap-loss

- 30-day readmission
- Positive surgical margins
- Oncological complications
 - Admission during chemotherapy or radiation
 - Salvage Surgery
 - Renal damage
 - Hearing loss
- Functioning
 - Gastrostomy tube during treatment
 - Tracheostomy during treatment
 - Gastrostomy six months after treatment
 - Tracheostomy six months after treatment
- Habits
 - Smoker at diagnosis
 - Alcoholic at diagnosis
 - Smoker six months after treatment
 - Alcoholic six months after treatment

Yale switched to EMR in late 2012, so data gathering began in 2013. The categories highlighted above were able to be obtained from the tumor registry, or information from the registry was analyzed in order to yield the relevant information. For instance, a description of the imaging input by the tumor registry was used to determine which patients had head or neck imaging, or chest imaging. Durations were obtained by

analyzing start and end dates of various diagnoses and treatments. Other metrics were able to be obtained directly from tumor registry data without further analysis. For the categories obtained from EPIC, chart review was required to obtain the necessary data.

The data that was gathered was fairly comprehensive, but there were many assumptions that had to be made in order to have complete data. The list of assumptions include:

- HPV status: non-squamous cell carcinoma cases were assumed to be negative
- Staged before treatment: Only counted if documented in EPIC
- Overall stage: Based on pathological stage if possible, otherwise clinical stage was used
- Academic vs. Non-academic: If a patient received any treatment at a non-Yale affiliated treatment site, they were classified as non-academic
- Head and Neck imaging/Chest imaging: If patient received a PET exam, both were counted
- Pathology reviewed at Yale: If pathology note was Smilow Cancer Center, St. Raphael's Hospital, or Bridgeport Hospital, it was counted (facilities directly owned by Yale)
- Audiogram/Nutrition/Speech Language Pathology/Dental: Only counted if documented in the chart (private dentists or nutritionists were not included, as private providers do not participate in the multidisciplinary treatment team)

- Multidisciplinary Tumor Board: Counted if included on the Weekly Tumor Board list
- Lymph nodes removed: Yield based on pathology report. This is only based on initial surgery, not any subsequent procedures.
- Date of last contact: any patients who had not been seen in over one year at the date of analysis were contacted by the tumor registry for follow-up data
- CT/MRI after treatment: Only included if strictly between 3 to 6 months after treatment
- TSH after treatment: Only includes analysis of radiation therapy patients who had TSH strictly between 11 and 13 months after treatment
- Dental (post treatment): Only if included in chart
- 1 year follow-up: Patients must have had at least 3 appointments in the year following treatment, each visit at least 2 months apart). If patients died before 1 year, they were not counted.
- 1 year Overall survival: If patients were unable to be followed up, they were considered alive
- 1 year disease specific survival: Unless patients were documented to have cancer at time of death, they were counted for disease specific survival
- 1 year recurrence: Patients counted only if they had documented recurrence at 1 year. Unknown patients were not counted.

- Renal Injury/Hearing Loss: cisplatin treated patients that had any documented renal injury (Creatinine clearance increase by 0.3) or hearing loss during treatment with cisplatin
- Tracheostomy during treatment: If patients received tracheostomy during surgery, but it was removed before patient was discharged, it was not included.
- Gastrostomy tube/tracheostomy six months after treatment: If patients expired before six months passed, they were not counted.
- Smoker/alcoholic six months after treatment: If patients expired before six months passed, they were not counted.

Once the data had been gathered, it was compiled into different tables and graphs.

Using Excel's PivotTable function, patients were sorted into various categories. Almost all structural metrics were graphed using all patients. HPV status was an exception to this, as oropharyngeal HPV status was measured separately from the overall population.

For all process and outcome metrics, overall percentages were measured, but each metric was then further broken down into early (defined as stage 1 or 2) and late (defined as stage 3 or 4) stage cancers.

Oropharyngeal Patients

The data for oropharyngeal patients was extracted from the Yale Database that was created by isolating patients who had cancers of the tonsil, soft palate, base of tongue, or general oropharyngeal area, as detailed by the tumor registry.

Patient Reported Outcomes

For the patient reported section of the data, the physicians for all patients who were currently alive were contacted to obtain permission to communicate with their patients. Only patients who had at least one Yale physician (as opposed to all private physicians) were contacted. Each patient was then sent a letter through the mail detailing basic elements of the study, and allowing them to opt out of the study. The patients were then phoned by the thesis author, as well as another medical student, and were then asked to give verbal consent to conduct the study. If the patient approved, the EORTC-35 would then be conducted over the phone.

The patient reported outcomes is presented similarly to the functional outcomes, but had to first be converted into a standardized format. This was necessary because each of the first 30 questions are rated on a 1-4 scale, while the remaining 5 are binary yes/no questions. In addition, creating different categories for each of the 35 questions becomes difficult to understand and to find patterns. Finally, different categories have different numbers of questions, which would lend greater weight to some categories, and less to others. By using a standardized format, we aimed to avoid these problems.

The EORTC QLQ-H&N35 was divided into 7 scales (pain, swallowing, sense, speech, social eating, social contact and sexuality) and transformed into a 0-100 scale, with 0 representing no problems with the aforementioned categories, and 100 representing severe problems. There were also 11 single items that were assessed separately, but using the same scoring system, as they do not fall into the previous categories (having to do with teeth problems, opening mouth, dry mouth, sticky saliva, coughing, feeling ill,

intake of painkillers, nutritional supplements, feeding tube, weight loss and weight gain). This scaling model is standardized and was originally proposed by the survey creators¹⁸ and has been used numerous times since then. There are different number of questions for each of the 7 scales, as follows:

category	questions	number of questions
pain	1-4	4
swallowing	5-8	4
sense	13-14	2
speech	16, 23-24	3
social eating	19-22	4
social contact	18, 25-28	5
sexuality	29-30	2
teeth problems	9	1
opening mouth	10	1
dry mouth	11	1
sticky saliva	12	1
coughing	15	1
feeling ill	17	1
intake of painkillers	31	1

nutritional supplements	32	1
feeding tube	33	1
weight loss	34	1
weight gain	35	1

Each of the first 30 questions was ranked on a 0-3 scale. For the 7 multiple question scales, the score of all questions in that category was summed then divided by the maximum possible score to get to a percentage that fit into the 0-100 scale. For the final five questions, the choice was binary. Those questions were therefore treated similarly to the functional outcomes metrics above, in that the aggregate score was simply a percentage. Once the categories were standardized, they could be treated similarly to the functional outcomes in both aims, but reported as percentages as opposed to binary choices.

Results

National Data

Of the 62 centers examined, 6 reported one or more H&N cancer quality or outcome metric (figure 1). Three of the six, Memorial Sloan Kettering Cancer Center, University of Iowa, and University of North Carolina reported the total number of patients seen. The other three (Massachusetts Eye and Ear Infirmary, Mount Sinai Health System, and Cleveland Clinic) had outcomes books with 2-4 pages pertaining to quality and outcome

metrics for H&N cancer. MEEI reported total number of free flaps (FF), type of antibiotics used in FF-cases, surgical site infection rate after FF surgery, and functional shoulder outcomes after a supraclavicular artery island flap. Cleveland reported type of FF used; FF success rates, length of stay for FF patients; outcome metrics for late-stage supraglottic cancers (larynx preservation rates, freedom from recurrence, overall survival, voice scores, and swallowing scores), late-stage p16+ oropharyngeal carcinoma (OS and DSS rates), and voice restoration with TEP. Mount Sinai reported complications rates after robotic surgery.

CLASS OF METRIC	METRIC SUBGROUP	SPECIFIC METRIC	Patients Included	MEEI	MSK	Mount Sinai	Cleveland Clinic	Iowa	UNC
STRUCTURAL		# of Patients Seen			✓			✓	✓
		# of Free Flaps		✓					
		Type of Free Flap					✓		
PROCESS	Pre-Treatment	Type of abx used in Free Flap	Receiving free flap	✓					
	Treatment								
	Post-Treatment								
OUTCOME	Treatment Complications	Free Flap Surgical Site Infection	Receiving free flap	✓					
	Surgical	Free Flap Success Rate	Receiving free flap				✓		
	Radiation	Length of Stay after Free Flap	Receiving free flap				✓		
	Chemotherapy	Complications After Robotic Surgery	Receiving TORS			✓			
Survival		Overall Survival	Stage III/IV BOT SCC p16+				✓		
		Disease Specific Survival	Stage III/IV BOT SCC p16+				✓		
		Overall Survival	Stage III/IV Supraglottic SCC				✓		
		Recurrence Free Survival	Stage III/IV Supraglottic SCC				✓		
Functional		Larynx Preservation	Stage III/IV Supraglottic SCC				✓		
		Voice Score	Stage III/IV Supraglottic SCC				✓		
		Swallowing Score	Stage III/IV Supraglottic SCC				✓		
		Shoulder function after SCAIF	Receiving SCAIF Flap	✓					
		TEP Voice restoration rates	After total laryngectomy				✓		
Patient-Reported									

Yale Database

The data at Yale was compiled successfully, though initial data gathering took significant amounts of time. In the initial examination of all patients seen by the head and neck surgeons at Yale for 2014 (in order to verify the reliability of tumor registry data), over 600 patients were catalogued. 242 were found to have a malignancy and were analytic

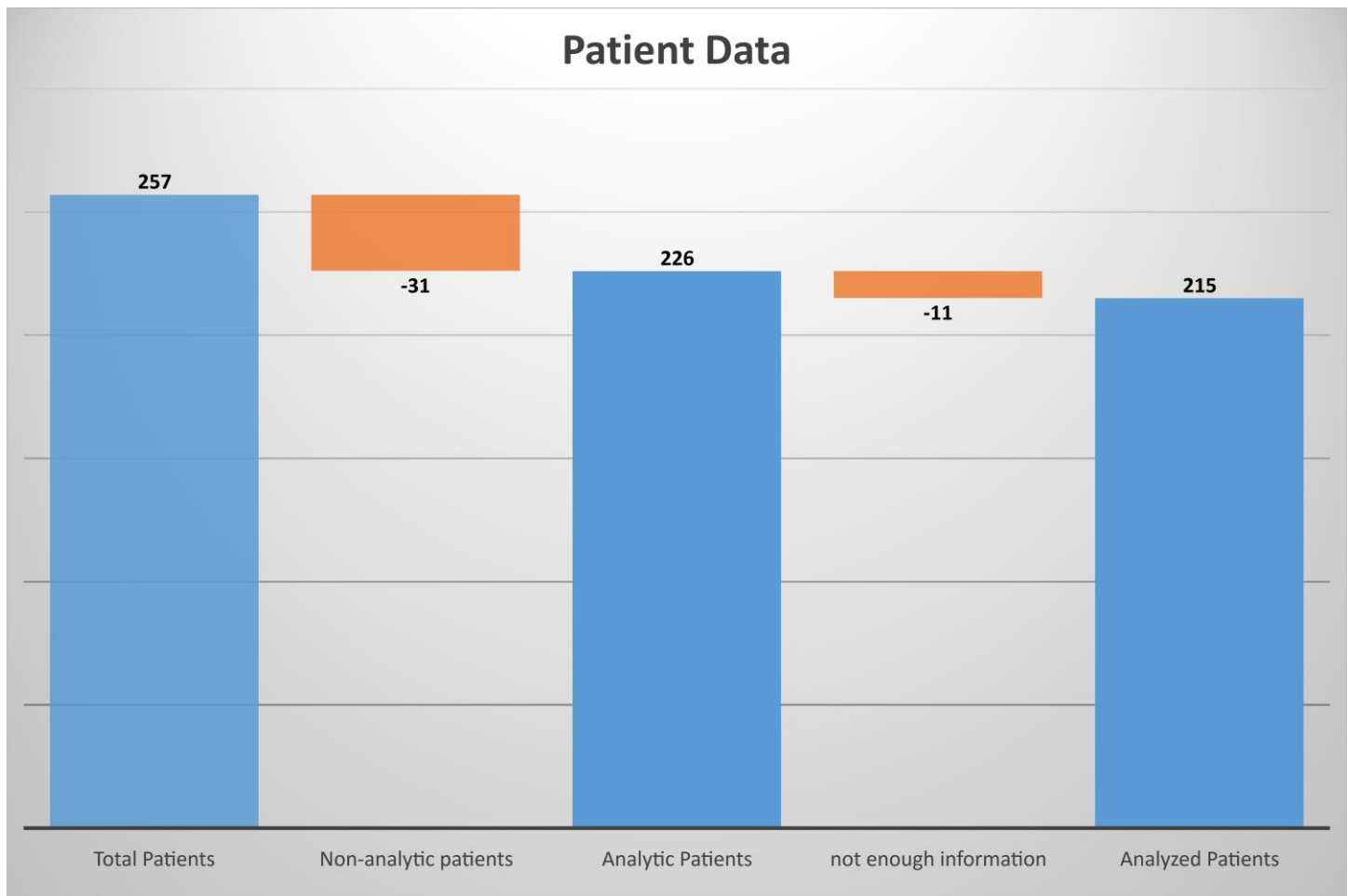
patients, and therefore included in the final analysis. Two comprehensive outcomes books (one for 2013 and one for 2014) focused on head and neck cancer were created from the data. The outcomes book was broken down into three sections. The first section contained basic information regarding head and neck cancers. The second section contained data concerning structural and process metrics. The final section contained the outcomes data. Each outcomes book is presented below, with the first section omitted so only the data is presented:

2013 Smilow – Yale New Haven Health Systems Head and Neck Outcomes Book

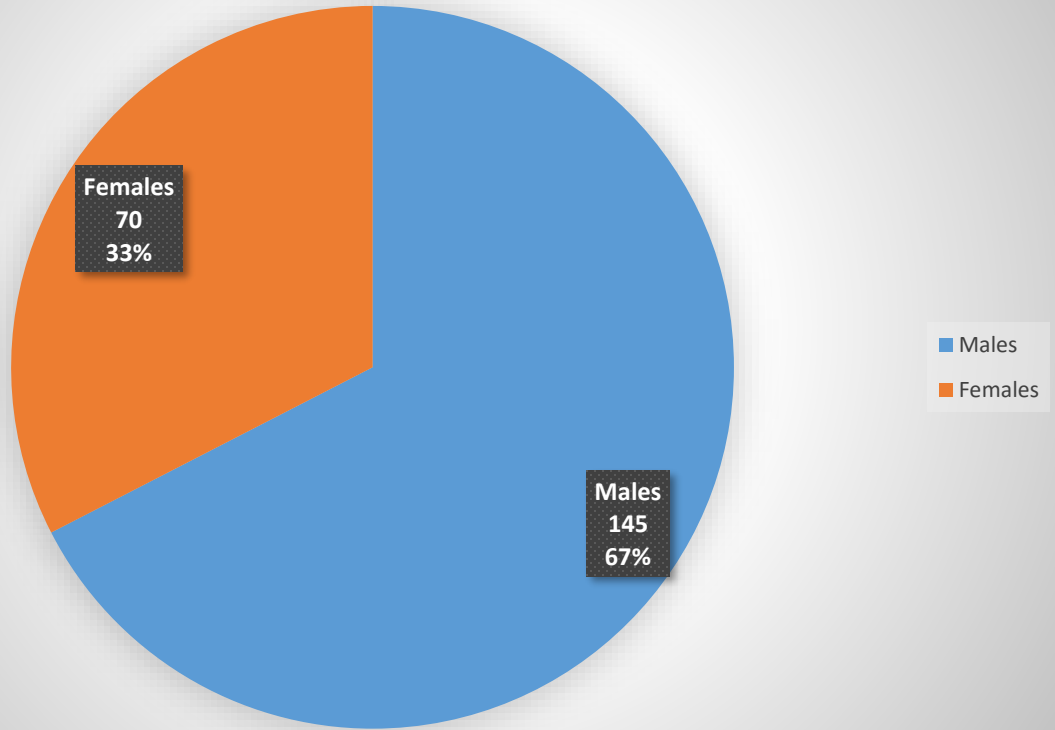


Part B: Structural Metrics

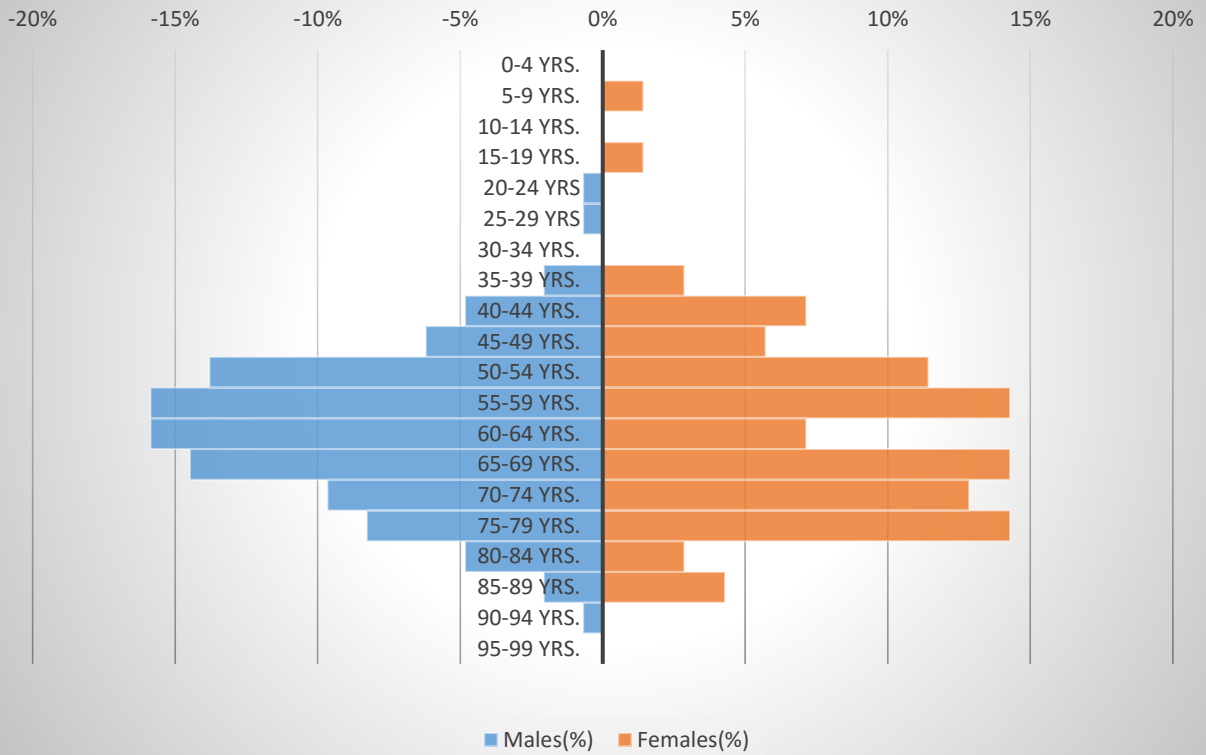
- 215 patients analyzed throughout the Yale-New Haven Hospital system
 - patients who received their diagnosis and/or their initial treatment at a Yale-New Haven Hospital affiliate
 - patients were weeded out if there was no information found in the electronic medical record, EPIC
- 19 hospitals included
 - YNHH System hospitals: Yale-New Haven, St. Raphael's, or Bridgeport Hospital, all of which are under the YNHH system
 - Other hospitals: West Haven Veteran's Affairs hospital, Lawrence and Memorial, Hartford Hospital, Greenwich Hospital, Memorial Sloan Kettering, Griffin Hospital, Danbury Hospital, Charlotte Hungerford Hospital, St. Anne's Hospital, Waterbury Hospital, Stamford Hospital, New York Medical Center, University of Connecticut Hospital, Backus Hospital, Harold Leever National Cancer Center, and St. Mary's Hospital.

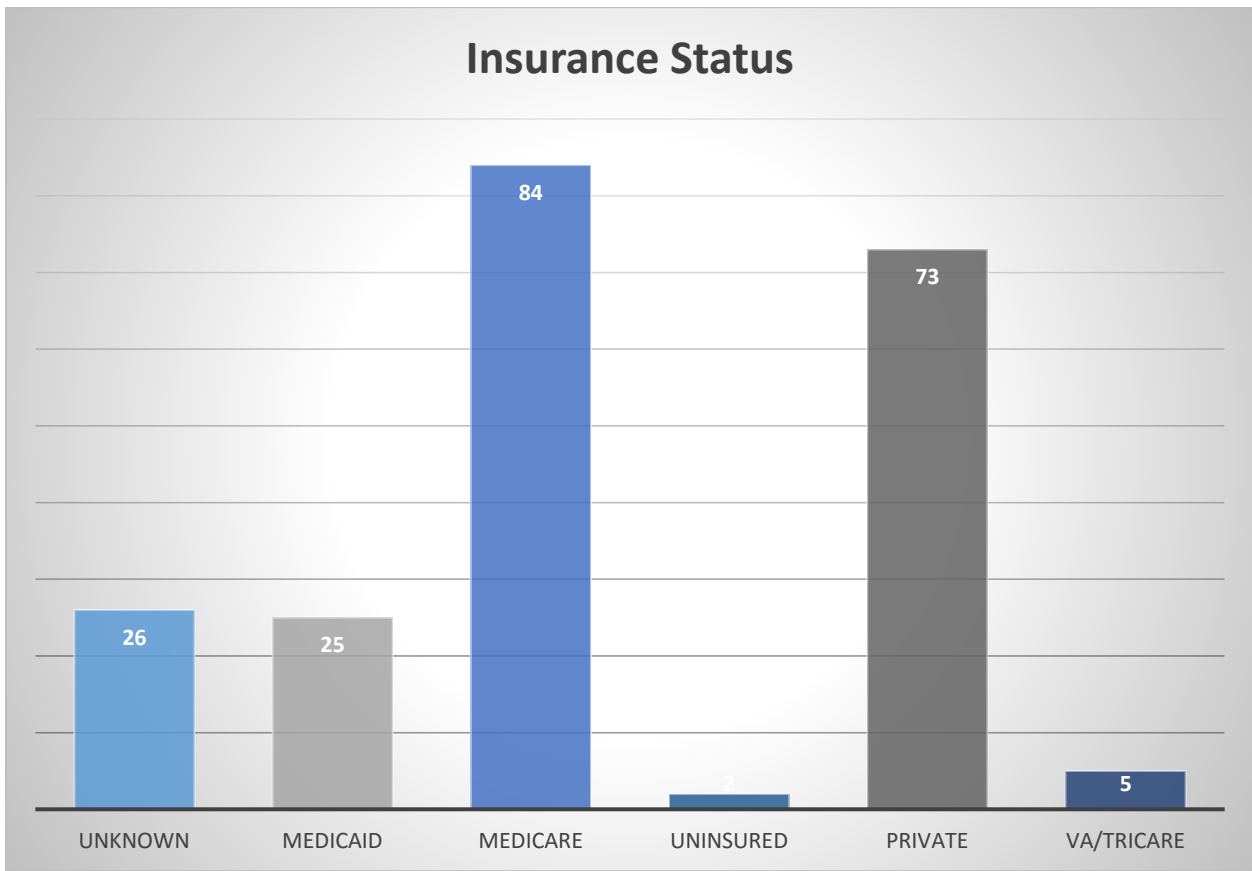
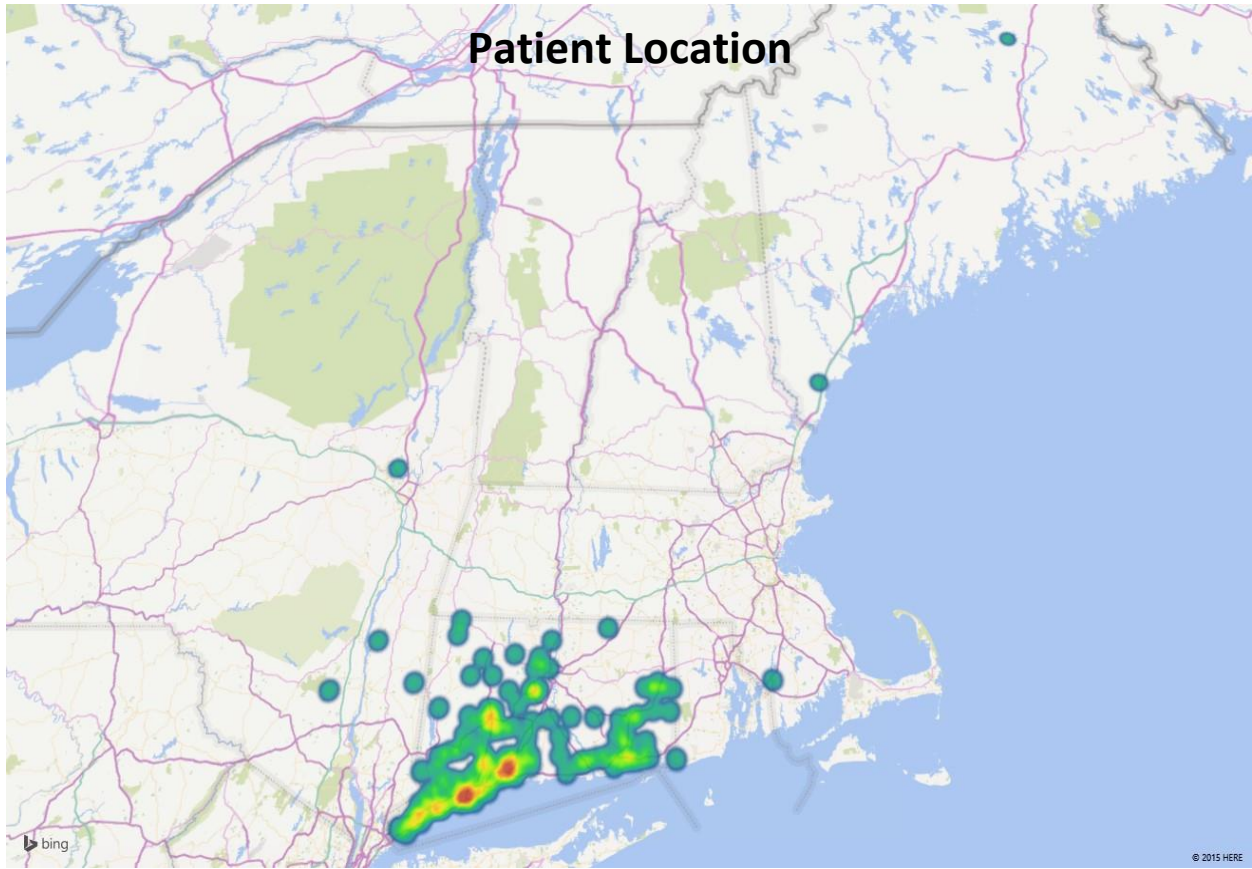


Gender Distribution

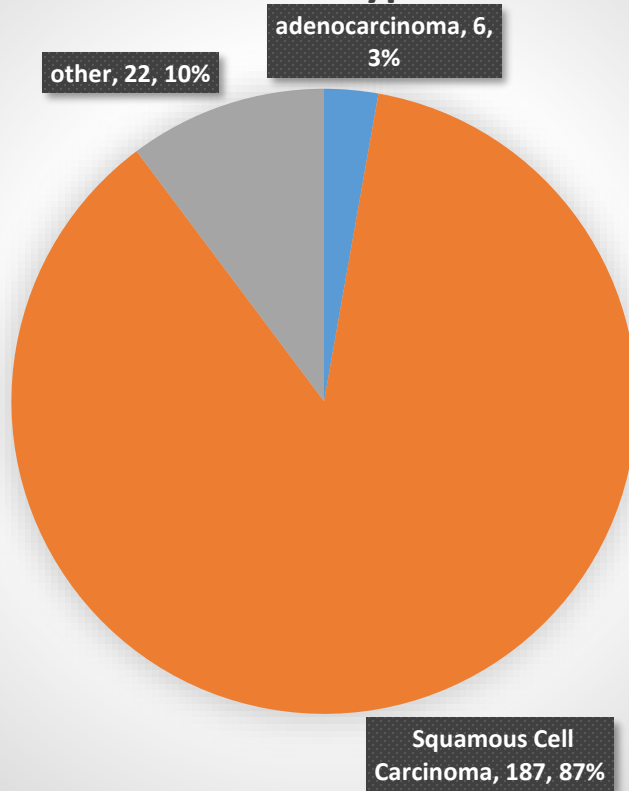


Patient Age-Sex Distribution

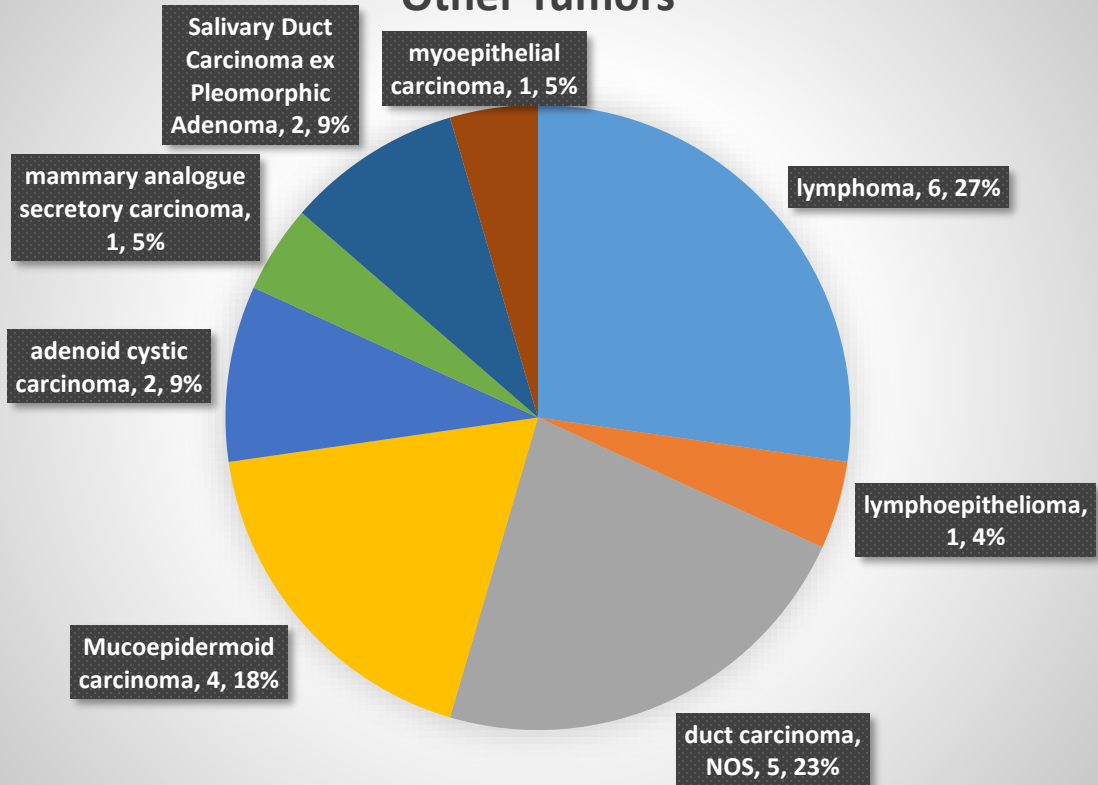




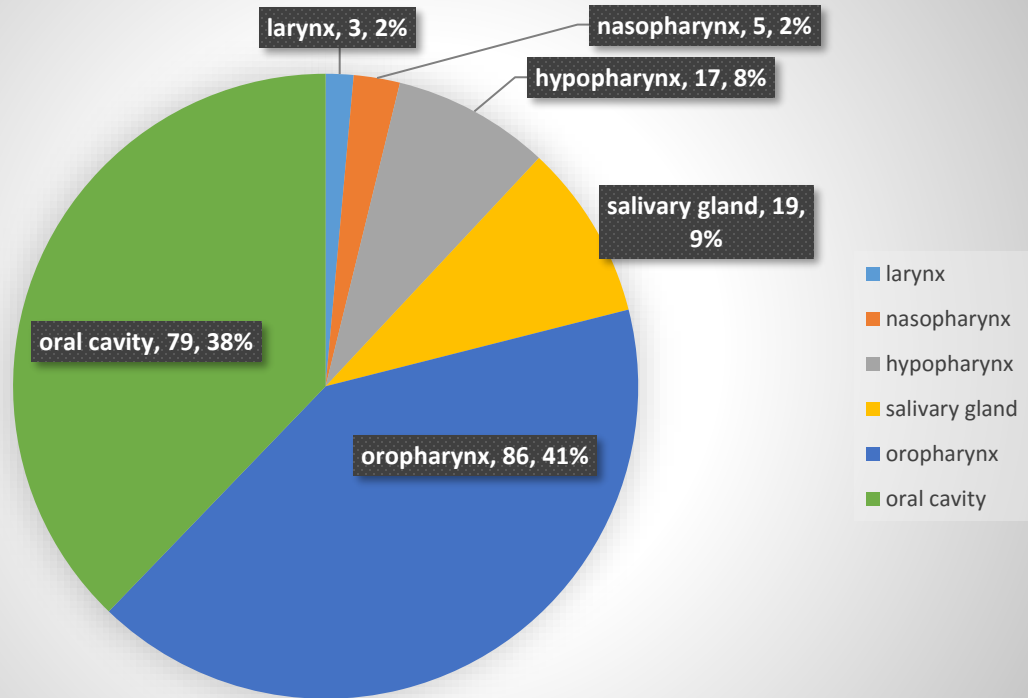
Cancer Types



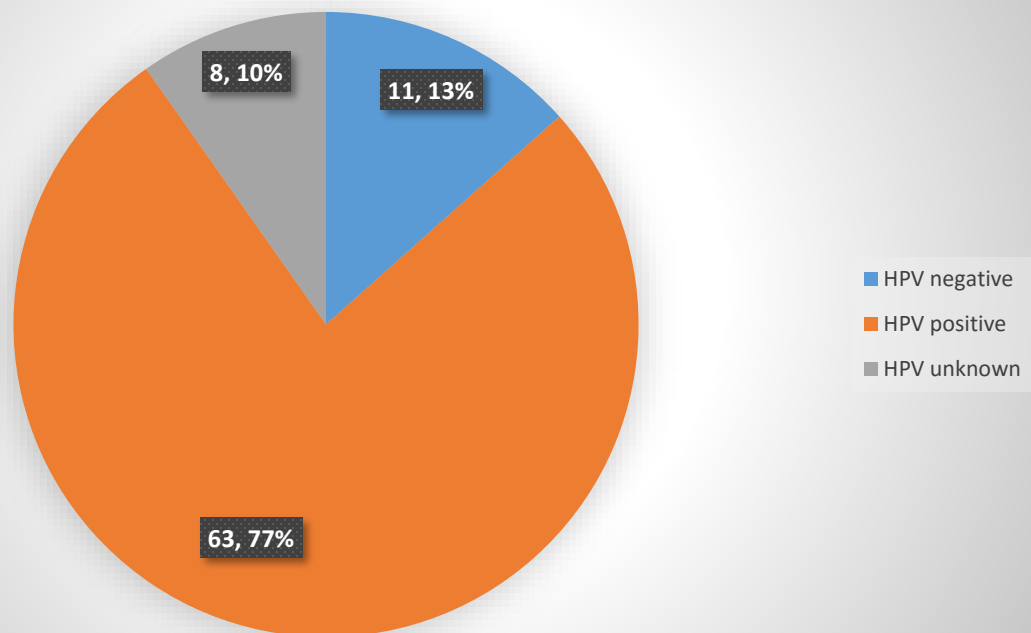
Other Tumors



Sites of Primary Tumor

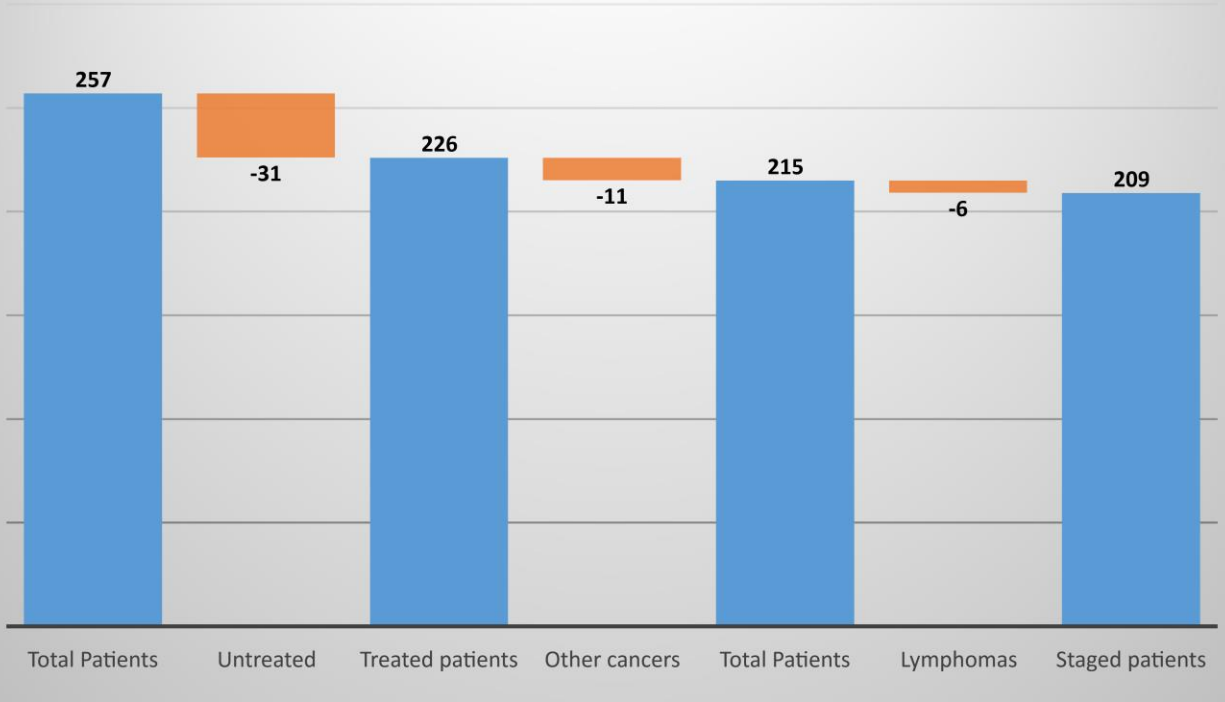


Oropharyngeal SCC HPV Status

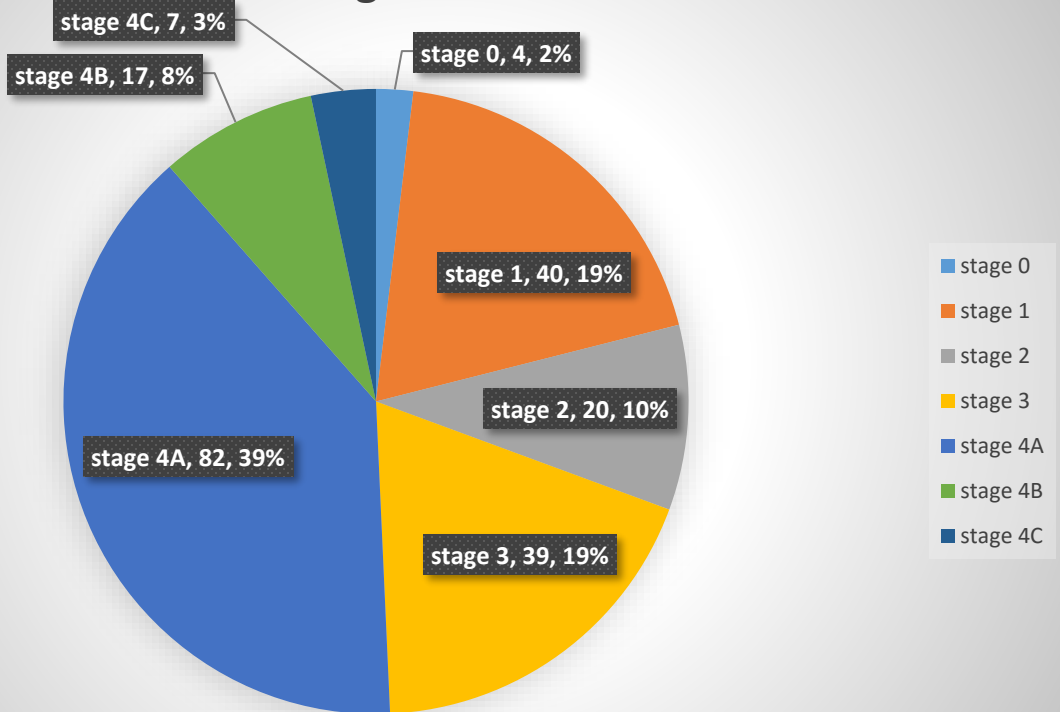


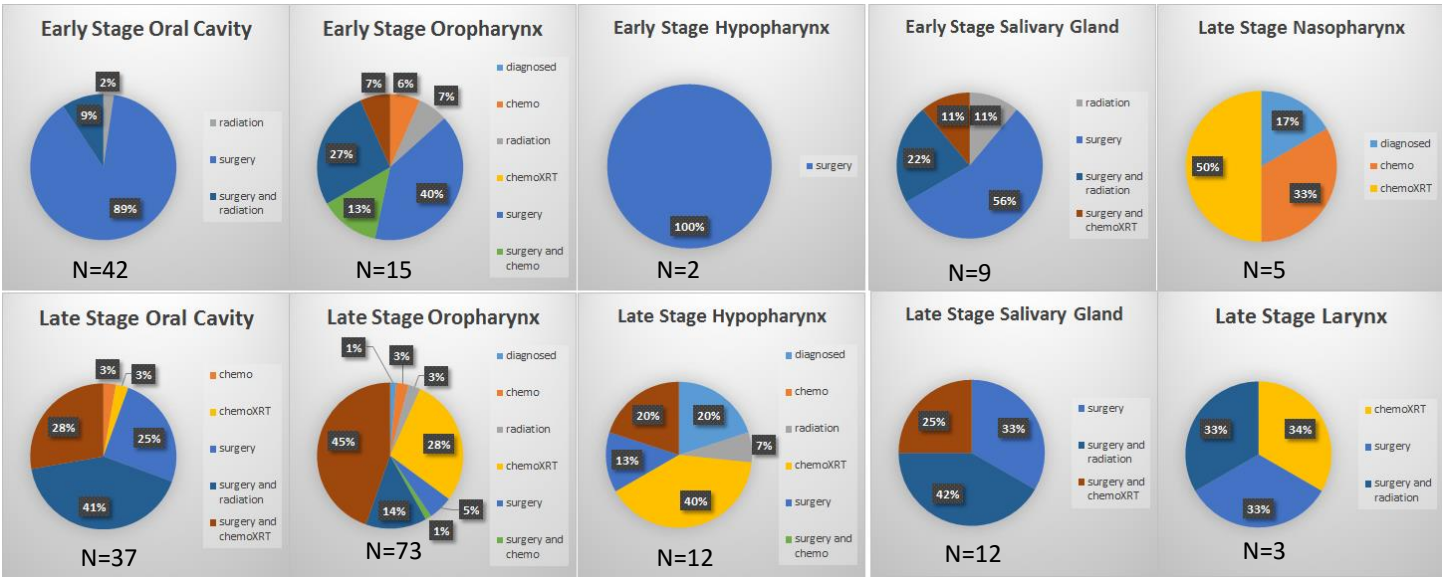
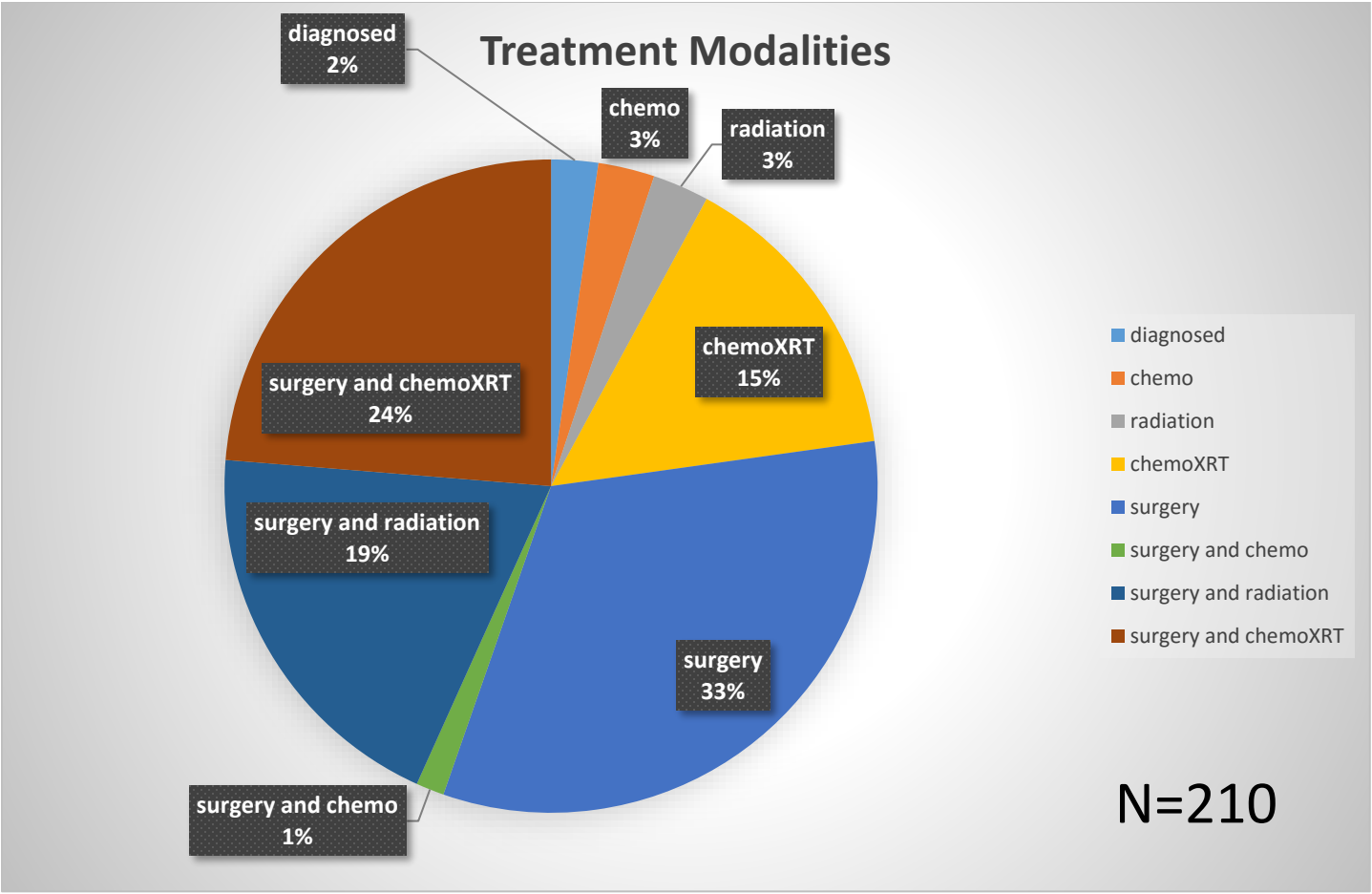
Staged Patients

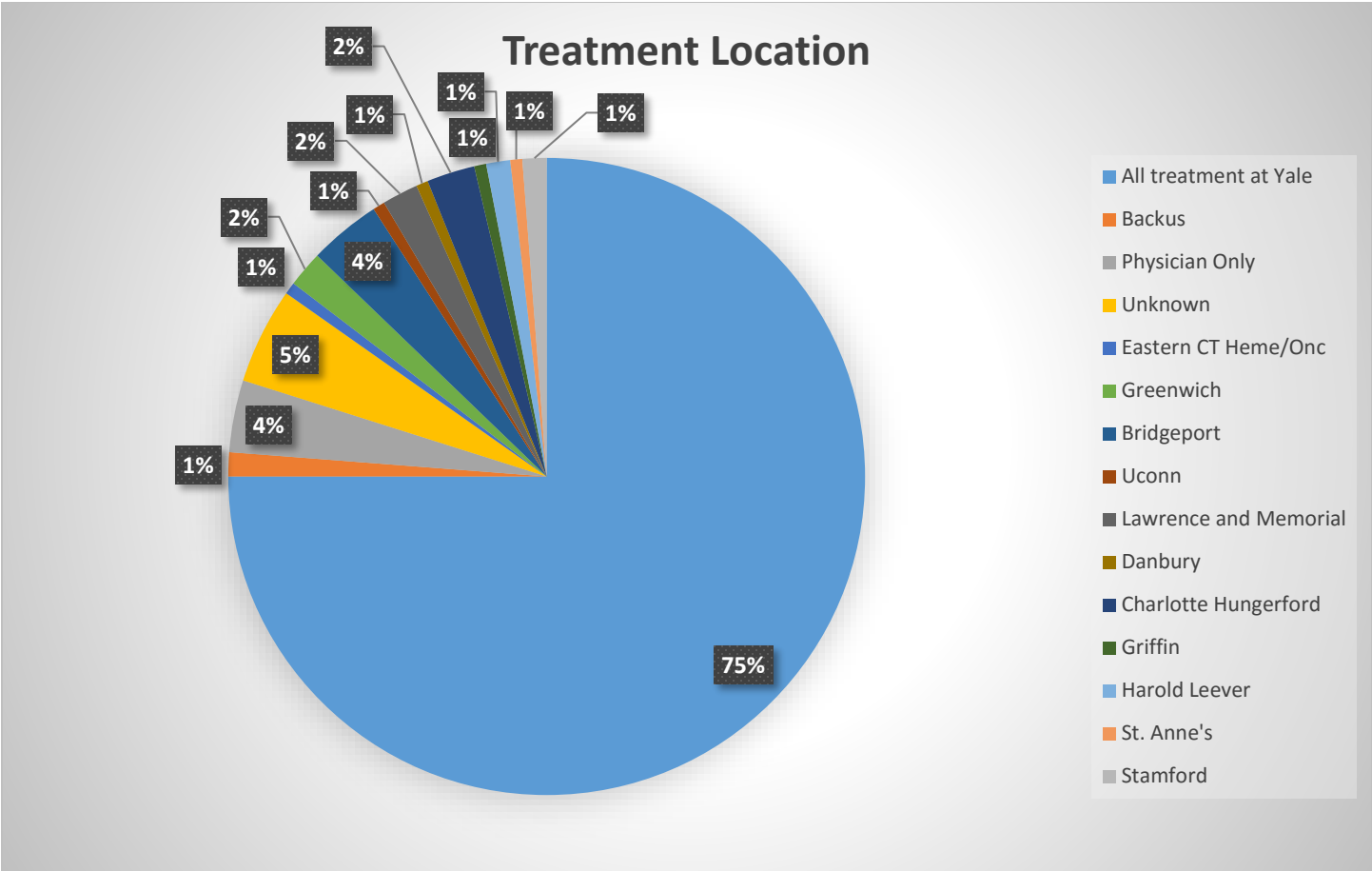
■ Increase ■ Decrease ■ Total



Stage of Cancer

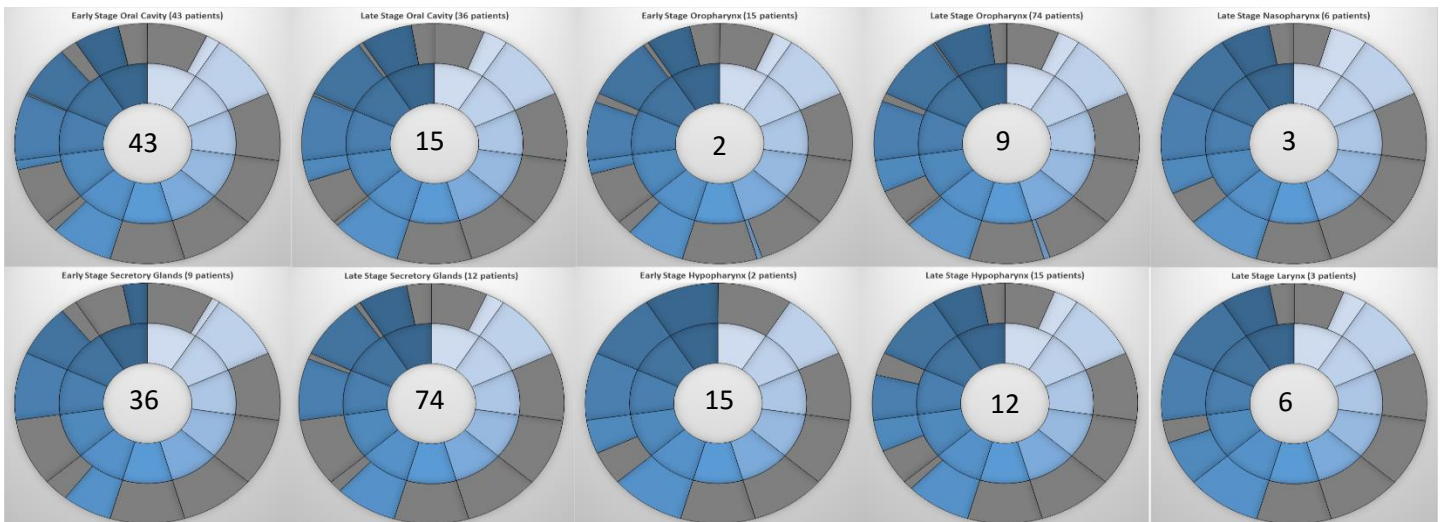
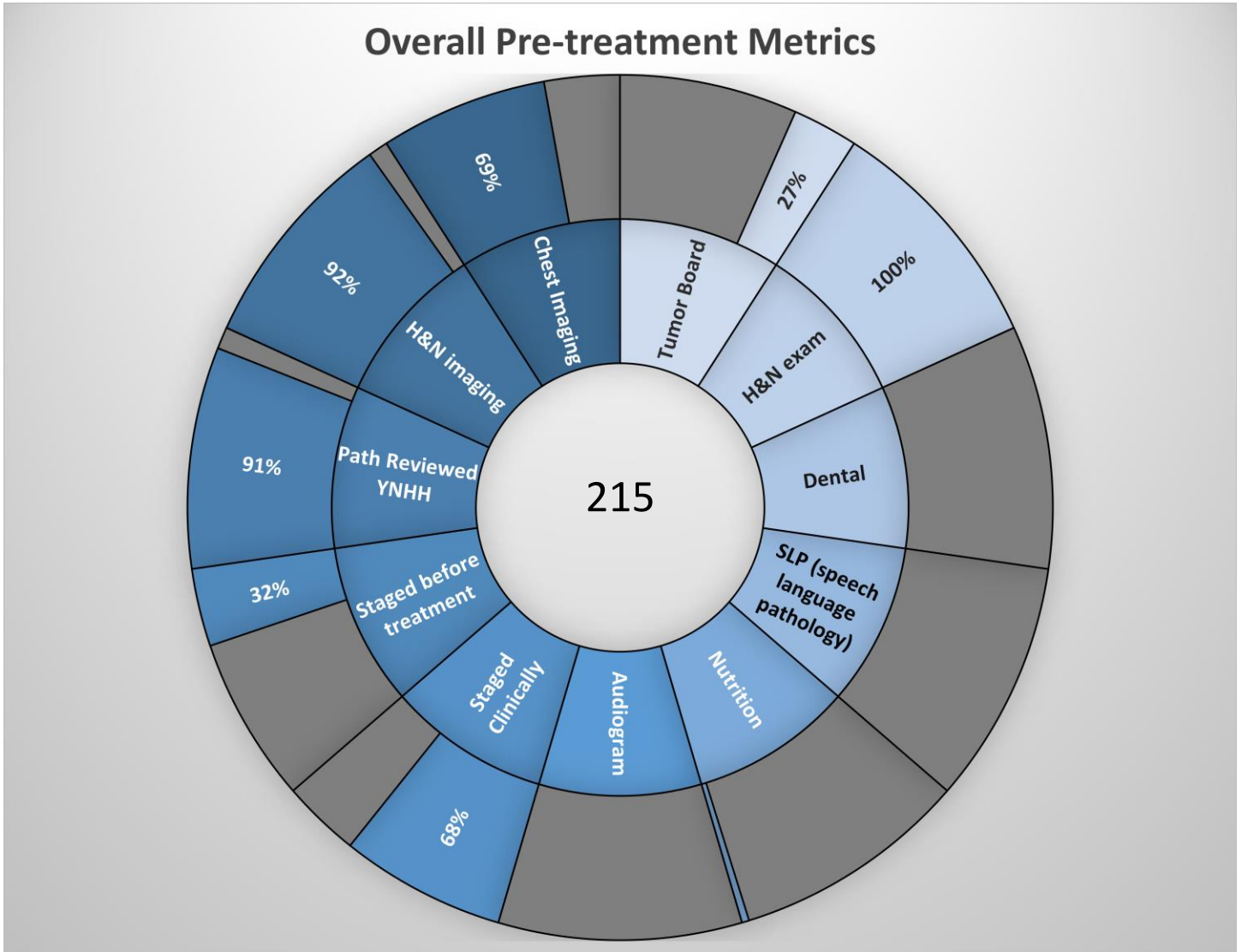


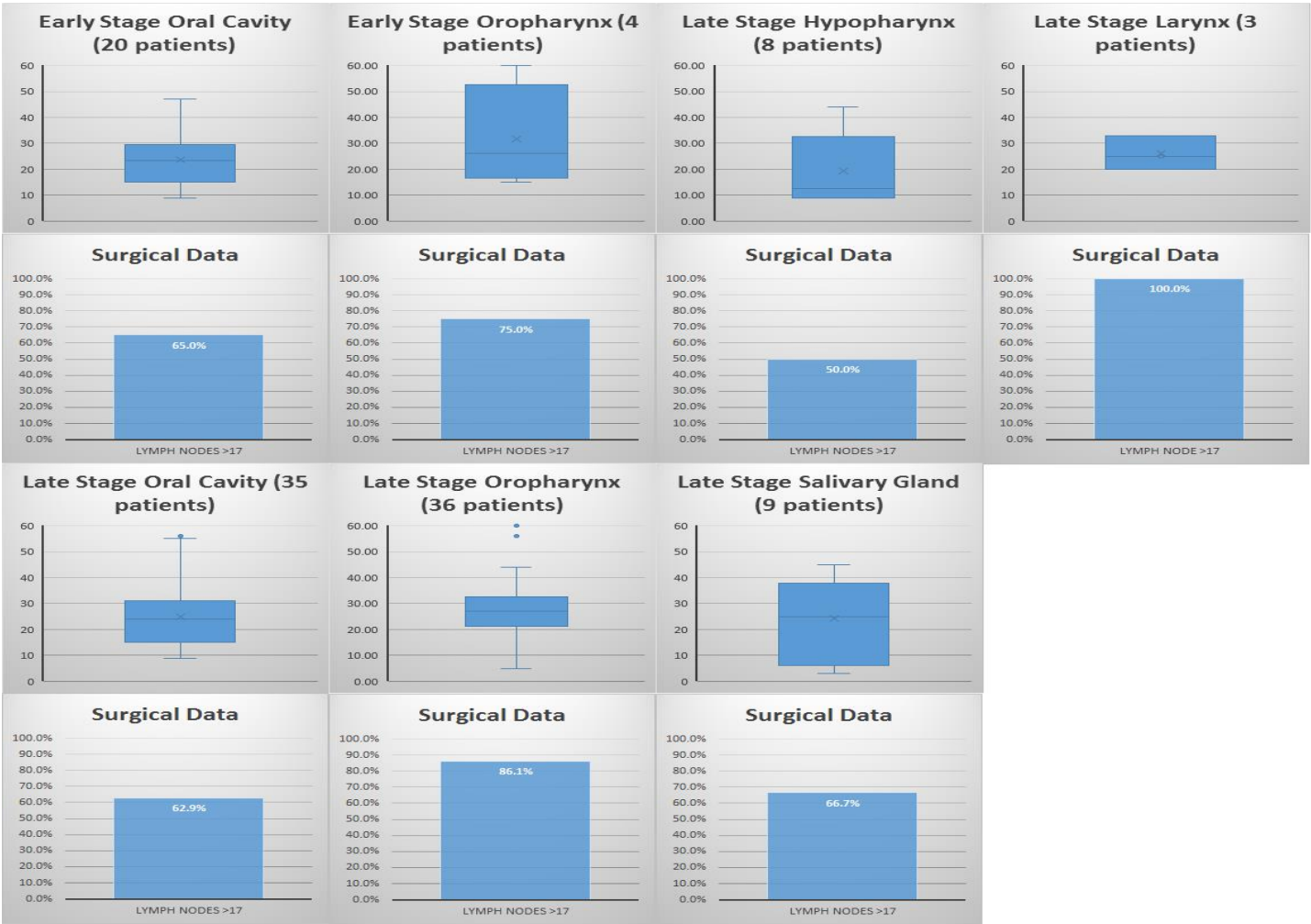
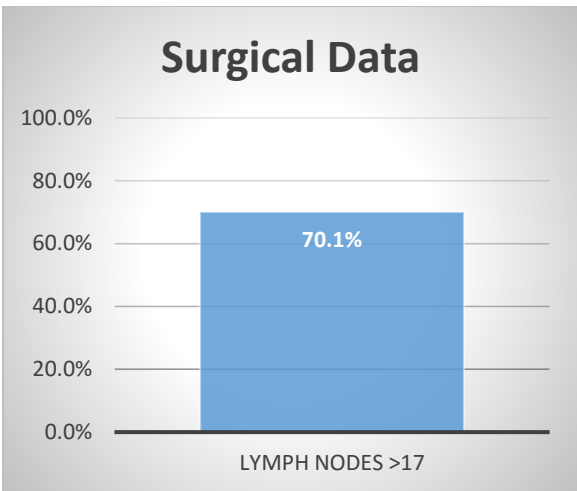
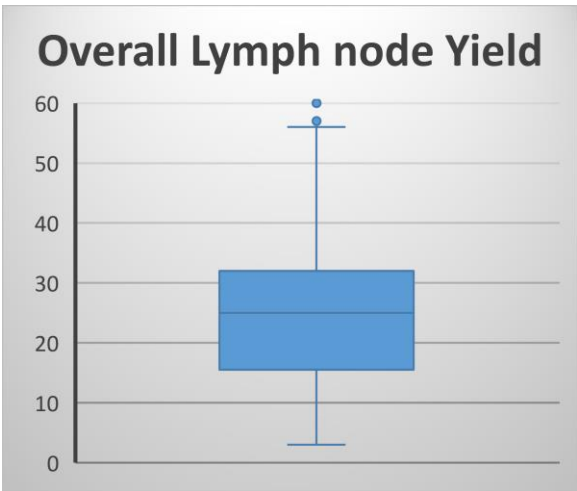




- Surgery at a YNHH hospital (164 patients)
- 123 received all subsequent treatment (including no further treatment) at YNHH
- 14 other sites locations for adjuvant therapy
- Site of chemotherapy chosen as primary site in cases where chemotherapy and radiation different

Part C: Process and Outcomes (Patient numbers listed in the middle of the graph)



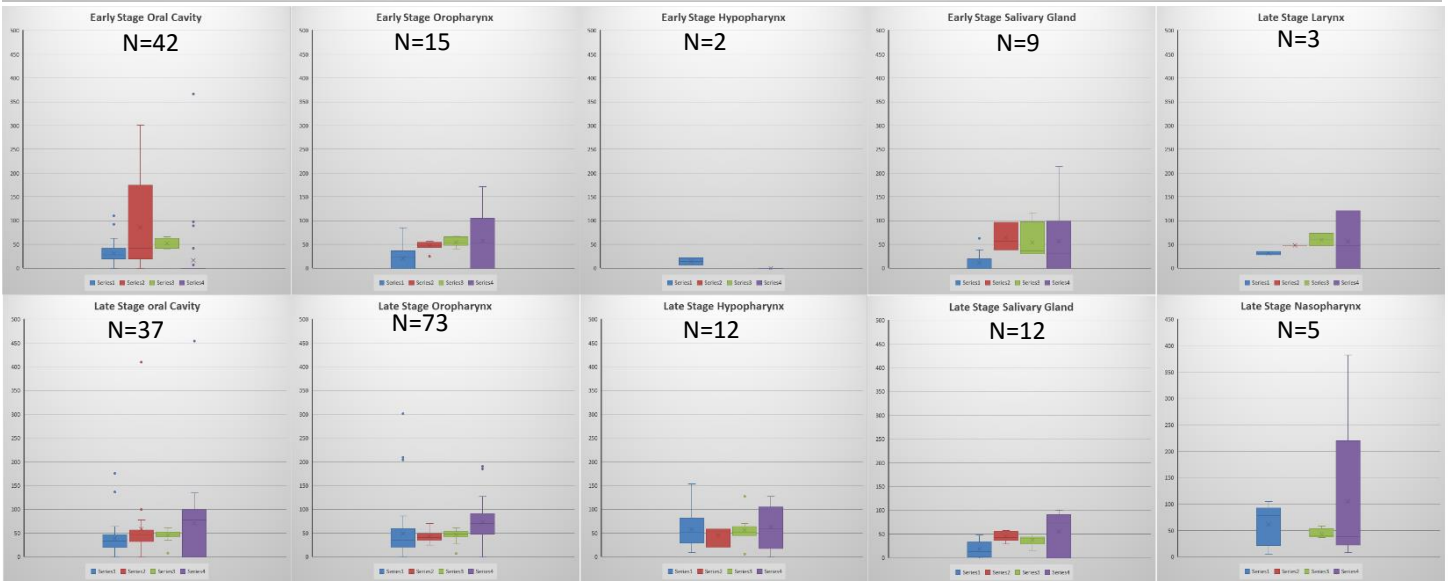
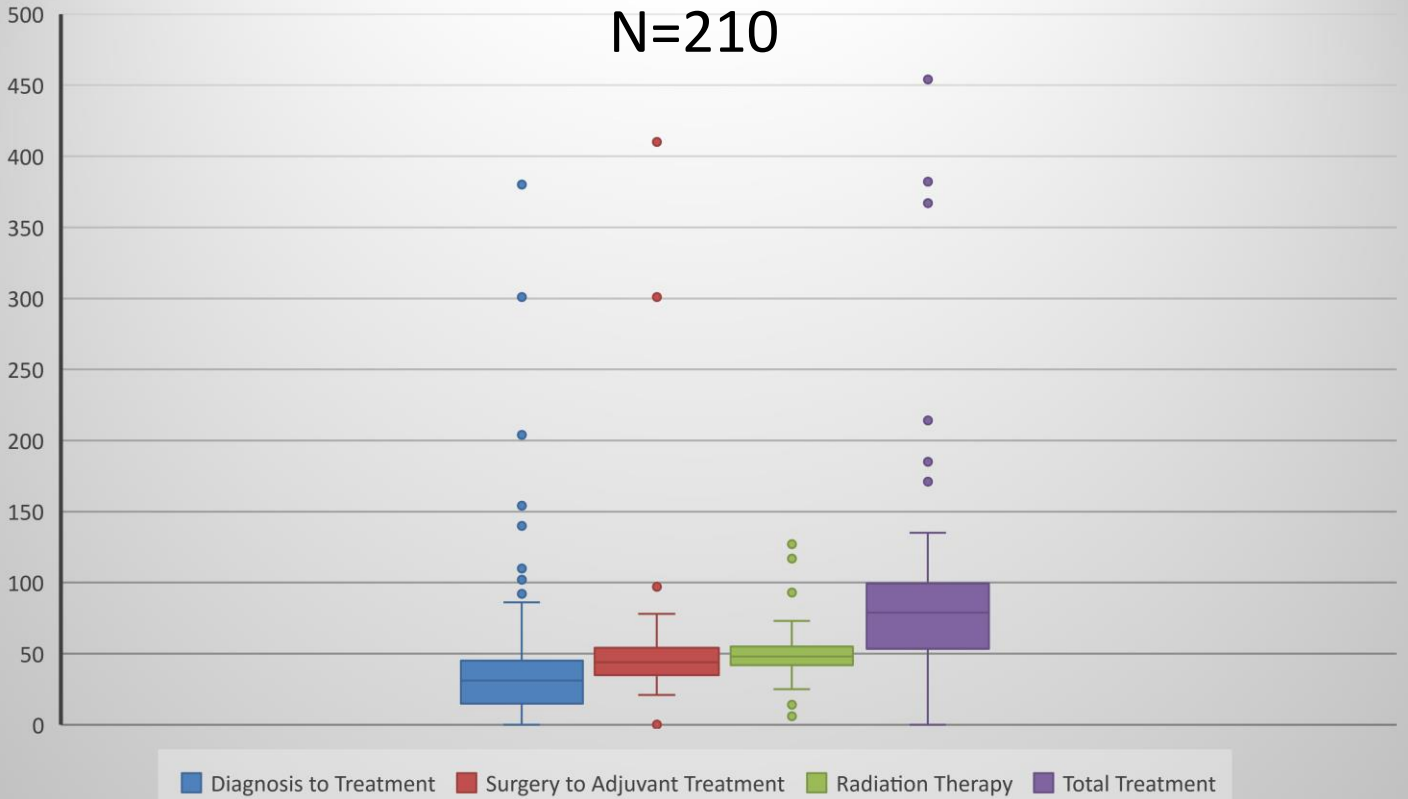


Surgical Data: Recent data from a large study done at Yale recommends that if elective neck dissection occurs, the patients who have more than 17 lymph nodes removed have a better outcome.

- 73 out of 102 patients had 18 or more nodes removed on one side
- 15 patients who had bilateral neck dissections
- Each side of the neck as a separate procedure, which brought our total neck dissections to 117
- 82 of those neck dissections had 18 or more nodes removed.

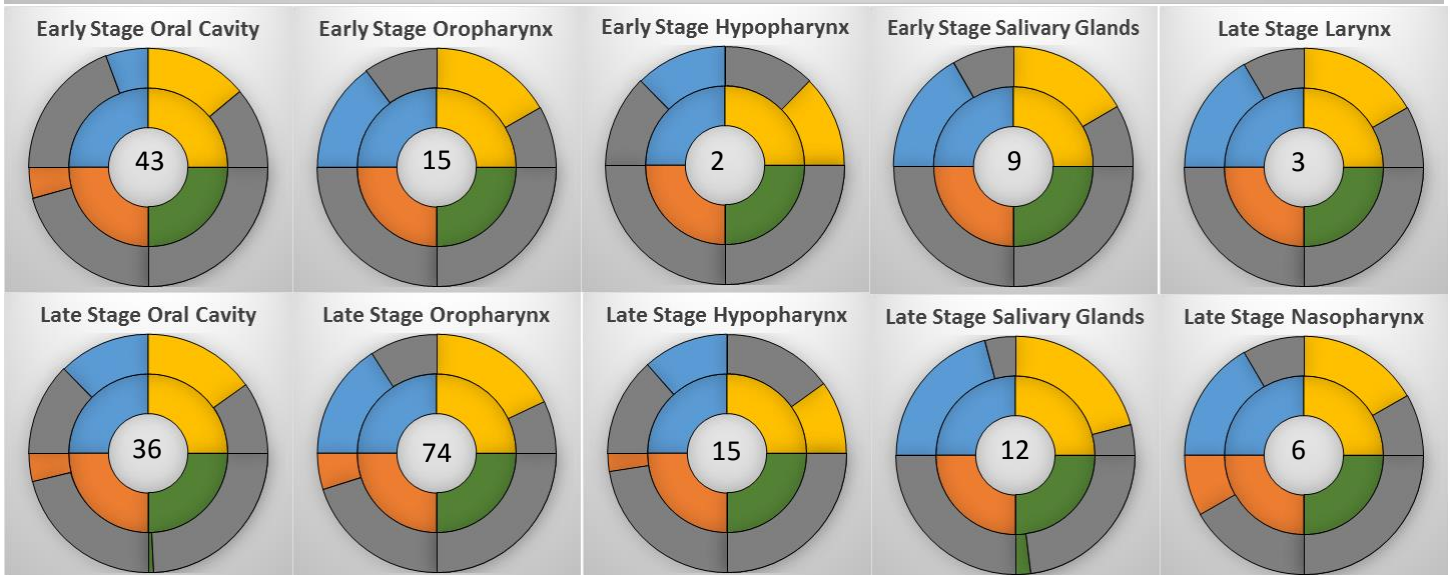
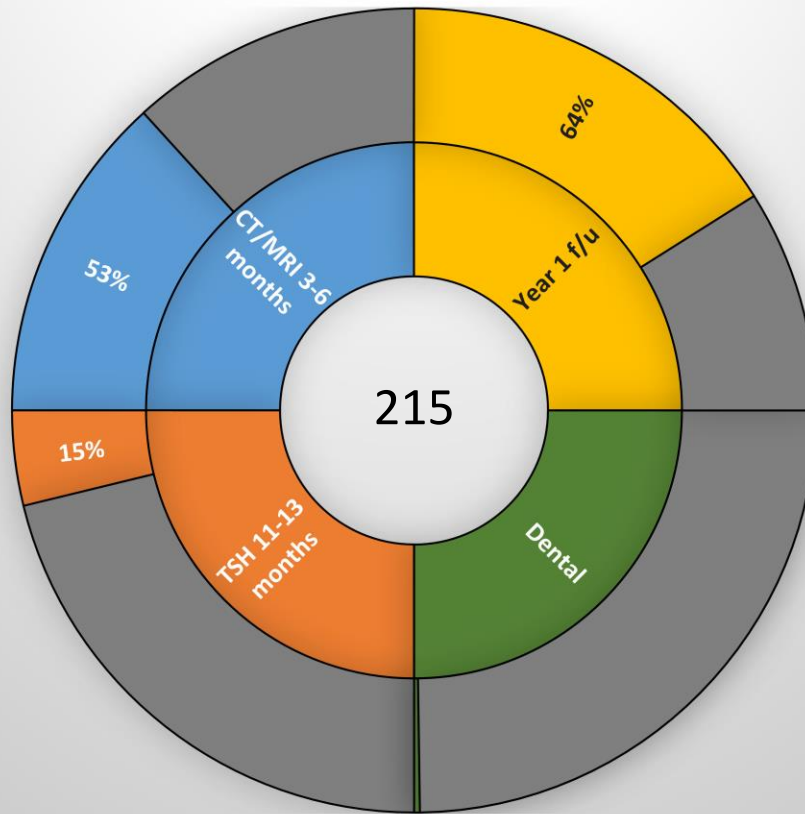
Times to Treatment

N=210



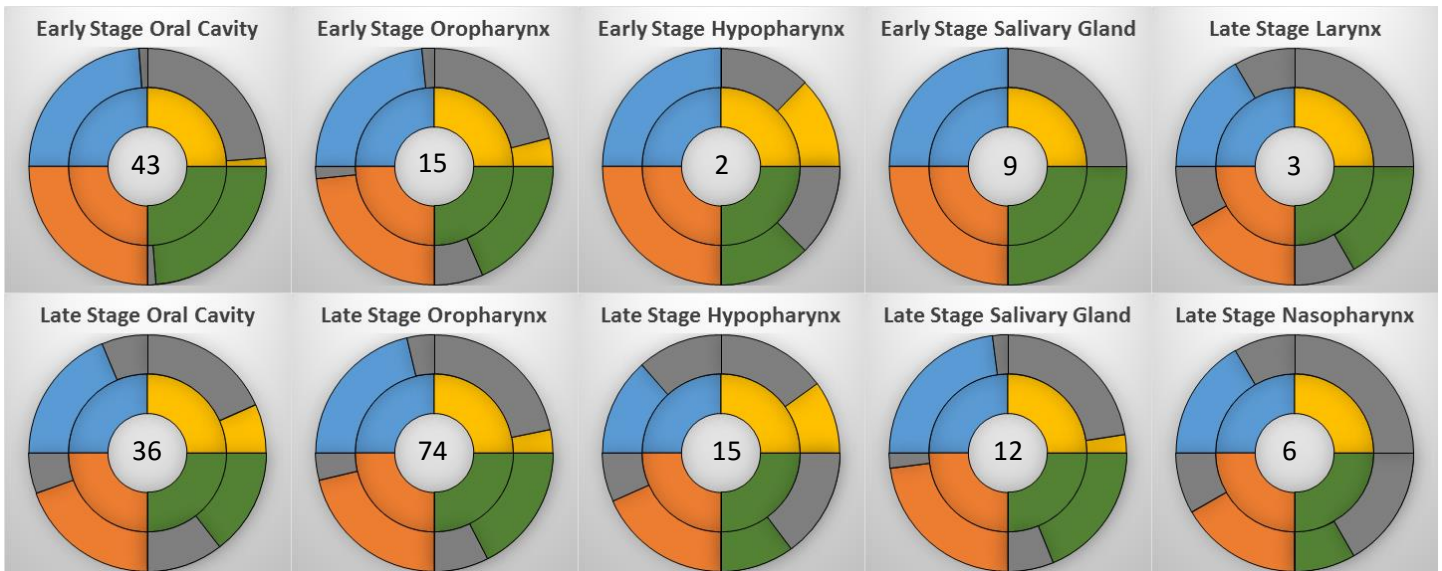
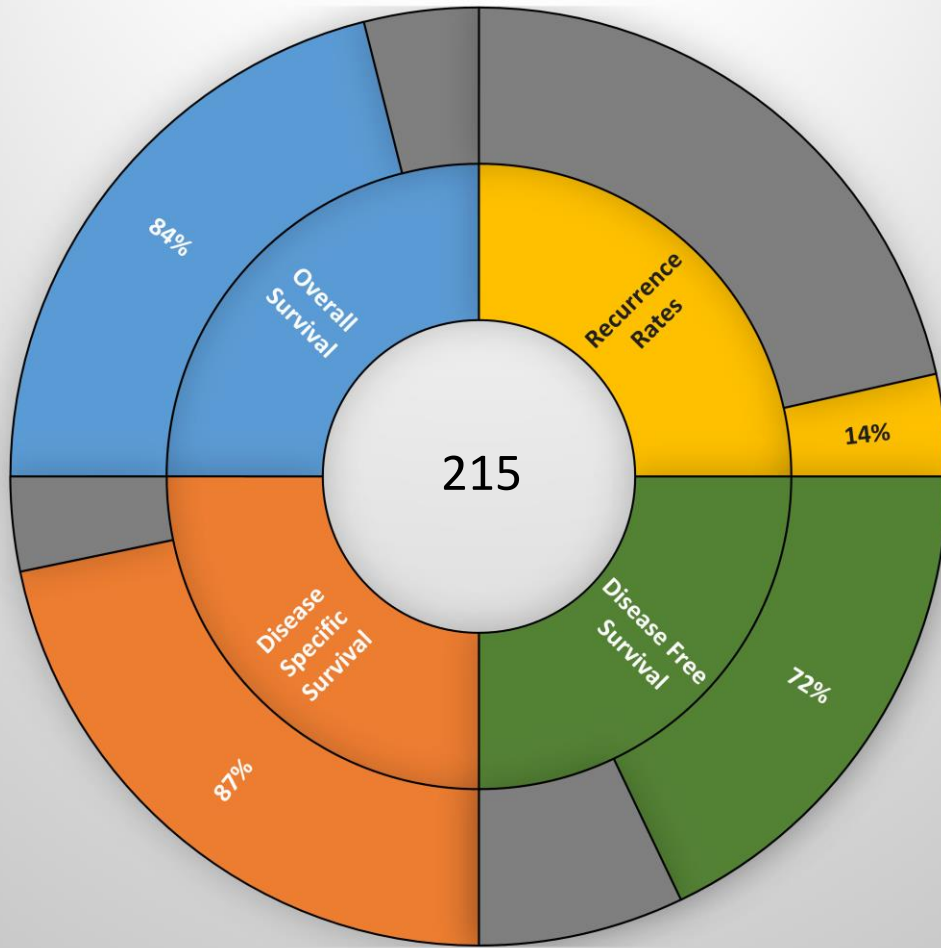
- 210 patients received treatment, the average length of time from diagnosis to treatment was 37 days.
- 93 patients who received adjuvant therapy after surgery. The average time from surgery to adjuvant therapy was 51 days.
- 130 patients who received radiation treatment. The average duration of treatment was 48 days.
- The average of the total duration of treatment was 85 days. Surgery only patients excluded from overall data, but due to early stage patients often only receiving surgery, they were not excluded from site and stage data.

One Year Follow-Up



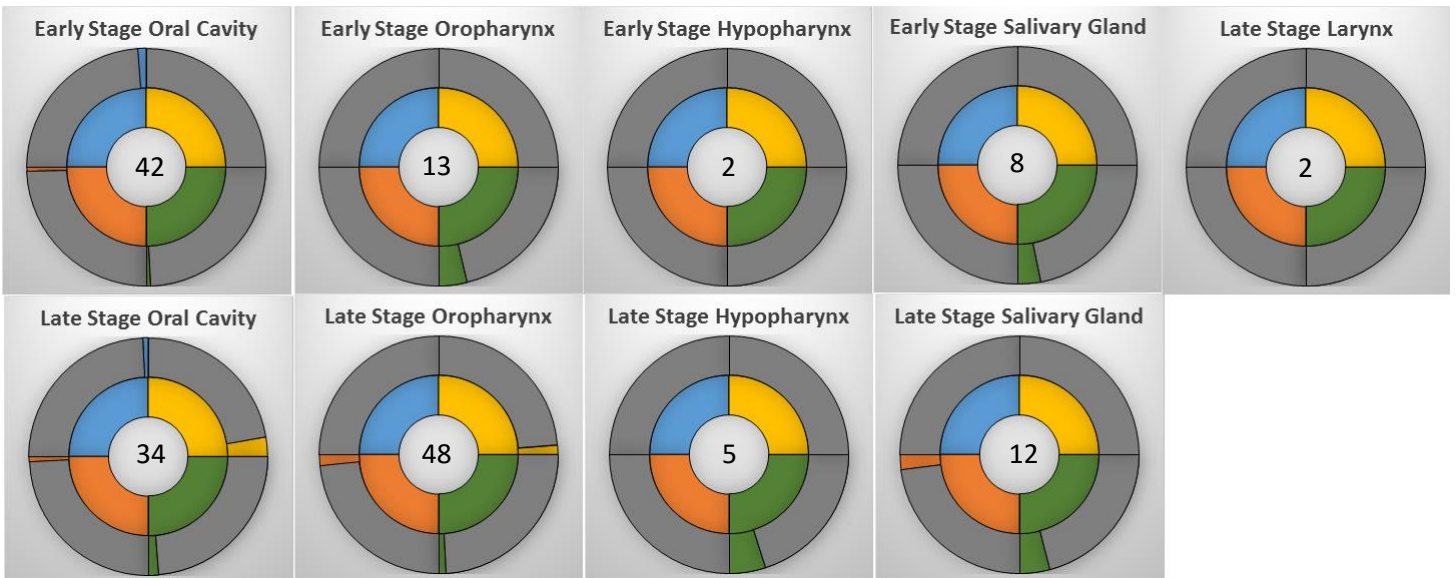
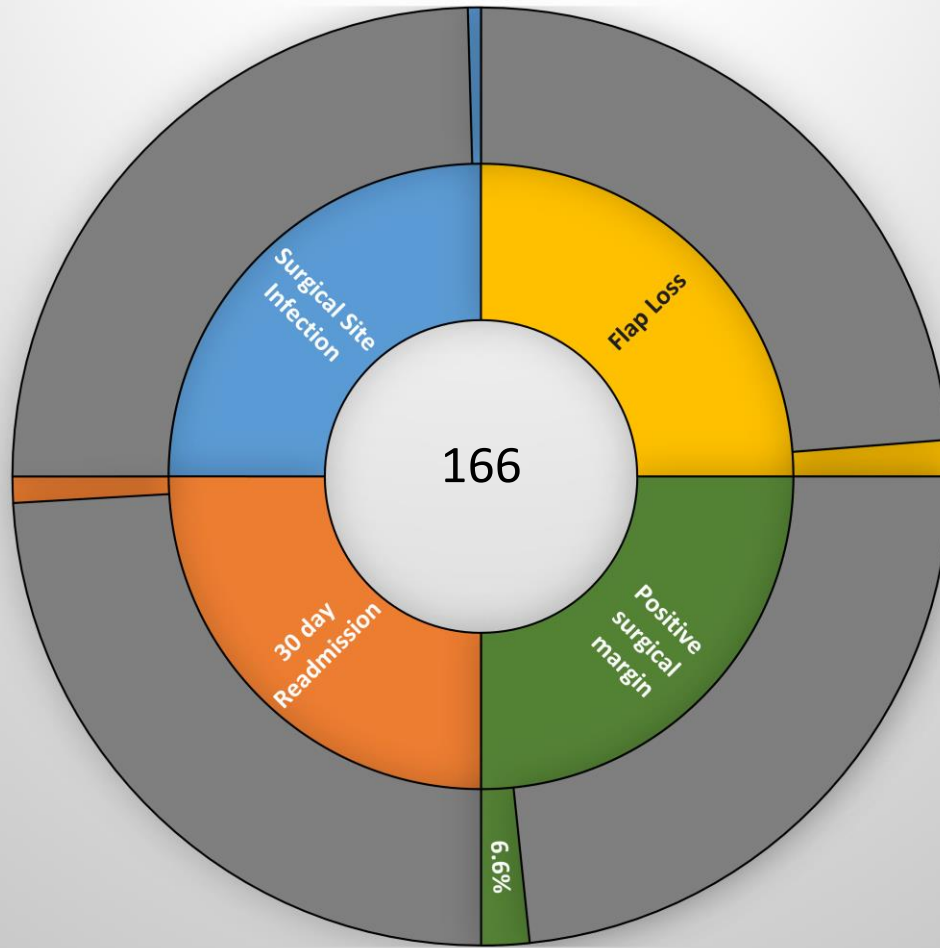
- AAHNS guidelines recommends that all patients receive a CT or MRI of their head and neck between 3 and 6 months after the conclusion of their treatment.
- It is also recommended that patients who underwent radiation therapy receive a TSH screening 11-13 after the conclusion of their treatment. In 2013, there were 131 patients who had radiation therapy.
- Patients are also at risk of dental issues after treatment, with dental follow-up recommended.
- Appropriate follow-up after 1 year defined as at least 3 visits at least 2 months apart.

Survival and Recurrence Rates



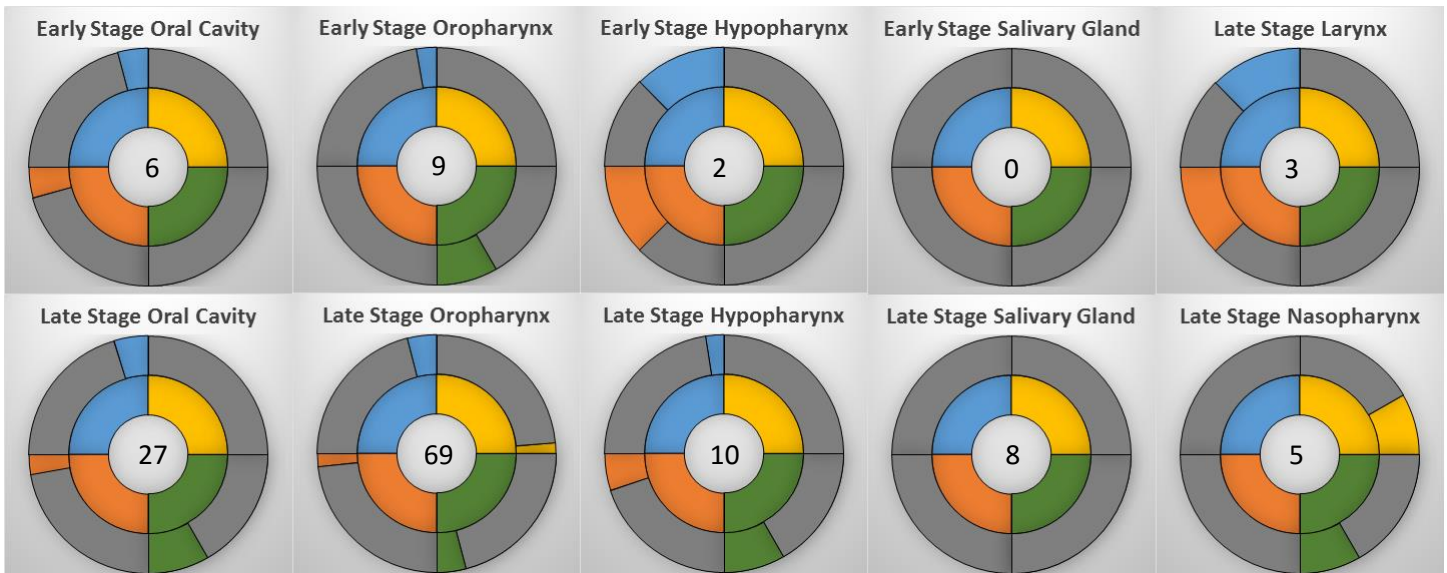
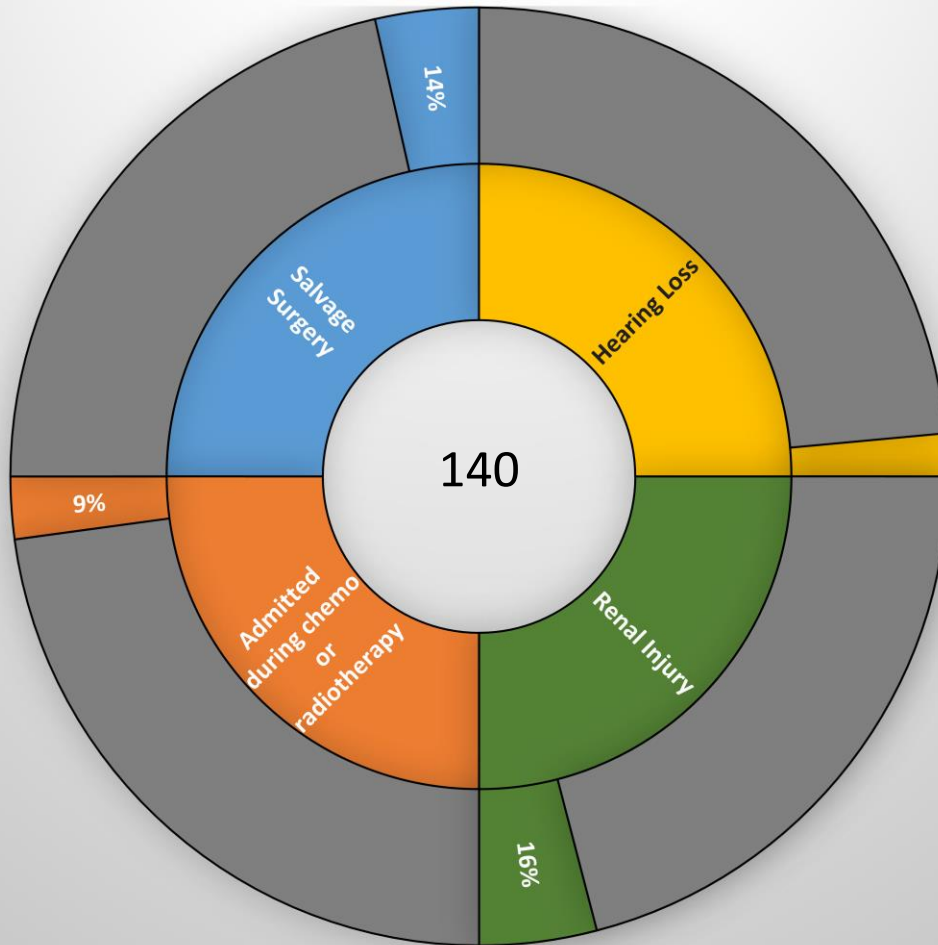
- 26 patients had a tumor recurrence, with 13 having local recurrence, 11 with regional recurrence, and 10 with distant recurrence (several patients were noted to have recurrence in multiple sites).
- 31 cases of progressive cancer.

Surgical Complications



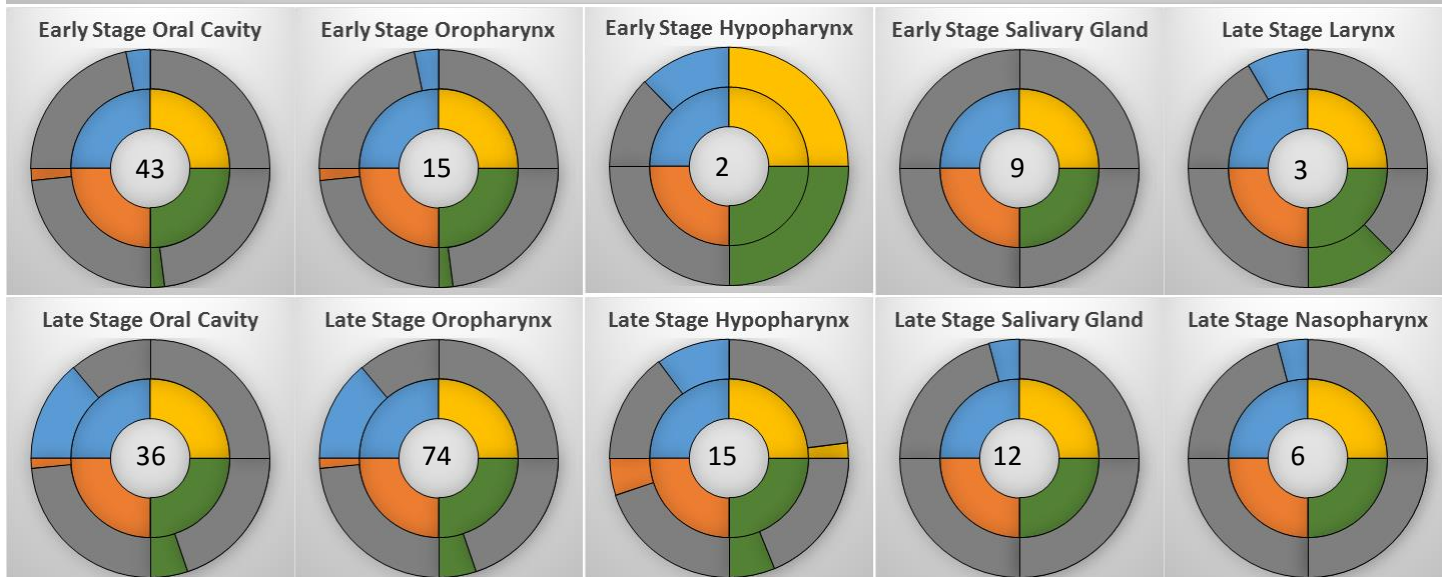
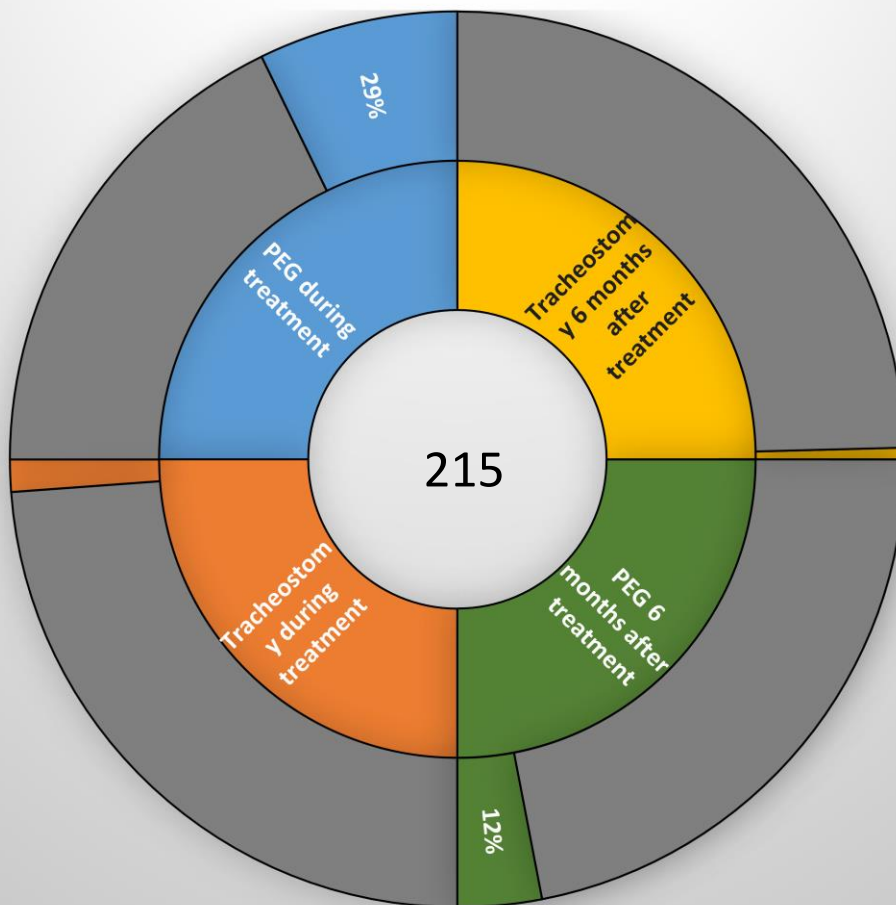
- 6 patients had to be readmitted within 30 days after surgery.
- 1 patient with a surgical site infection.
- 2 patients who had a flap-loss out of 40 patients.

Chemotherapy and Radiation Therapy Complications



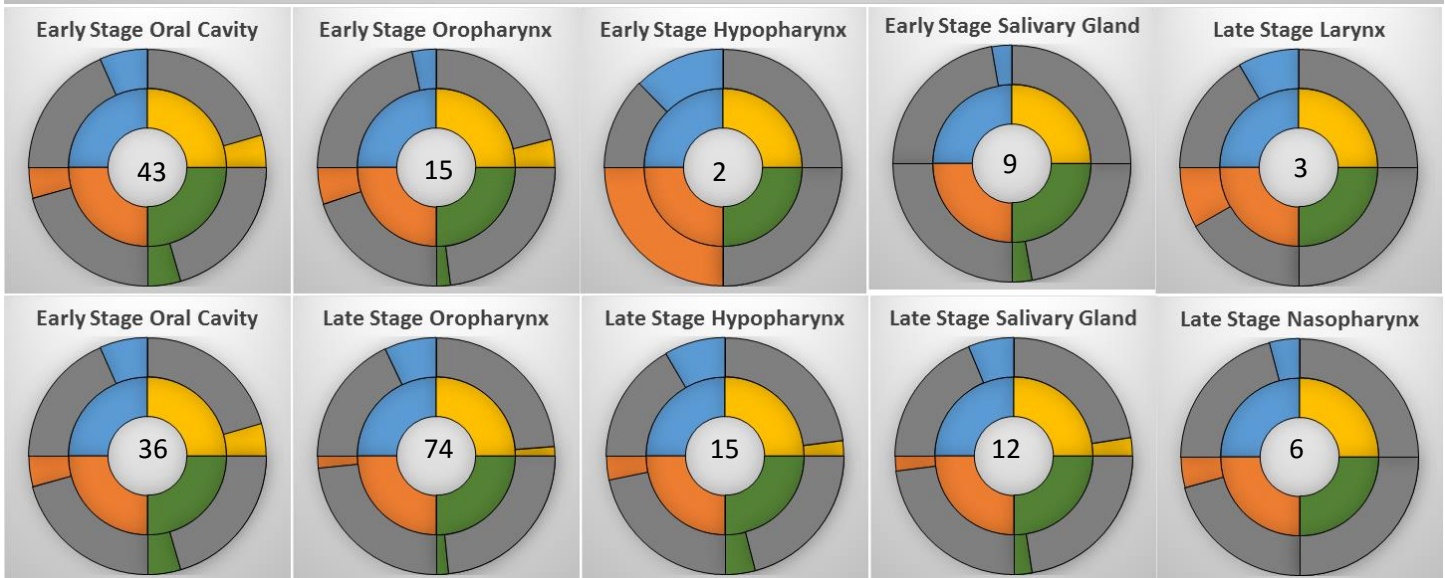
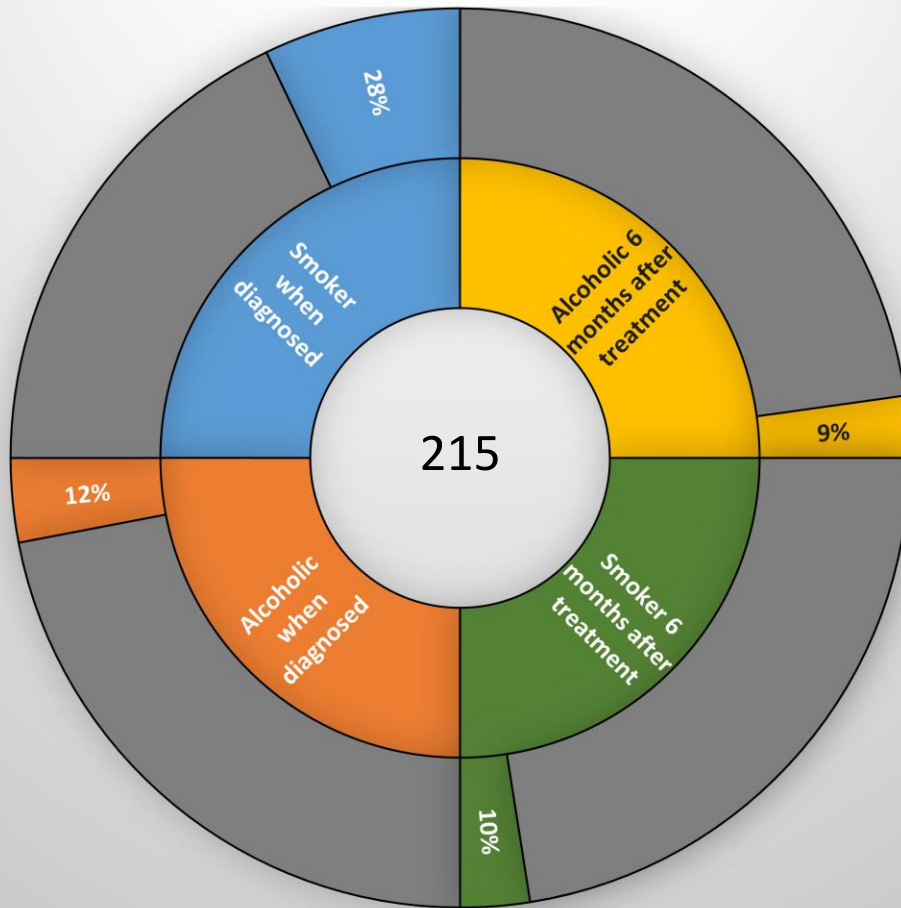
- 88 patients who received cisplatin based chemotherapy, and were included when assessing renal damage or hearing loss

Functioning



- 62 patients had a percutaneous endoscopic gastrostomy (PEG) tube
- 10 patients had a tracheostomy during treatment. Any patients who received a tracheostomy during surgery that was removed before discharge were not counted.
- 24 patients had a PEG 6 months after treatment
- 4 patients had a tracheostomy 6 months after treatment

Patient Habits



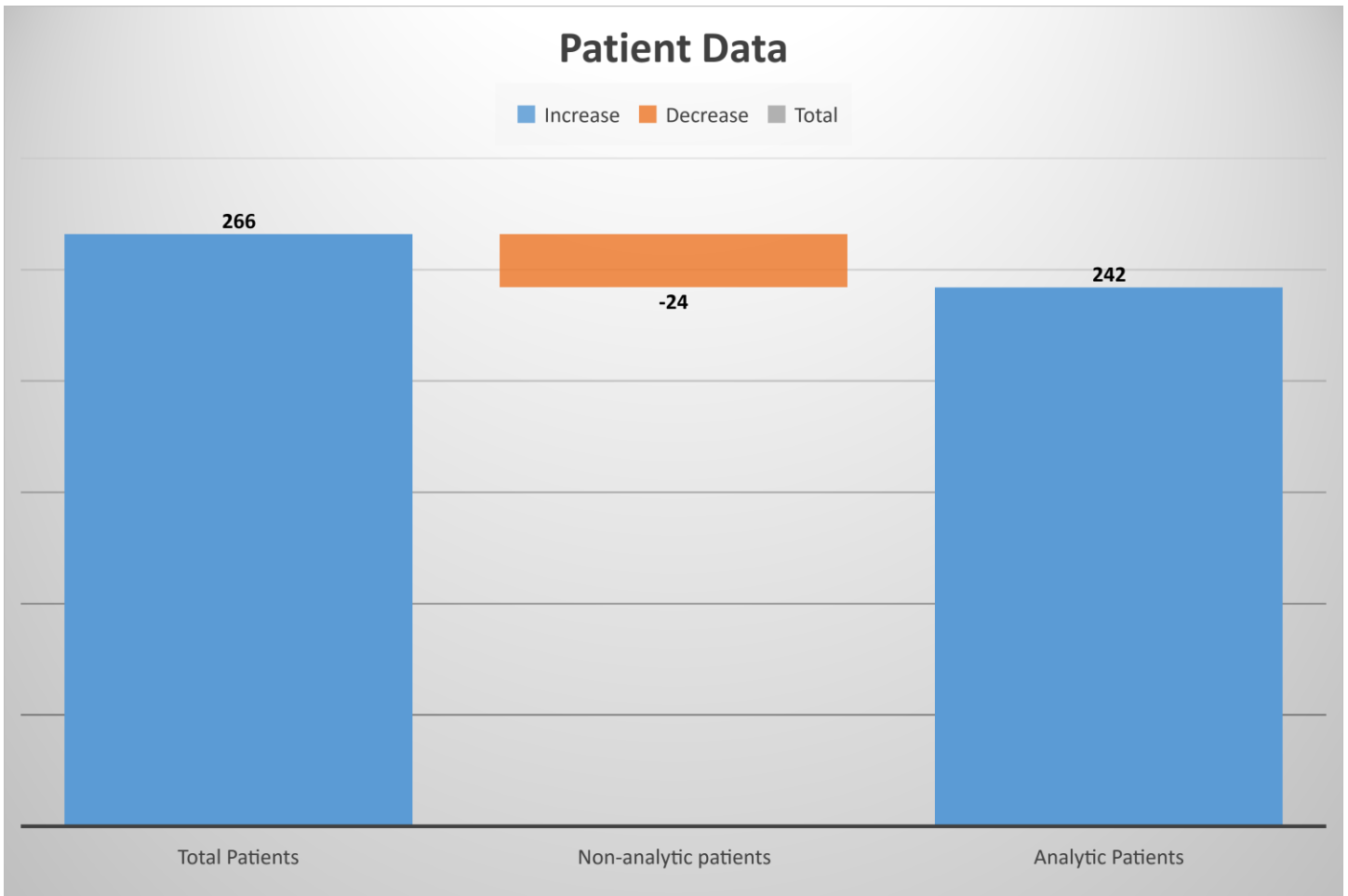
- 61 patients were smokers at diagnosis
- 26 patients were alcoholics at diagnosis
- 19 patients were smokers 6 months after treatment conclusion
- 16 patients were alcoholics 6 months after treatment conclusion

2014 Smilow – Yale New Haven Health Systems Head and Neck Outcomes Book

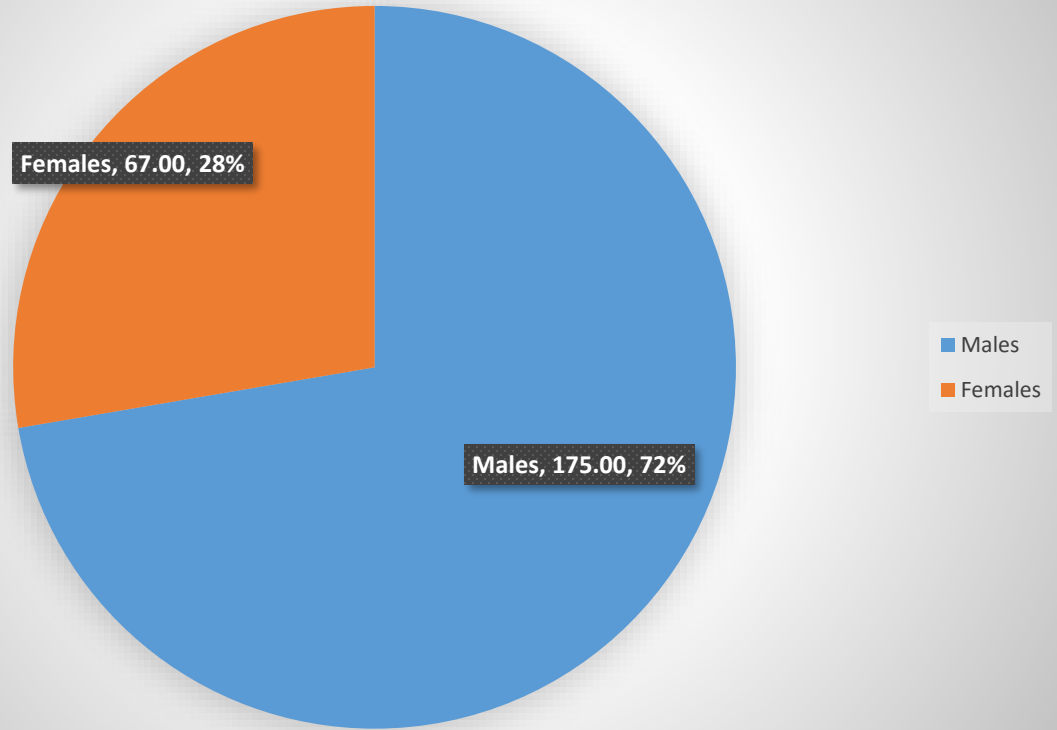


Part B: Structural Metrics

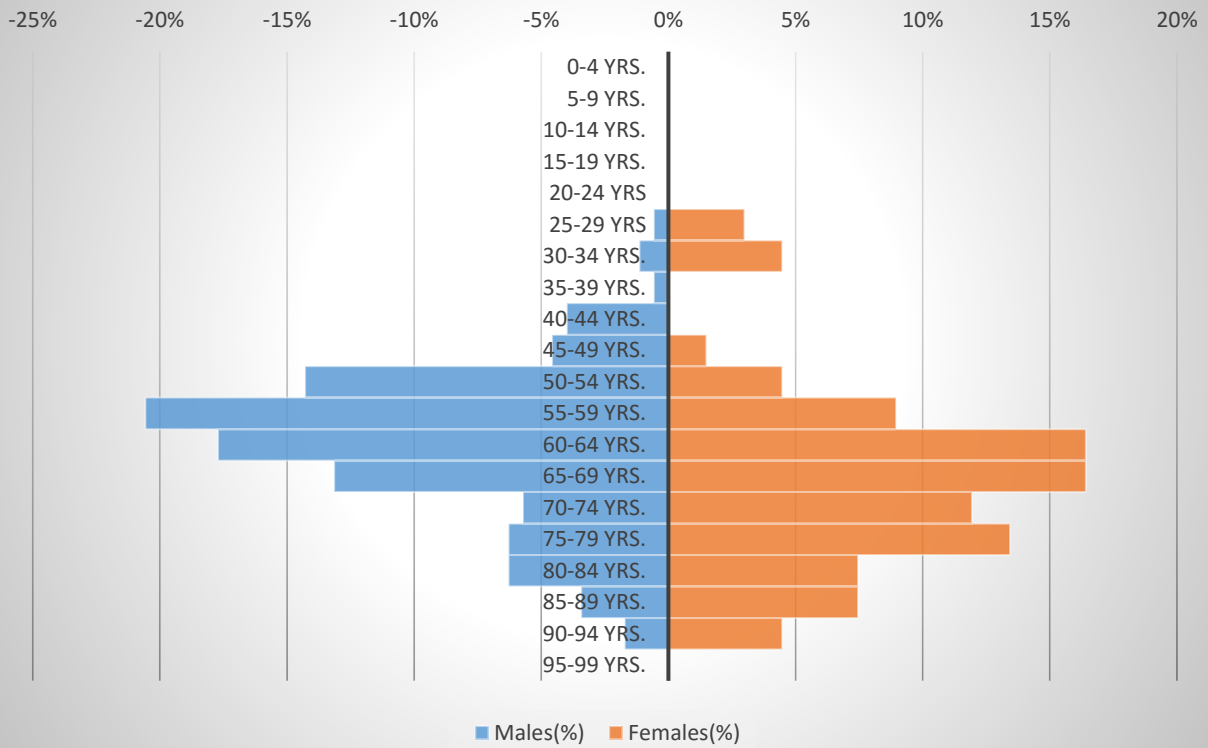
- 242 patients analyzed throughout the Yale-New Haven Hospital system
 - patients who received their diagnosis and/or their initial treatment at a Yale-New Haven Hospital affiliate
 - patients were weeded out if there was no information found in the electronic medical record, EPIC
- 19 hospitals included
 - YNHH System hospitals: Yale-New Haven, St. Raphael's, or Bridgeport Hospital, all of which are under the YNHH system
 - Other hospitals: West Haven Veteran's Affairs hospital, Lawrence and Memorial, Danbury Hospital, Charlotte Hungerford Hospital, St. Francis Hospital, Backus Hospital, Harold Leever National Cancer Center, Griffin Hospital, and St. Vincent's Hospital.

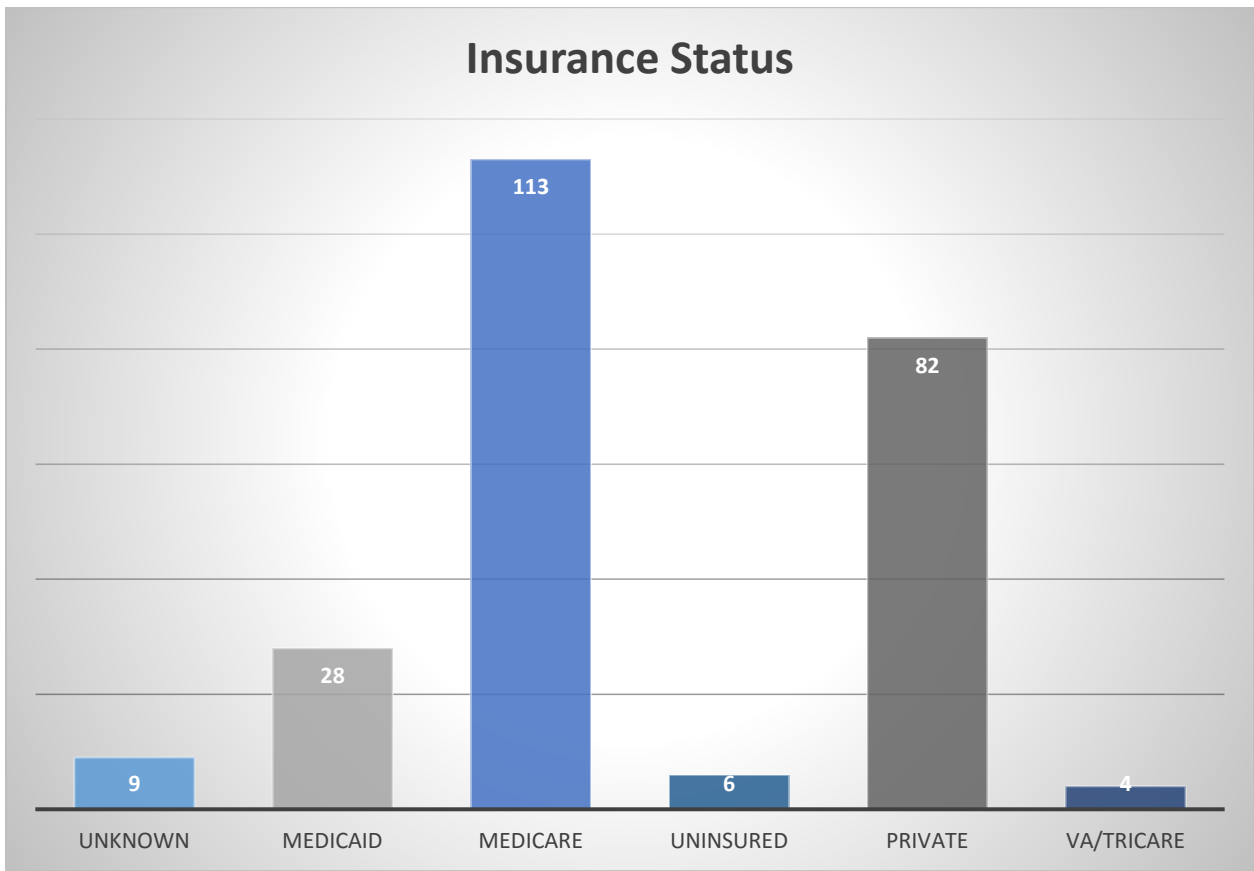
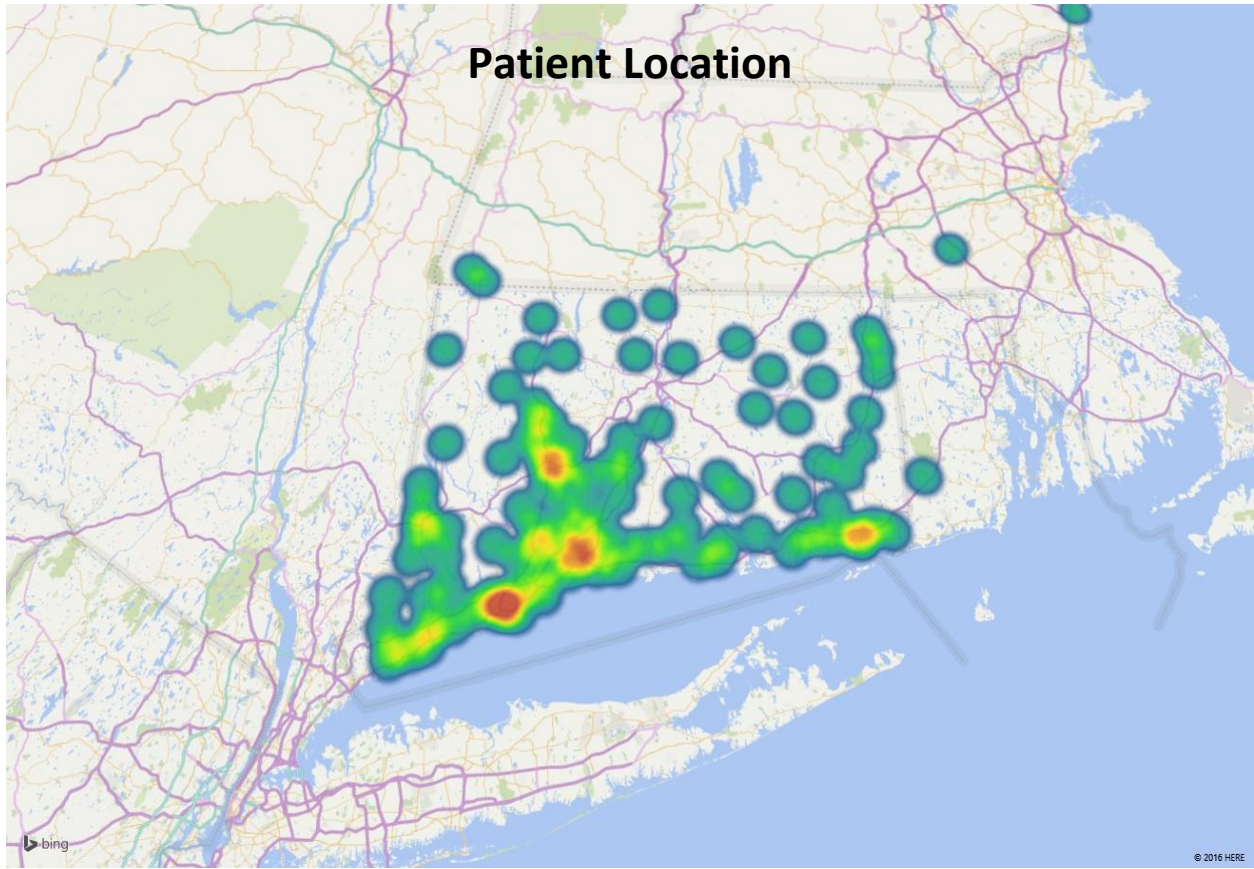


Gender Distribution

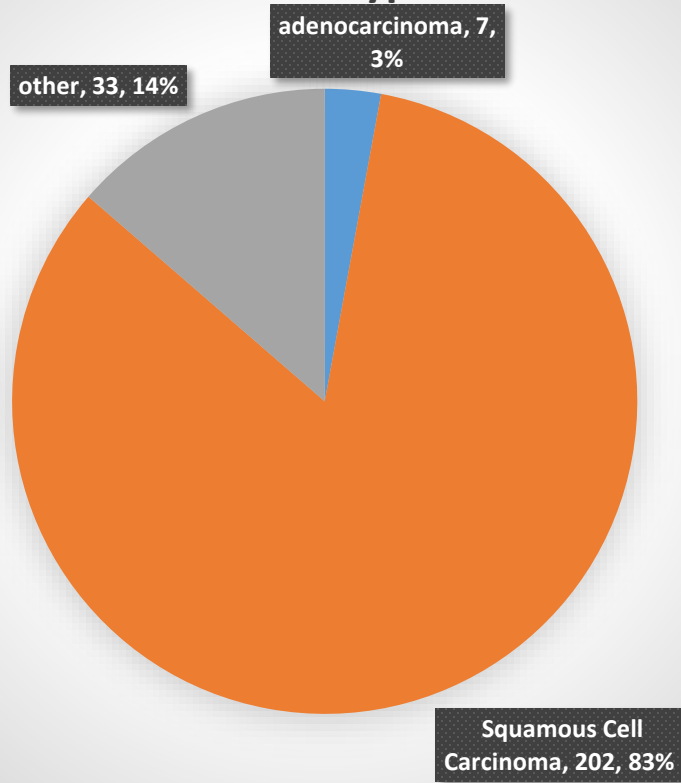


Patient Age-Sex Distribution

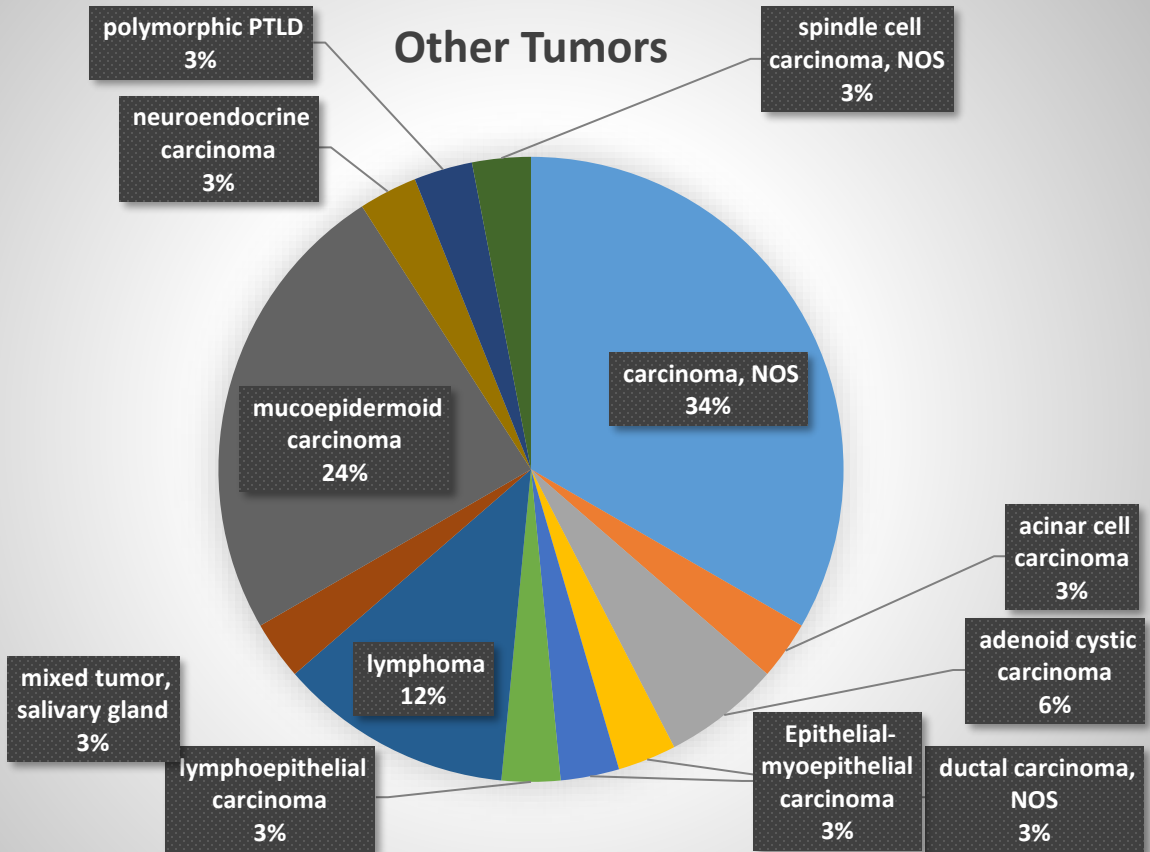


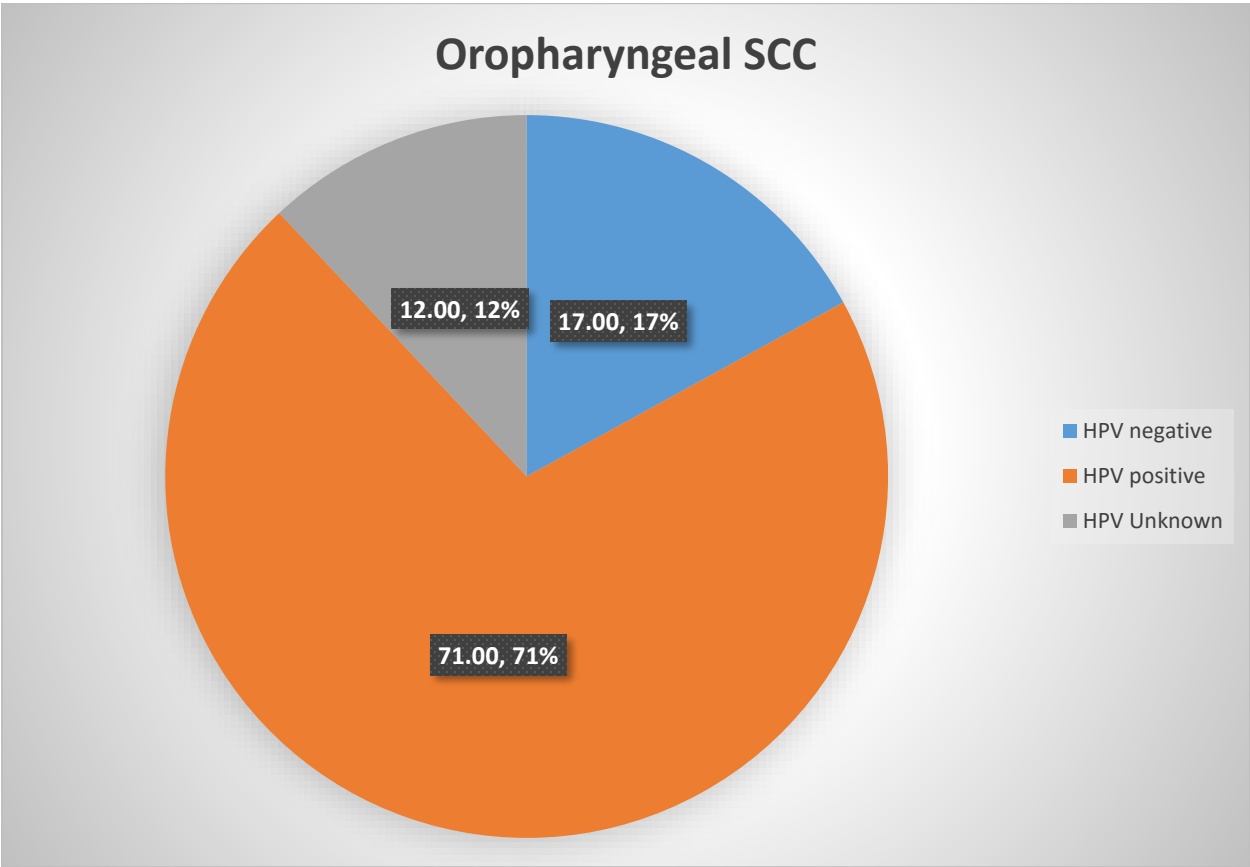
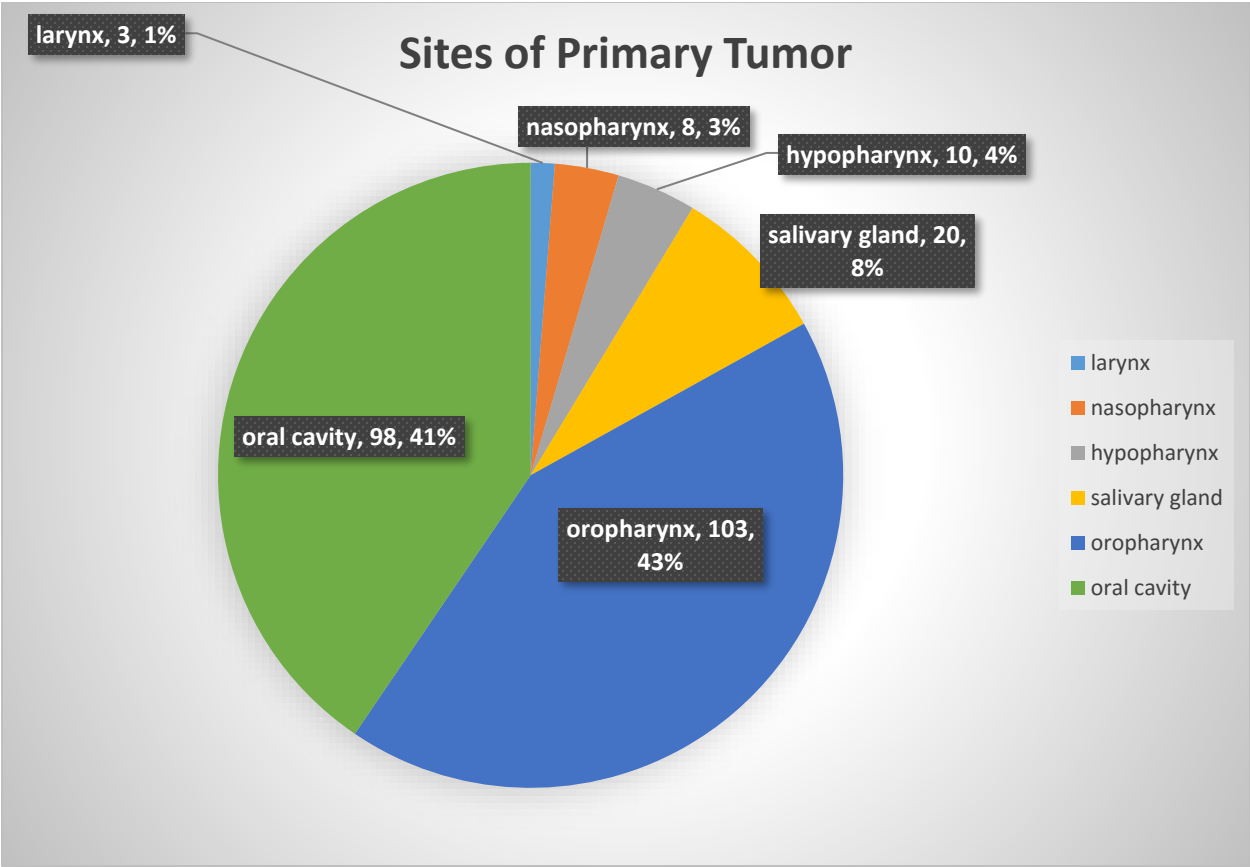


Cancer Types



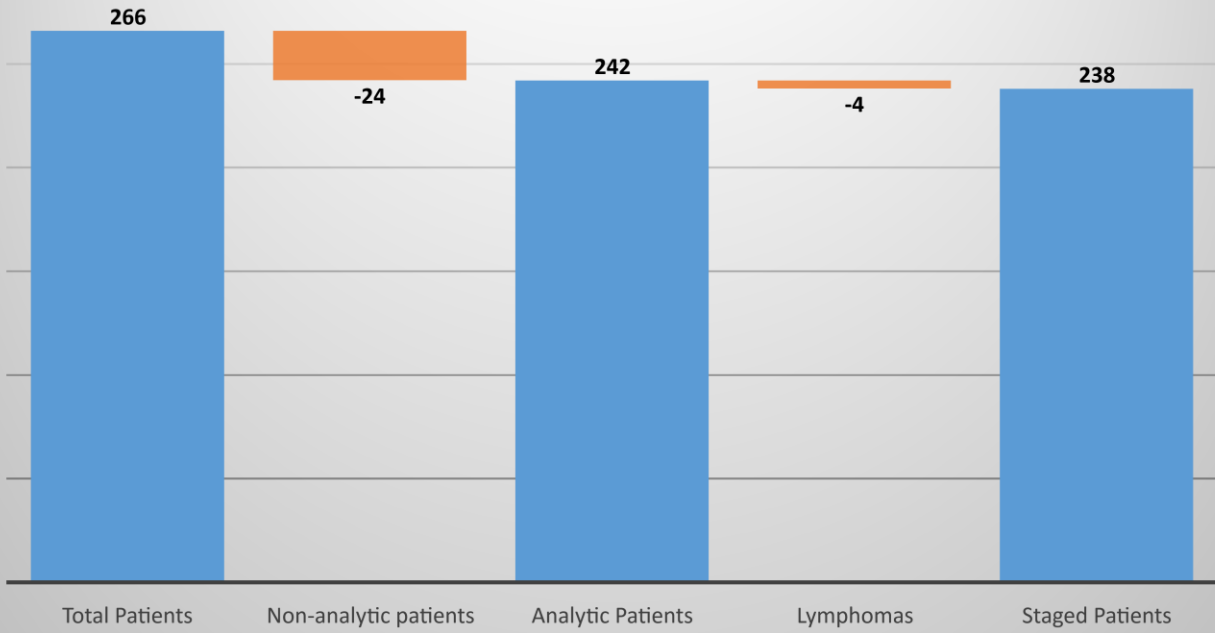
Other Tumors



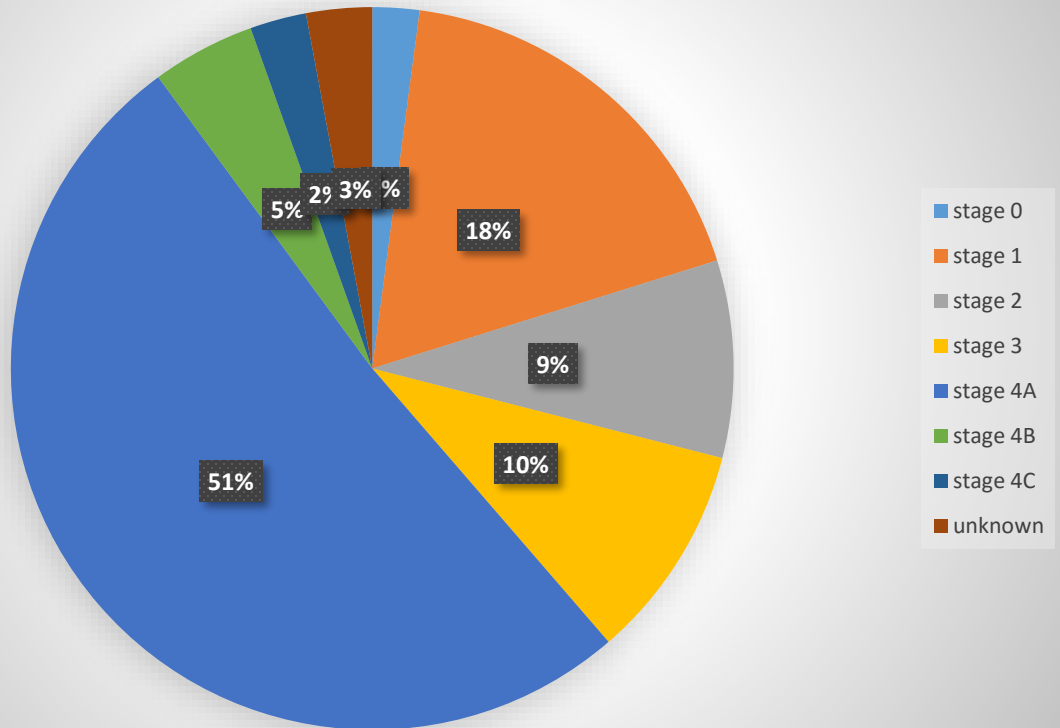


Staged Patients

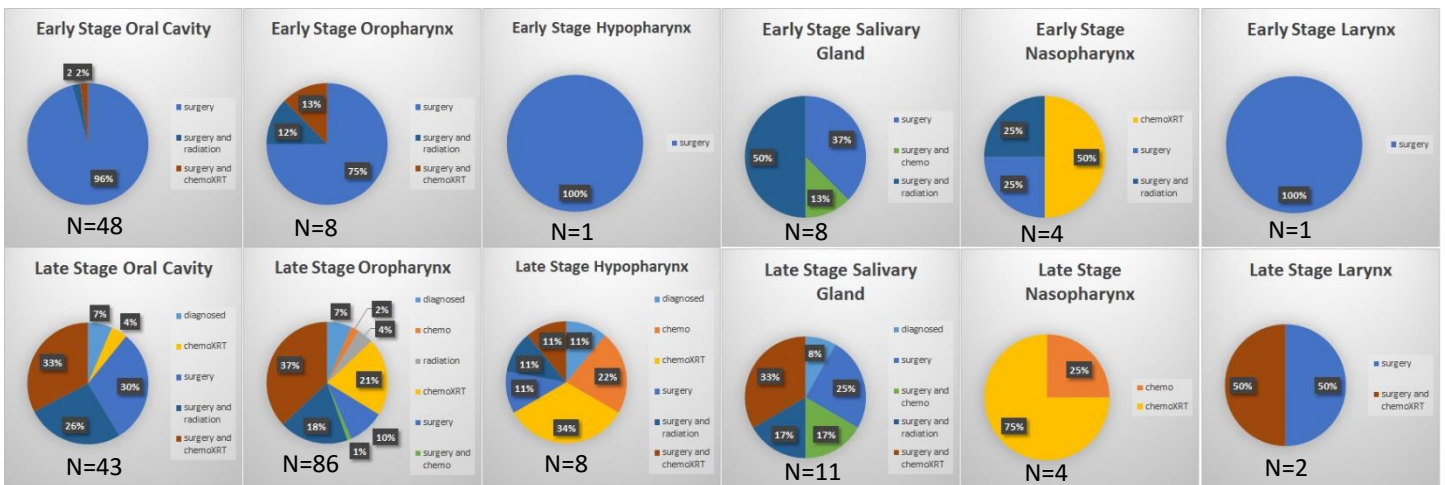
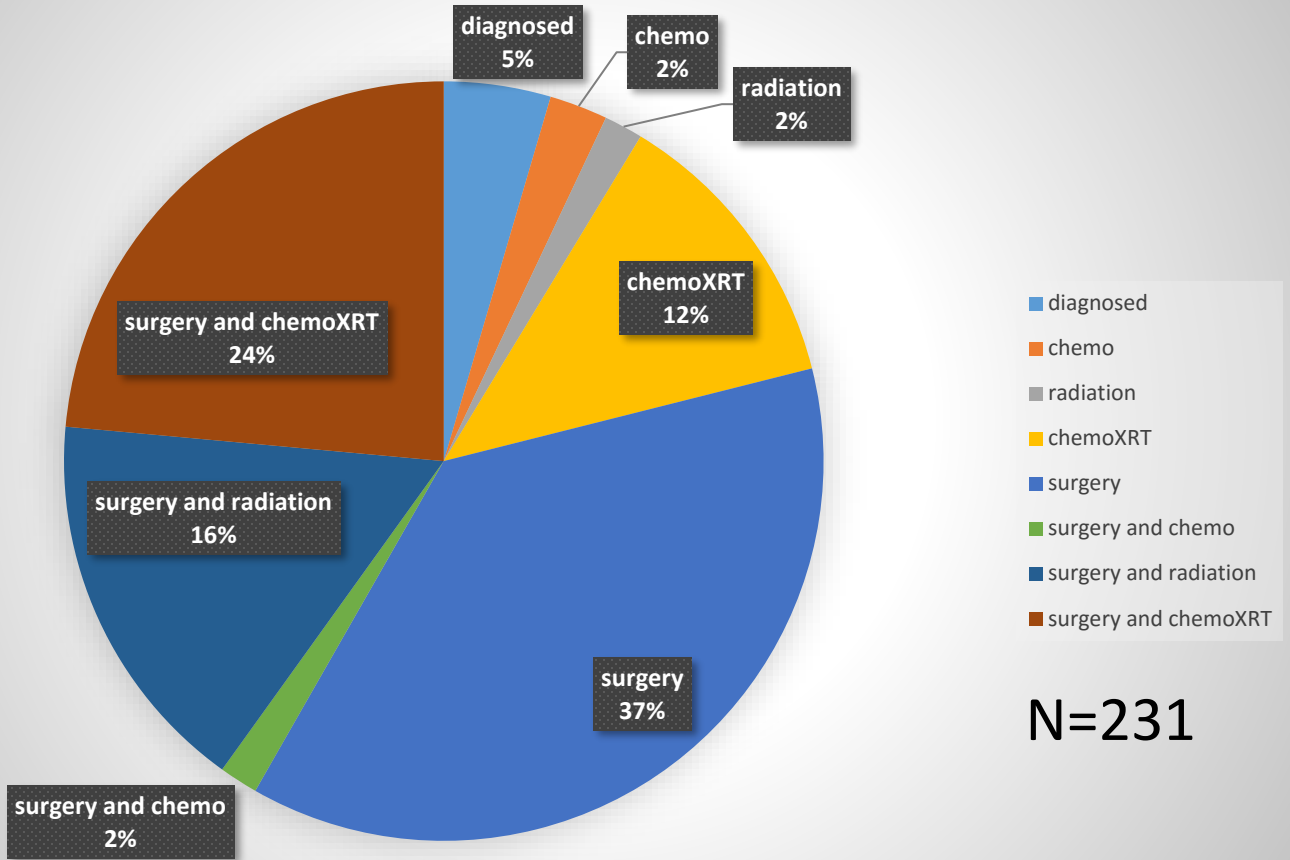
■ Increase ■ Decrease ■ Total

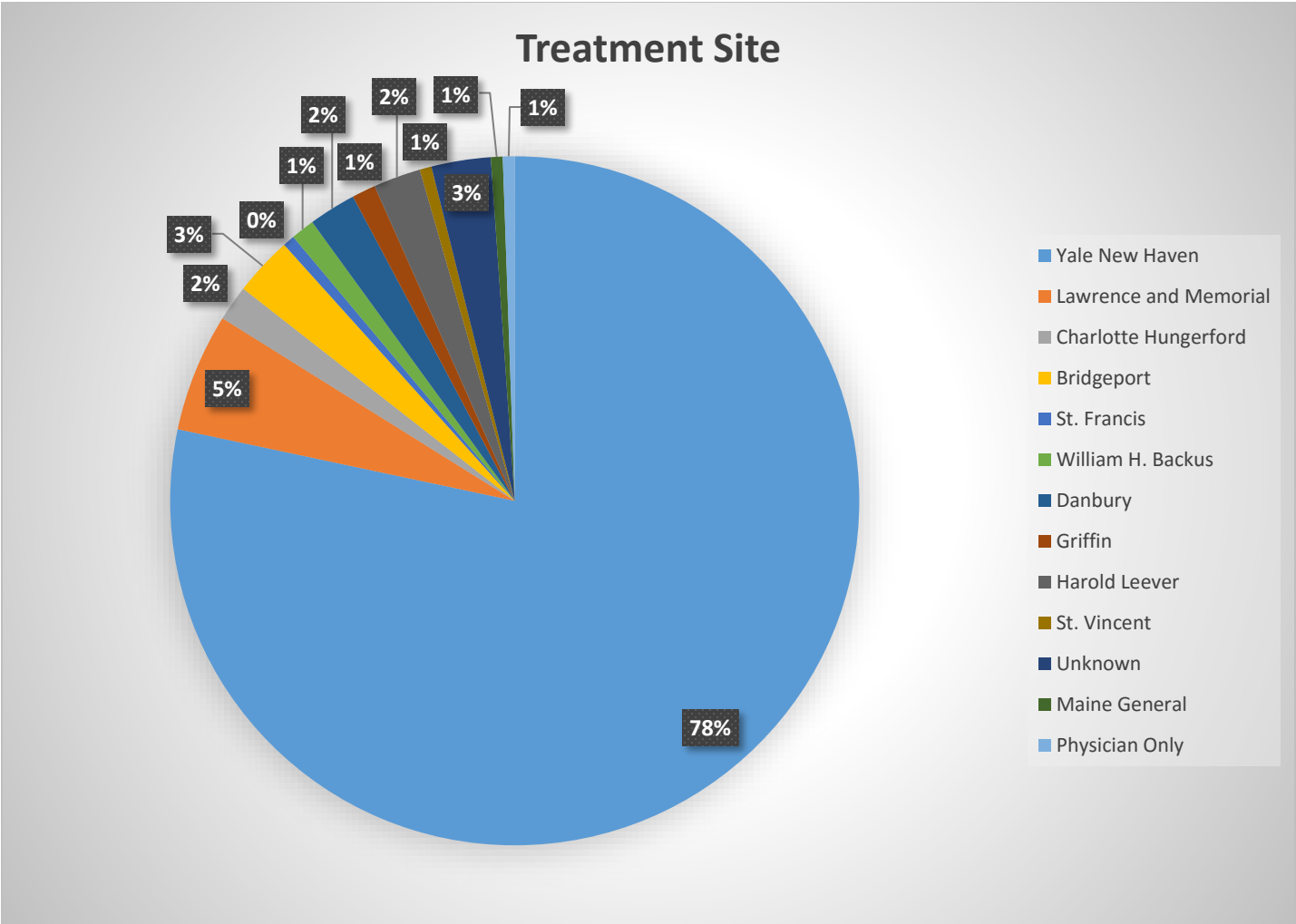


Stage of Cancer



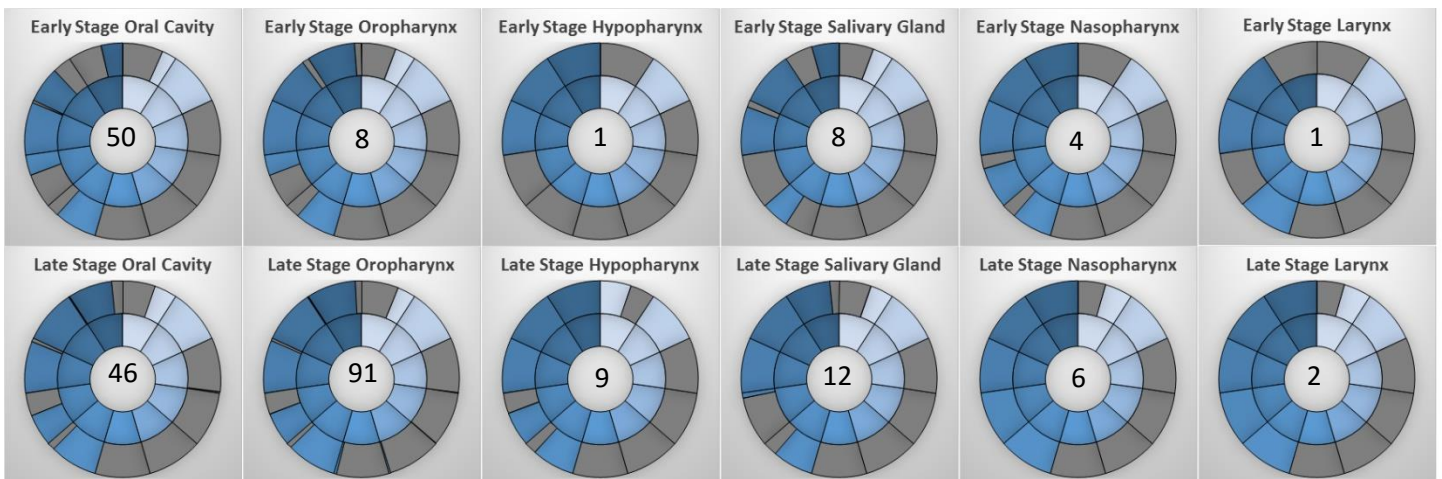
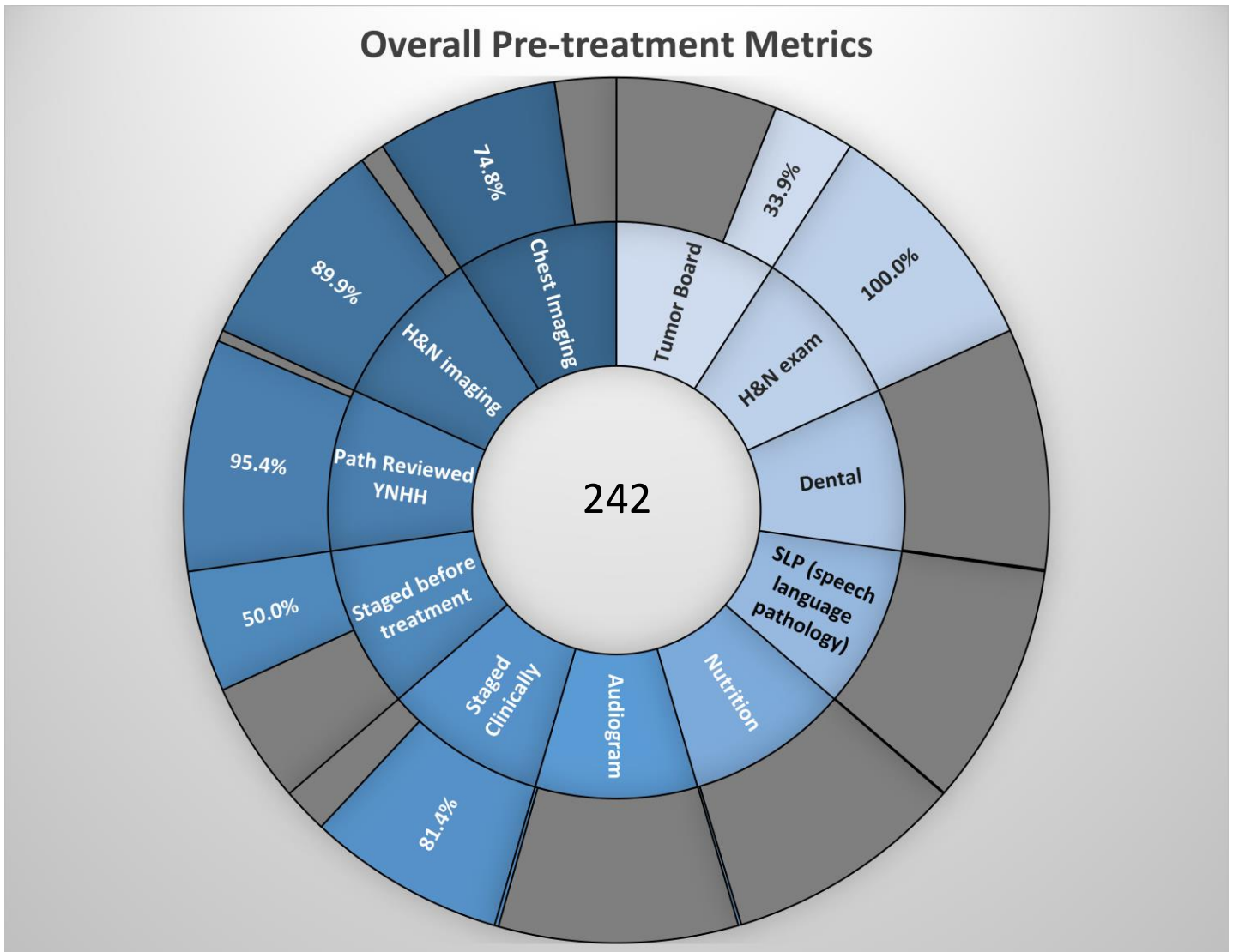
Treatment Modalities

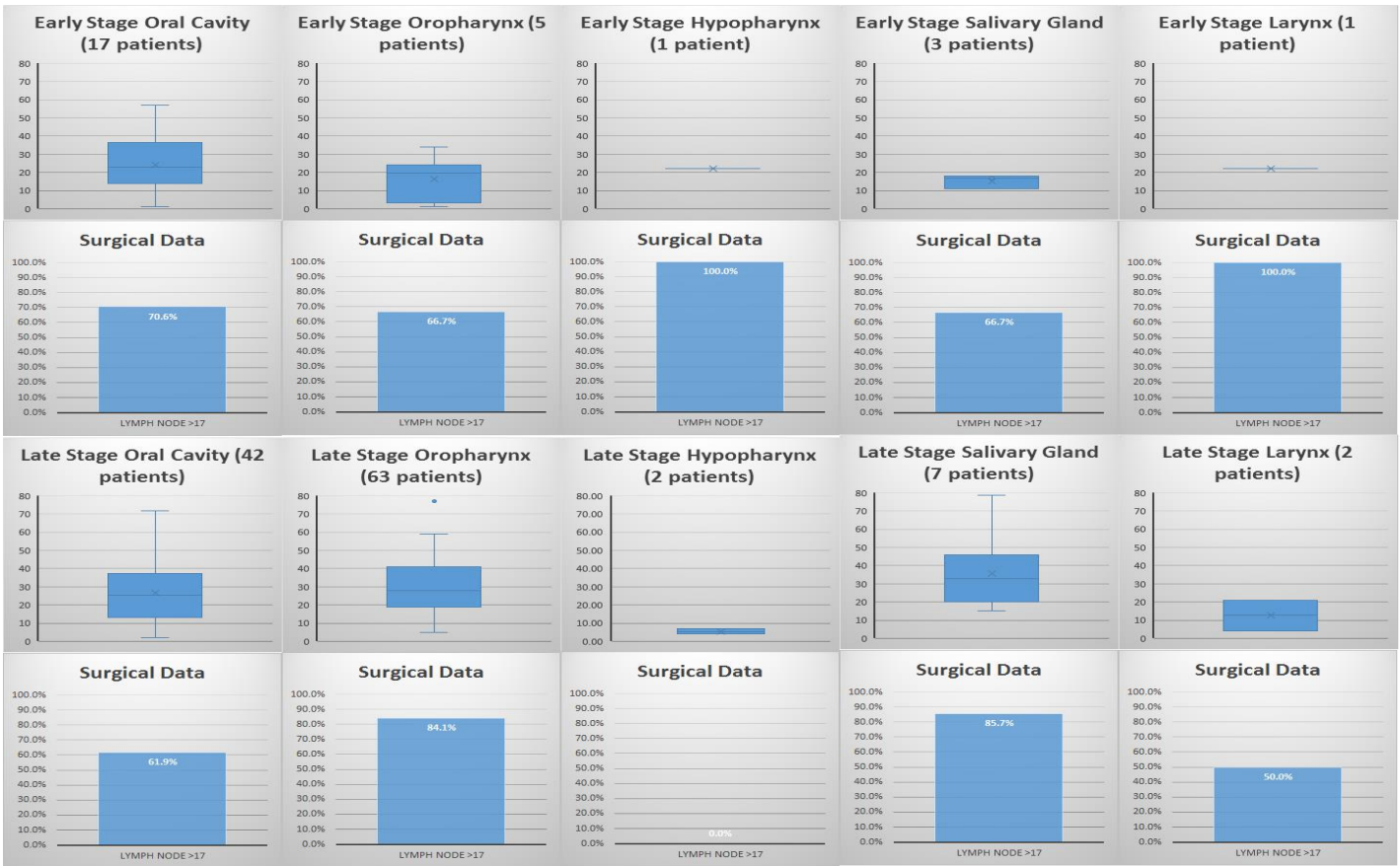
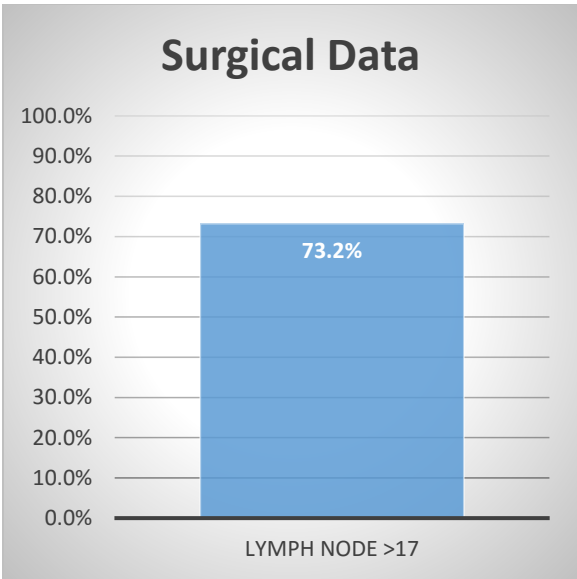
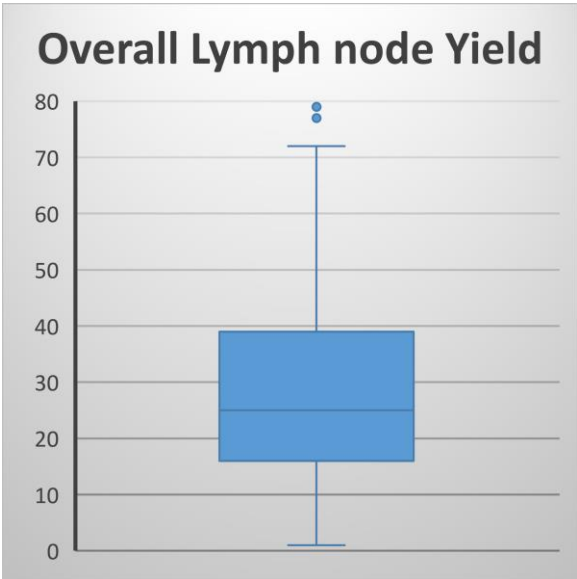




- Surgery at a YNHH hospital (180 patients)
- 141 received all subsequent treatment (including no further treatment) at YNHH
- 12 other sites locations for adjuvant therapy
- Site of chemotherapy chosen as primary site in cases where chemotherapy and radiation different

Part C: Process and Outcomes (Patient numbers listed in the middle of the graph)



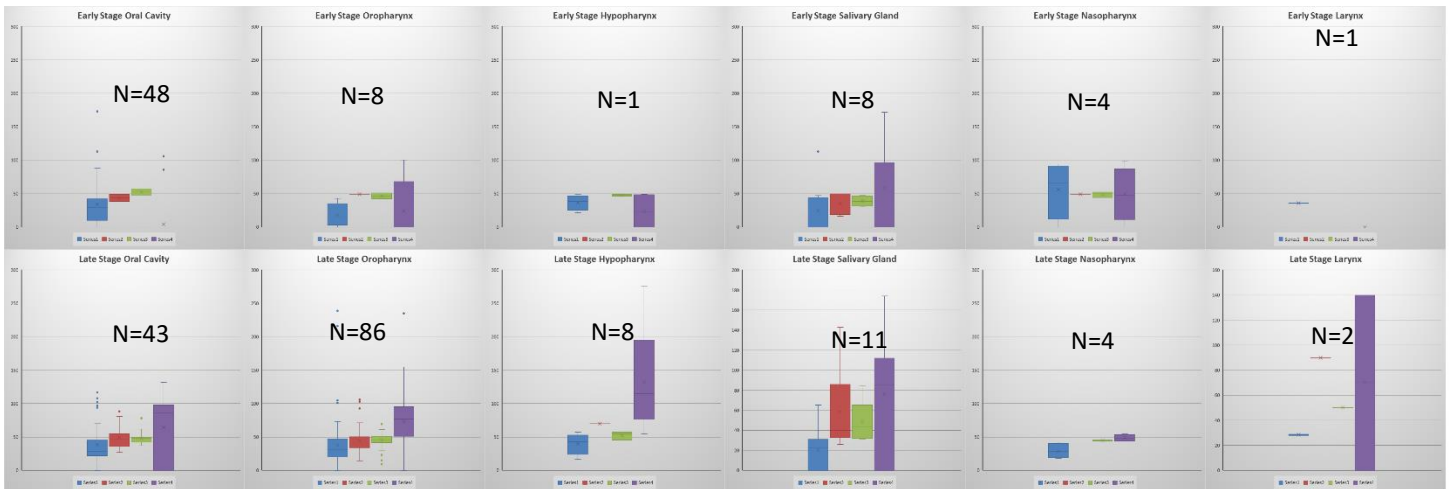
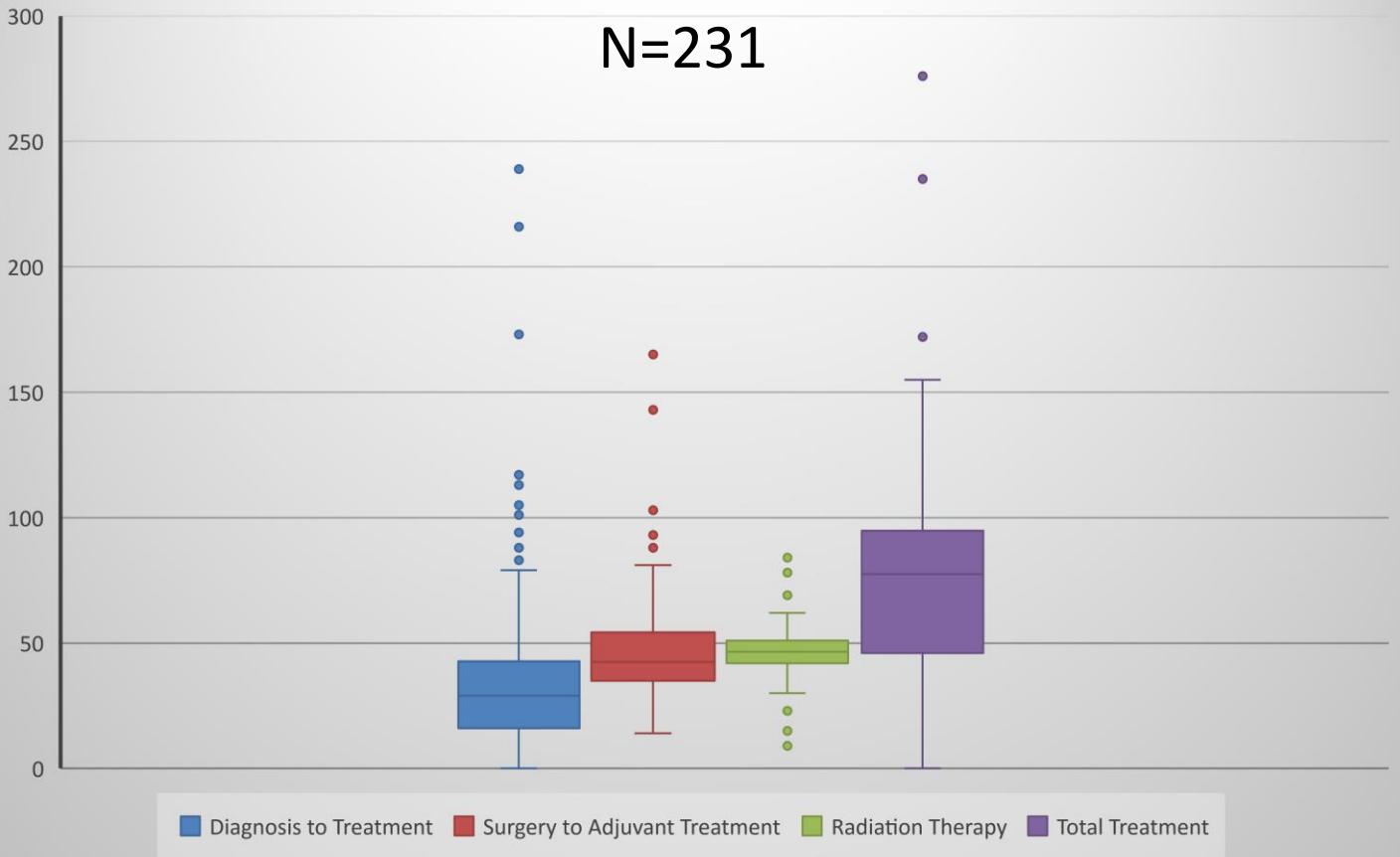


Surgical Data: Recent data from a large study done at Yale recommends that if elective neck dissection occurs, the patients who have more than 17 lymph nodes removed have a better outcome.

- 98 out of 127 patients had 18 or more nodes removed on one side
- 15 patients who had bilateral neck dissections
- Each side of the neck as a separate procedure, which brought our total neck dissections to 142.
- 104 of those neck dissections had 18 or more nodes removed.

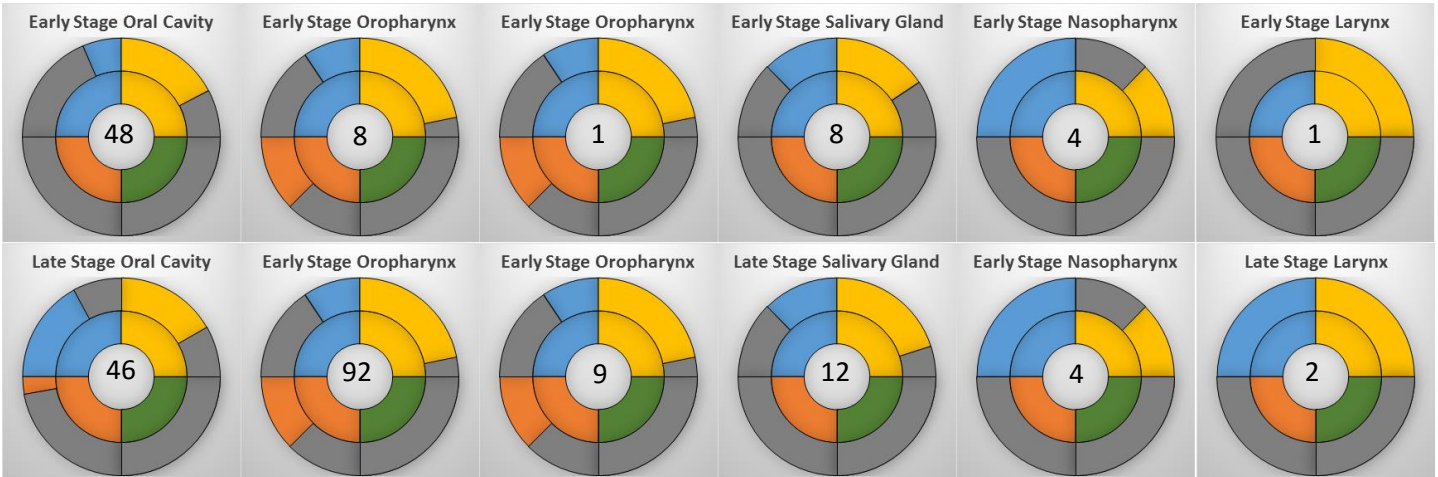
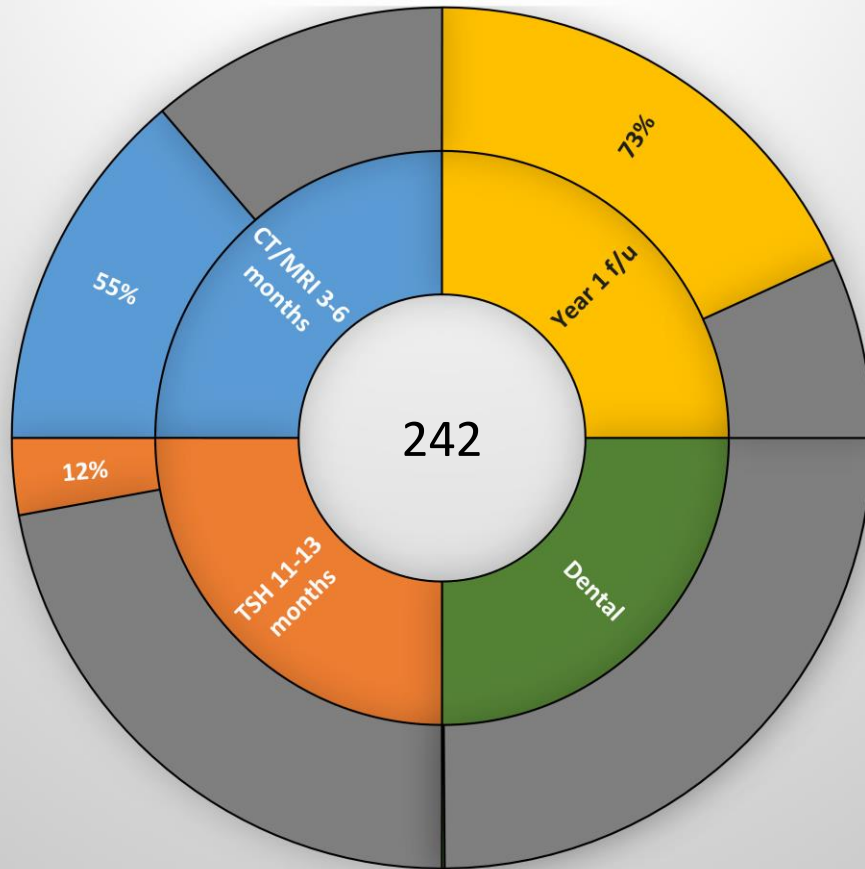
Times to Treatment

N=231



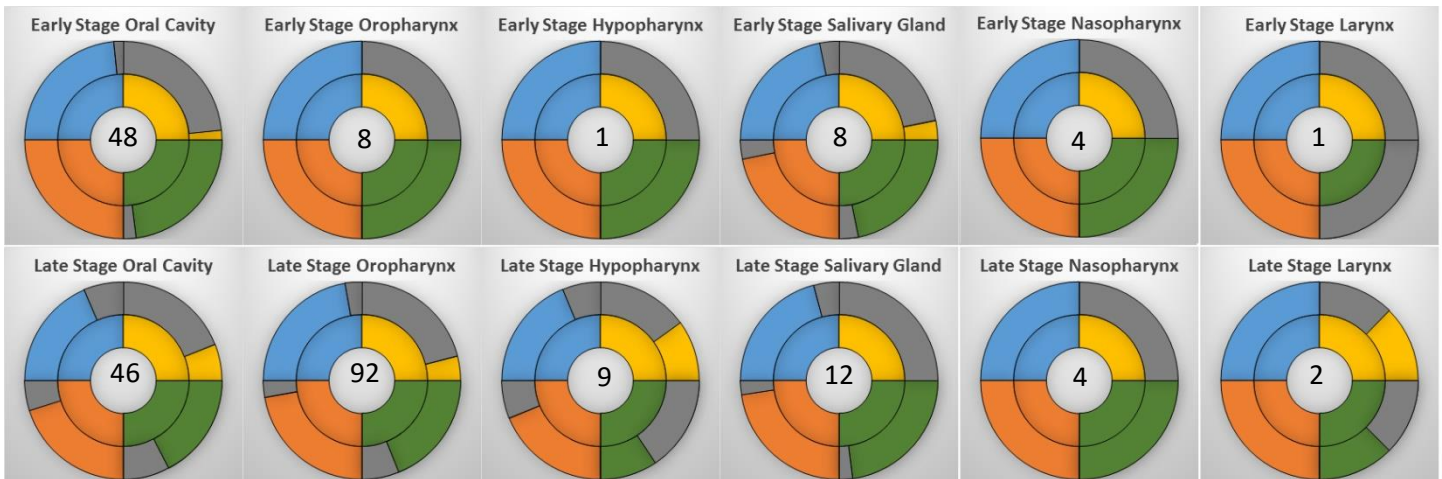
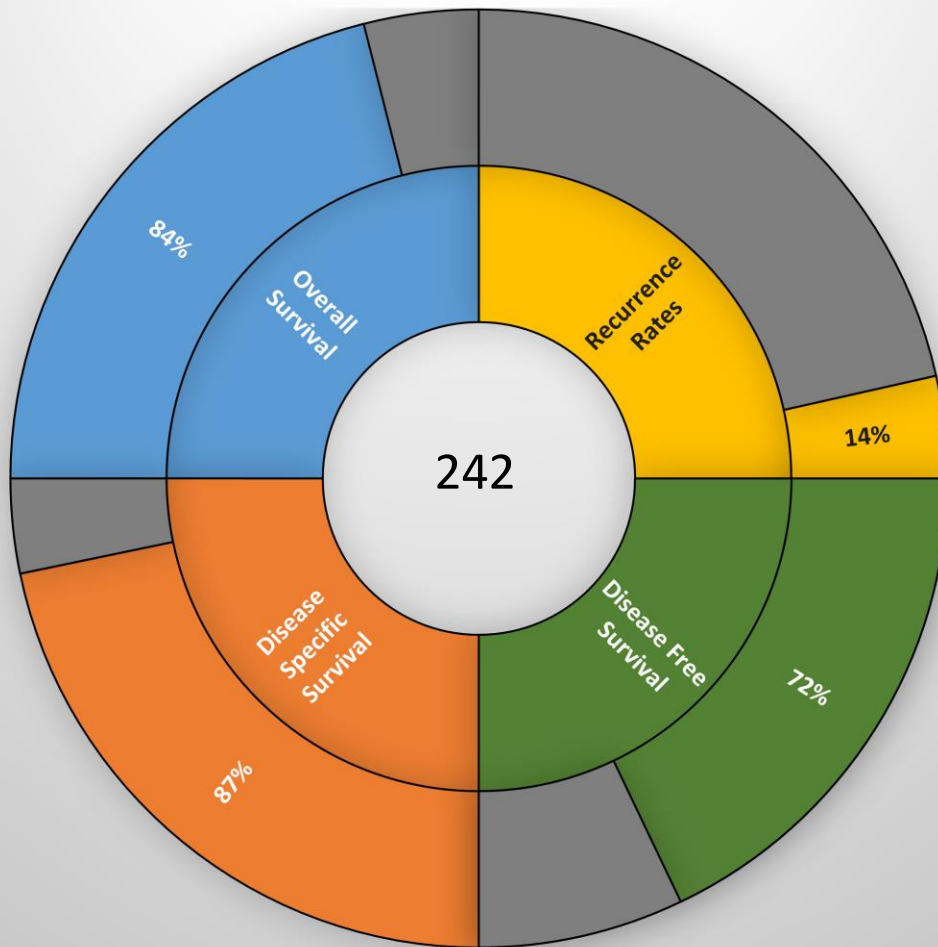
- 231 patients received treatment, with 29 days as the average length of time from diagnosis to treatment.
- 96 patients who received adjuvant therapy after surgery. The average time from surgery to adjuvant therapy was 43 days.
- 130 patients who received radiation treatment. The average duration of treatment was 47 days.
- The average of the total duration of treatment was 78 days. Surgery only patients excluded from overall data, but due to early stage patients often only receiving surgery, they were not excluded from site and stage data.

One Year Follow-Up



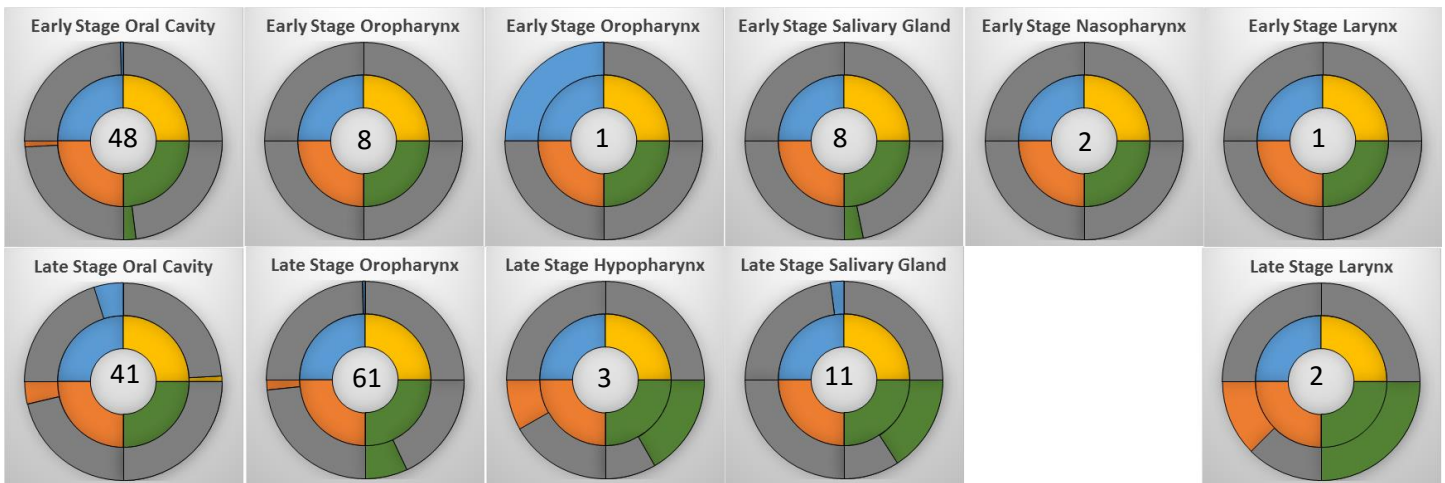
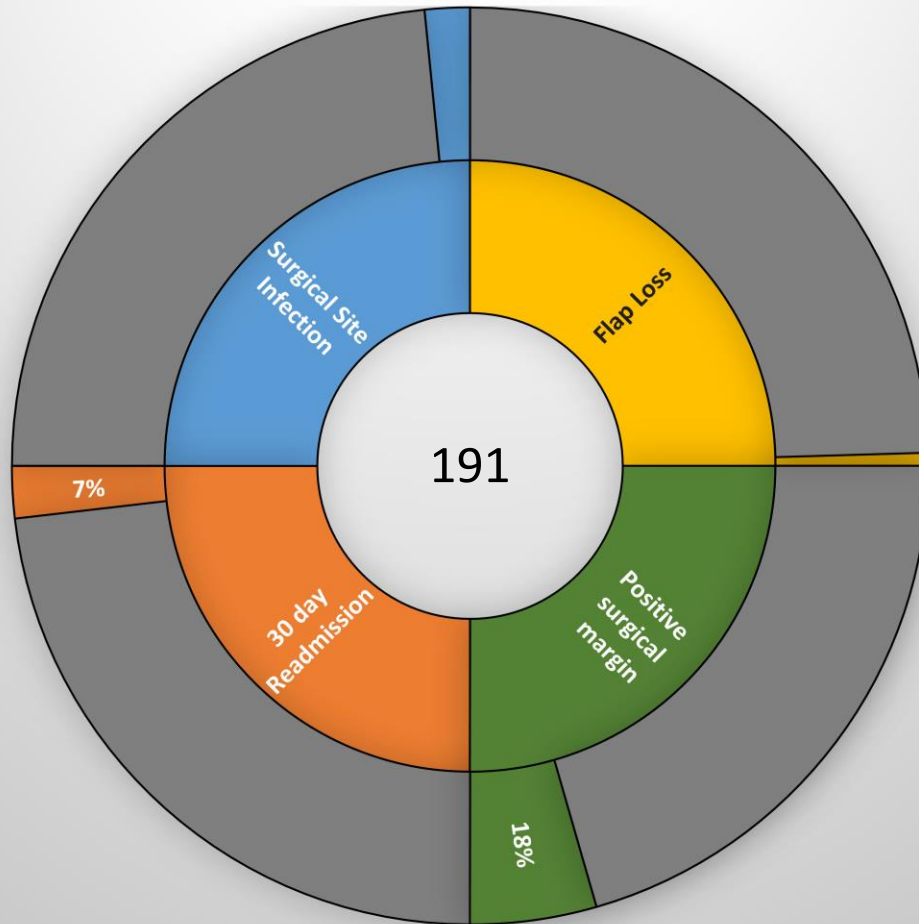
- AAHNS guidelines recommends that all patients receive a CT or MRI of their head and neck between 3 and 6 months after the conclusion of their treatment.
- It is also recommended that patients who underwent radiation therapy receive a TSH screening 11-13 after the conclusion of their treatment. In 2014, there were 132 patients who had radiation therapy.
- Patients are also at risk of dental issues after treatment, with dental follow-up recommended.
- Appropriate follow-up after 1 year defined as at least 3 visits at least 2 months apart.

Survival and Recurrence Rates



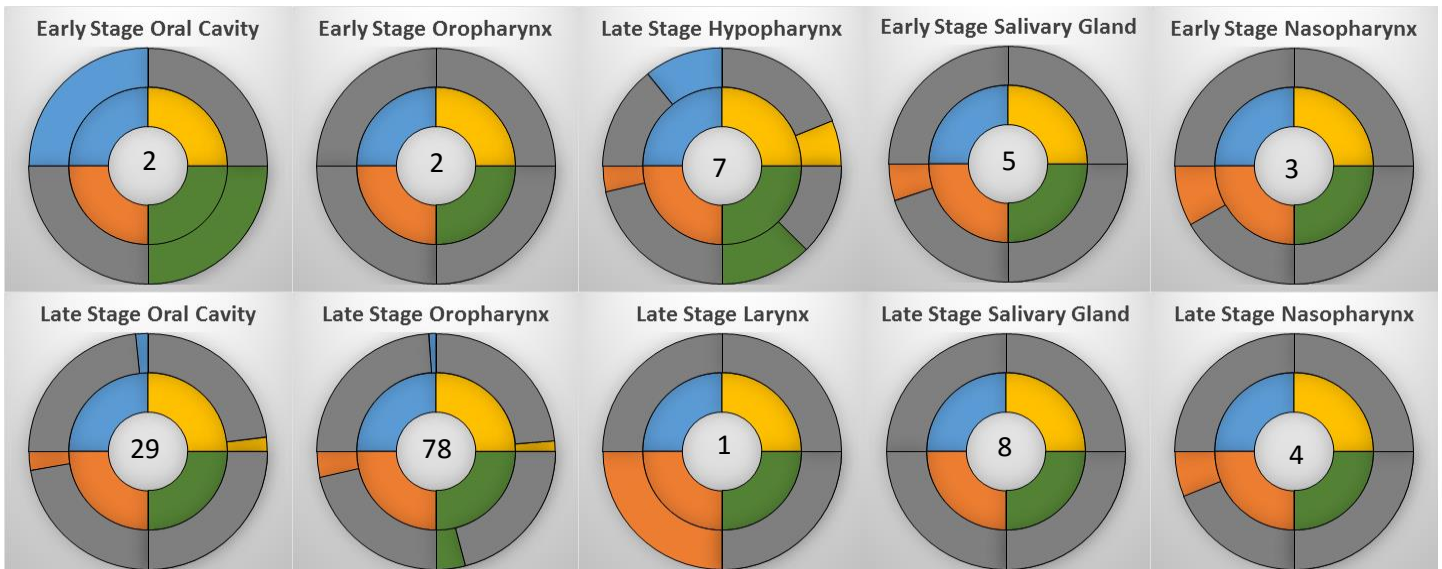
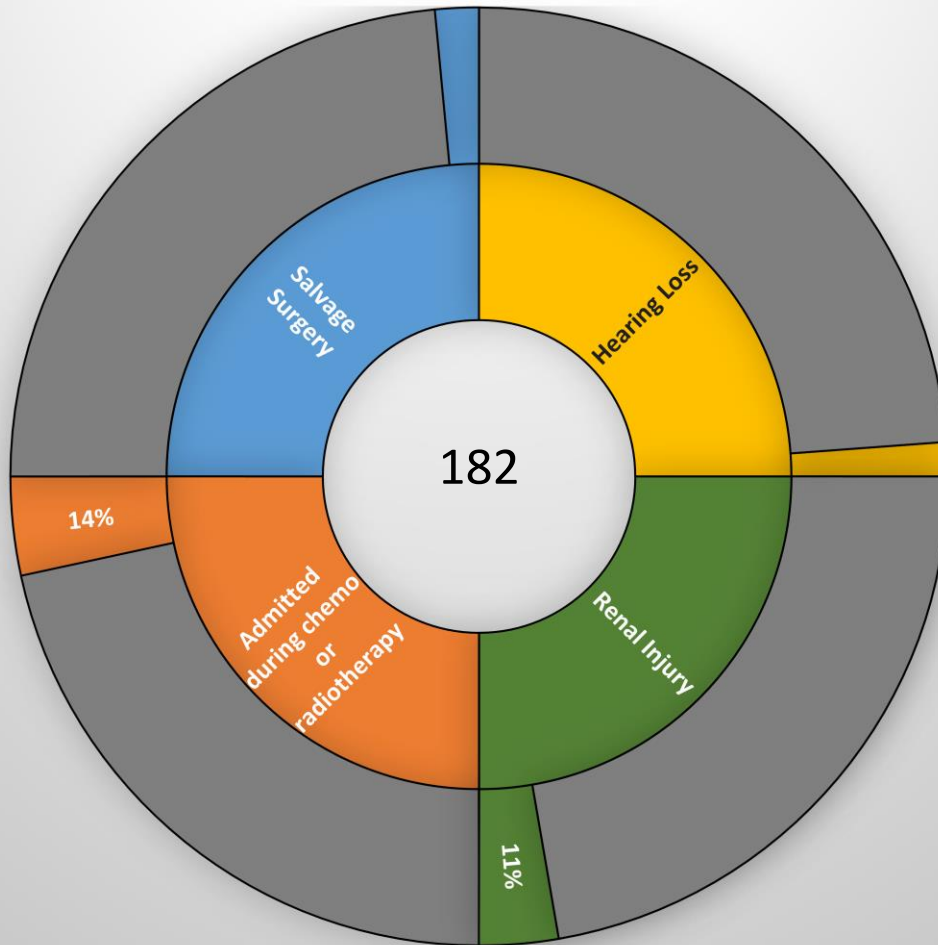
- 31 patients had a tumor recurrence, with 22 having local recurrence, 15 with regional recurrence, and 11 with distant recurrence (several patients were noted to have recurrence in multiple sites).
- 21 cases of progressive cancer.

Surgical Complications



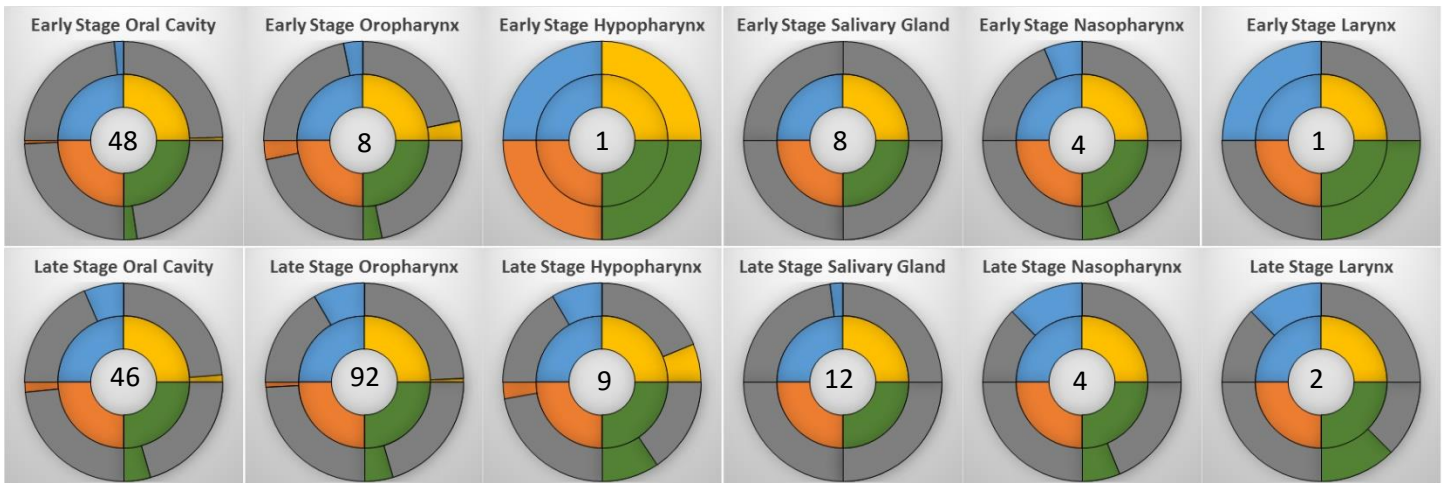
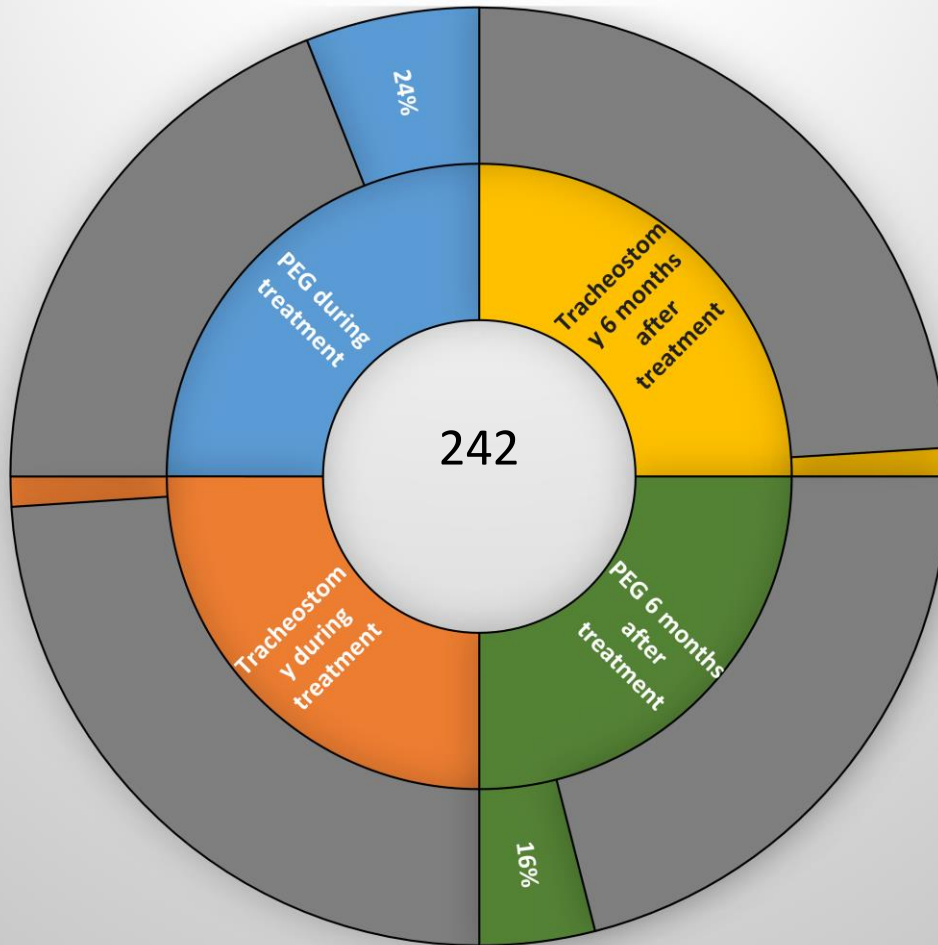
- 14 patients had to be readmitted within 30 days after surgery.
- 12 patients with a surgical site infection.
- 1 patient who had a flap-loss out of 55 patients.

Chemotherapy and Radiation Therapy Complications



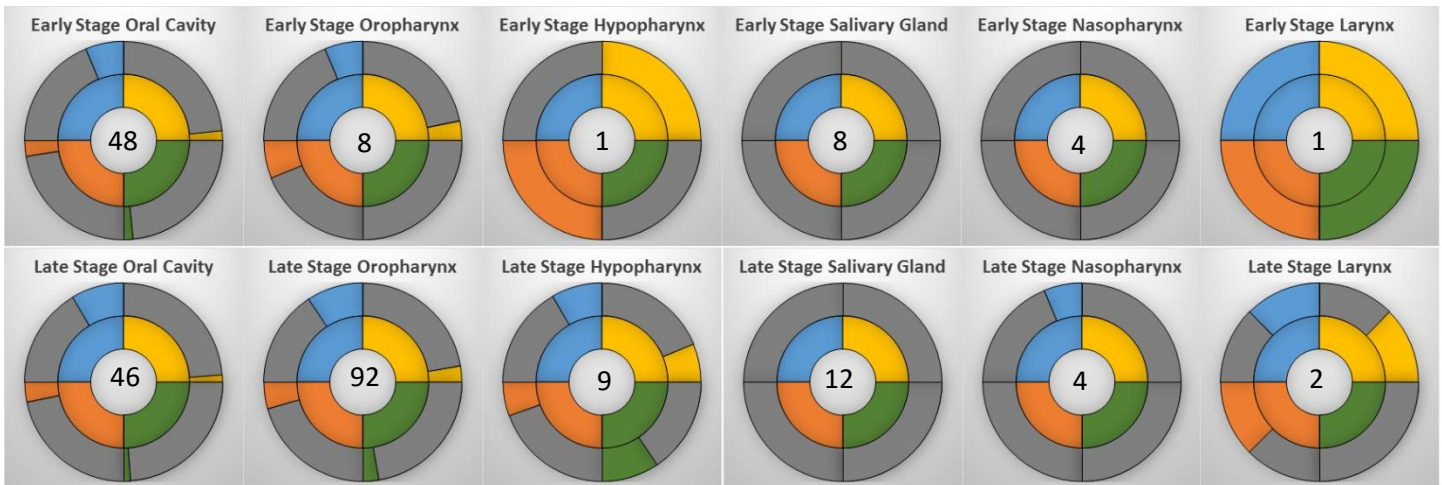
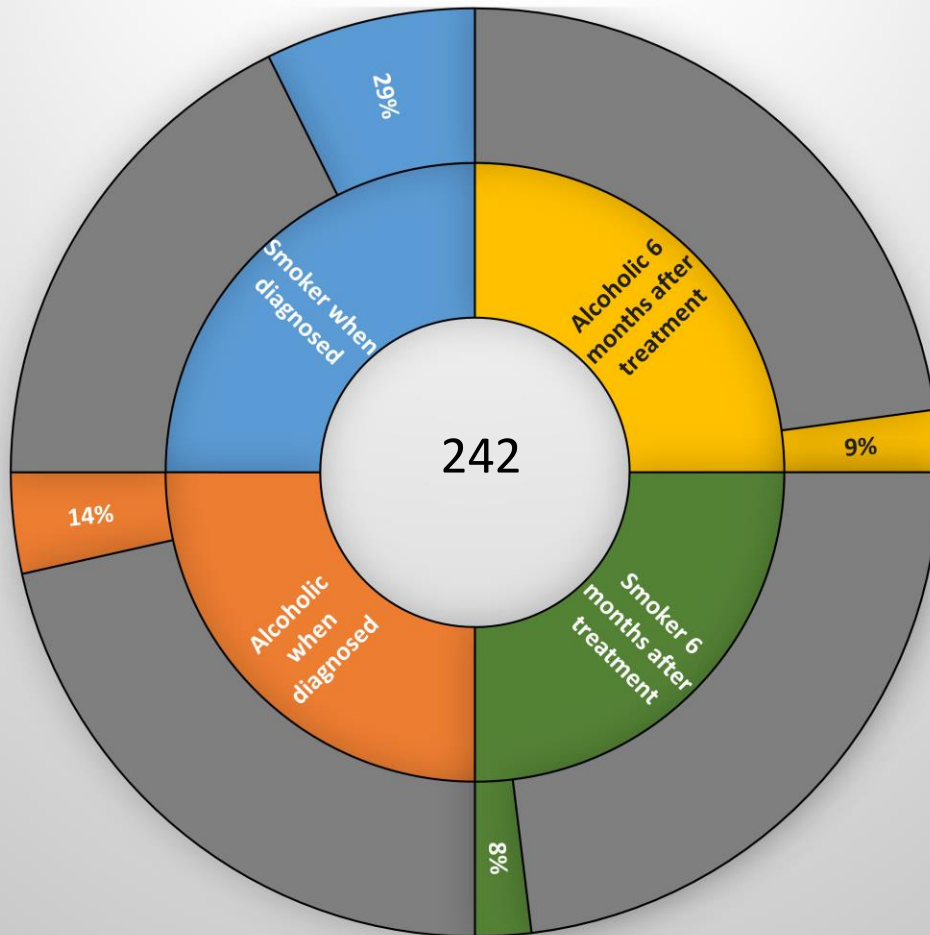
- 73 patients who received cisplatin based chemotherapy, and were included when assessing renal damage or hearing loss

Functioning



- 58 patients had a percutaneous endoscopic gastrostomy (PEG) tube
- 10 patients had a tracheostomy during treatment. Any patients who received a tracheostomy during surgery that was removed before discharge were not counted.
- 36 patients had a PEG 6 months after treatment
- 9 patients had a tracheostomy 6 months after treatment

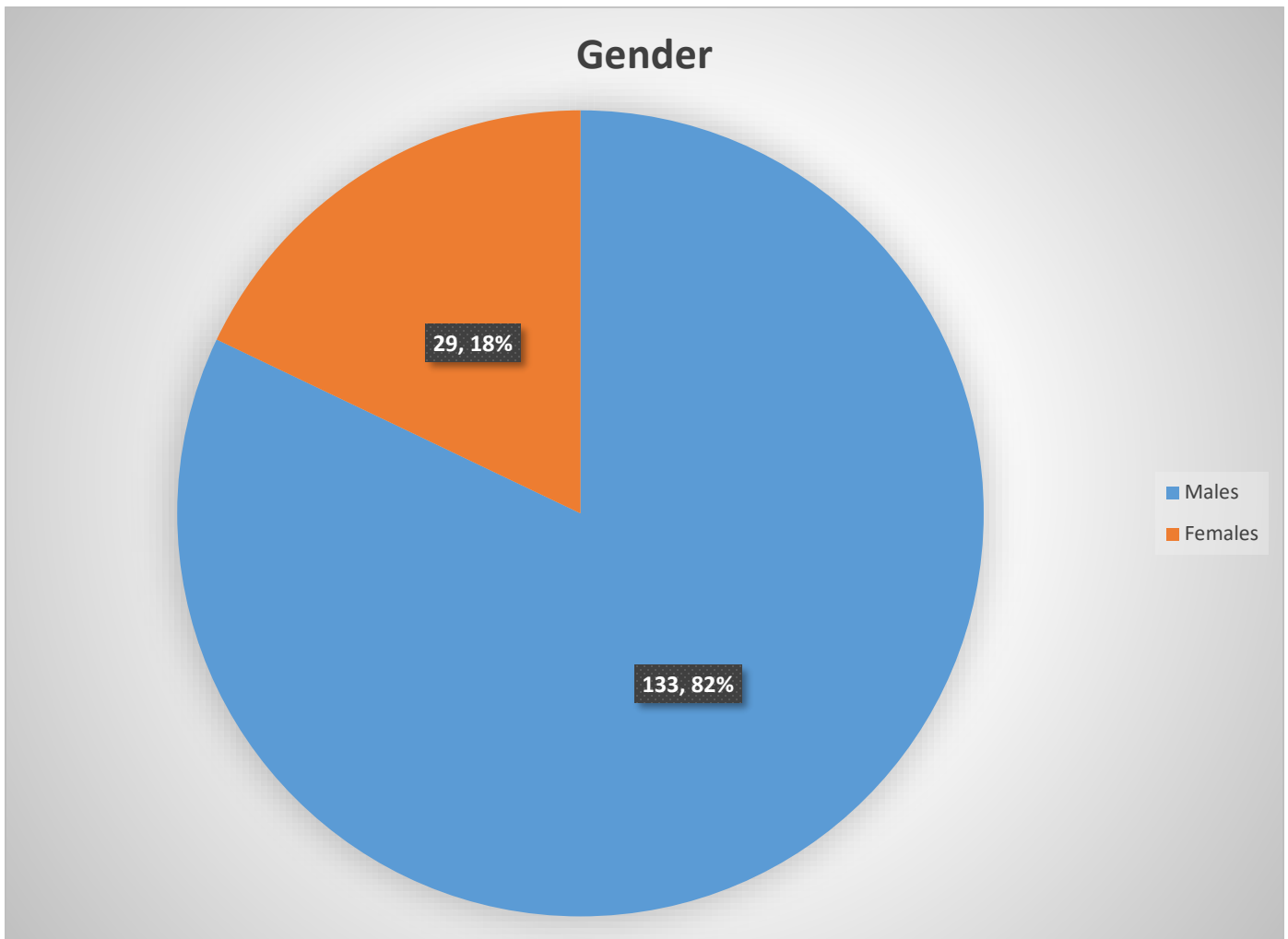
Patient Habits



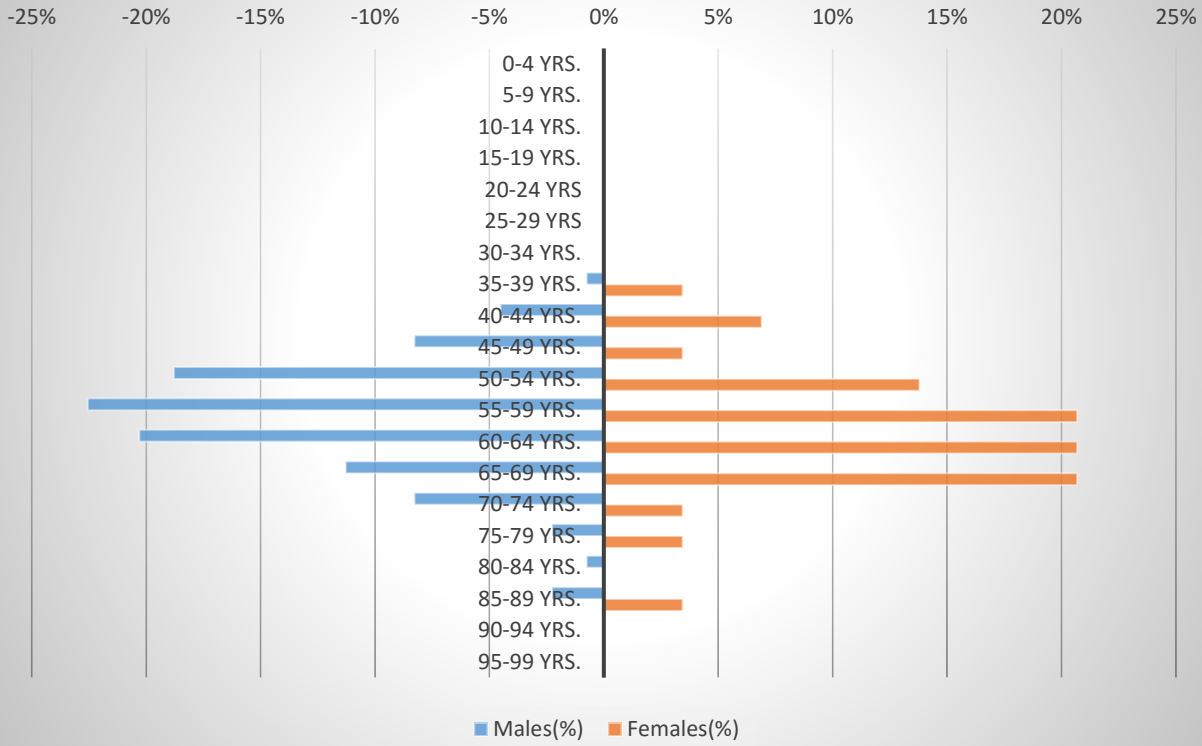
- 71 patients were smokers at diagnosis
- 34 patients were alcoholics at diagnosis
- 19 patients were smokers 6 months after treatment conclusion
- 21 patients were alcoholics 6 months after treatment conclusion

Oropharyngeal Patients

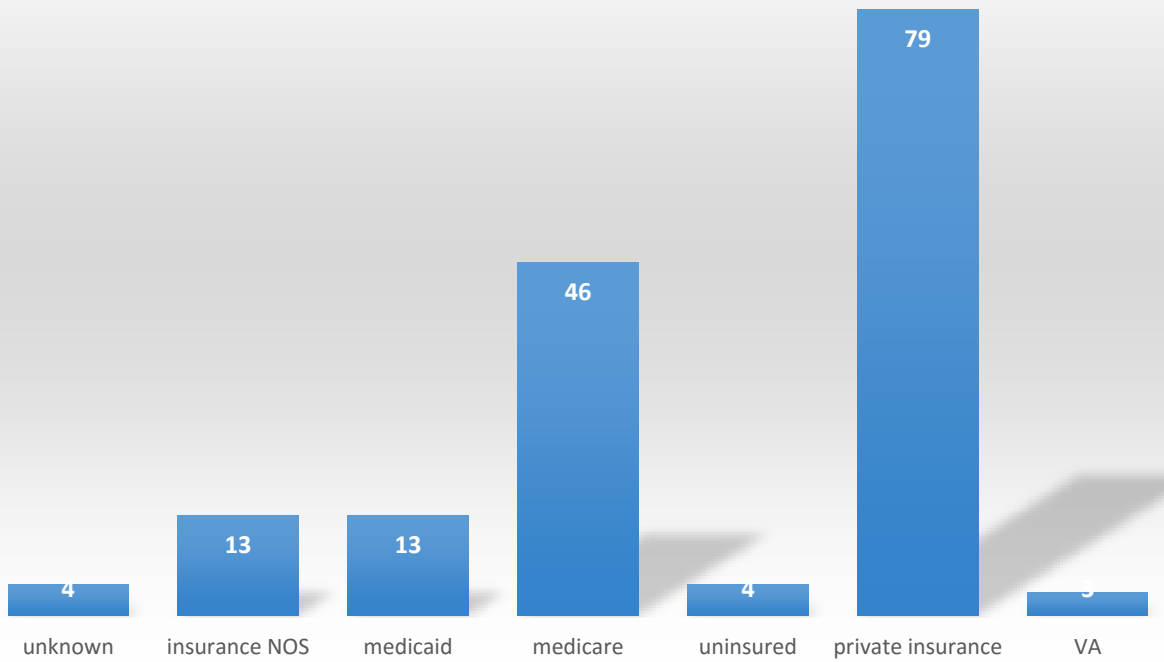
The oropharyngeal patients were then isolated from this initial data set. The structural data for all 162 oropharyngeal cancer patients (patients combined from 2013 and 2014) is presented below:



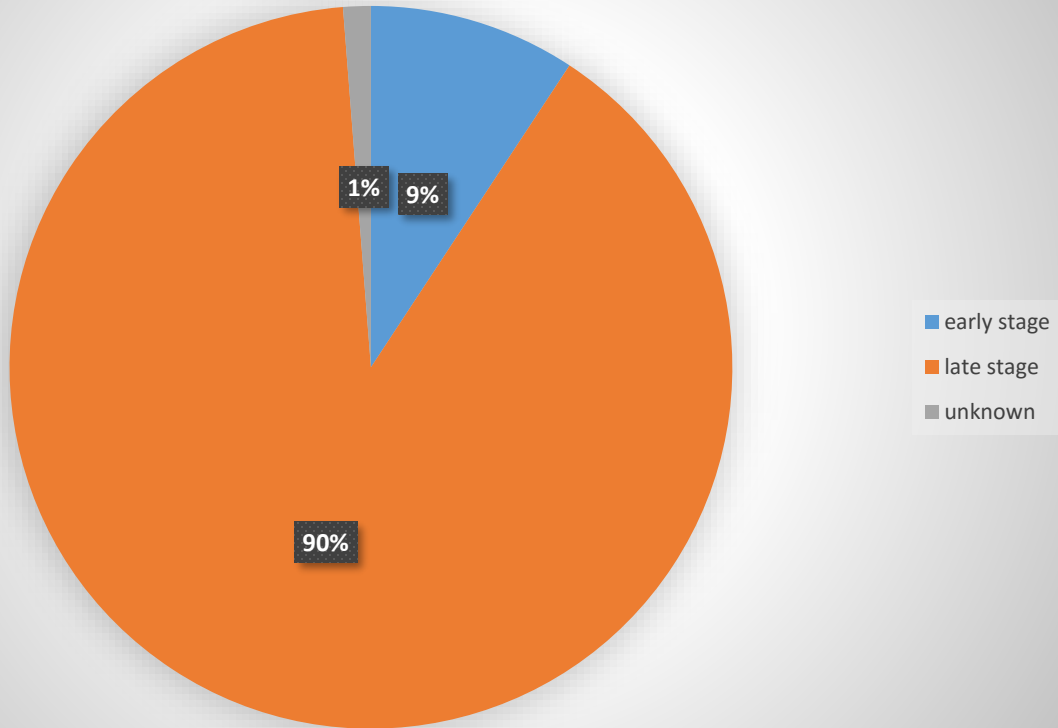
Age Gender Breakdown



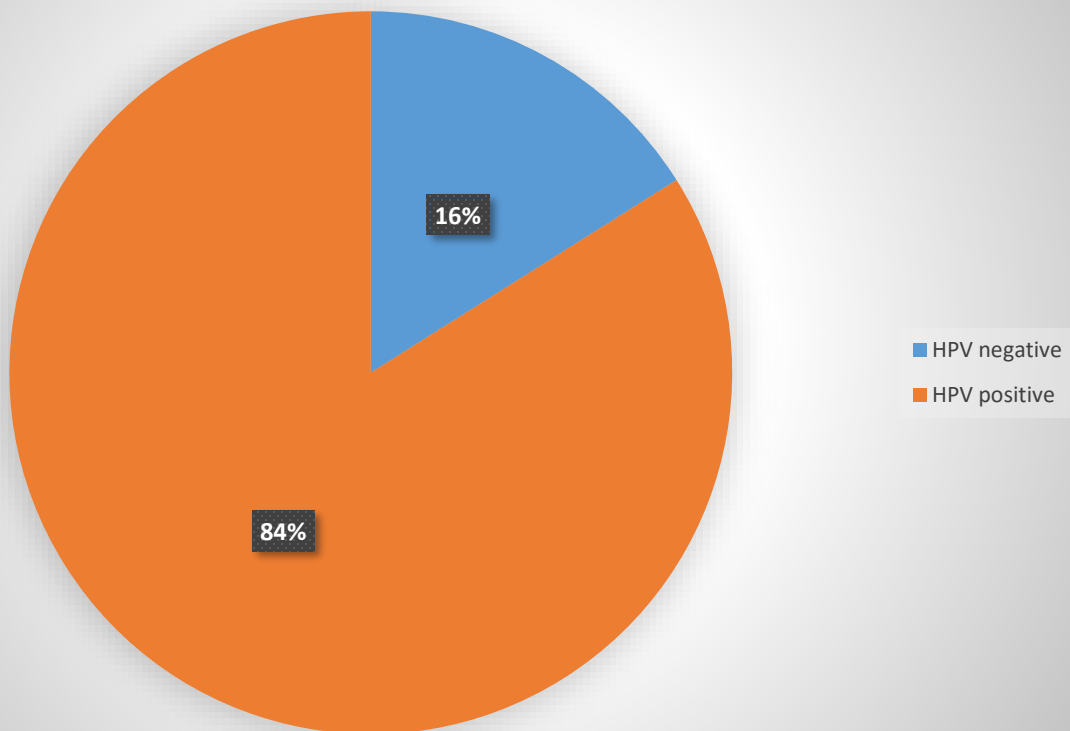
Insurance Types



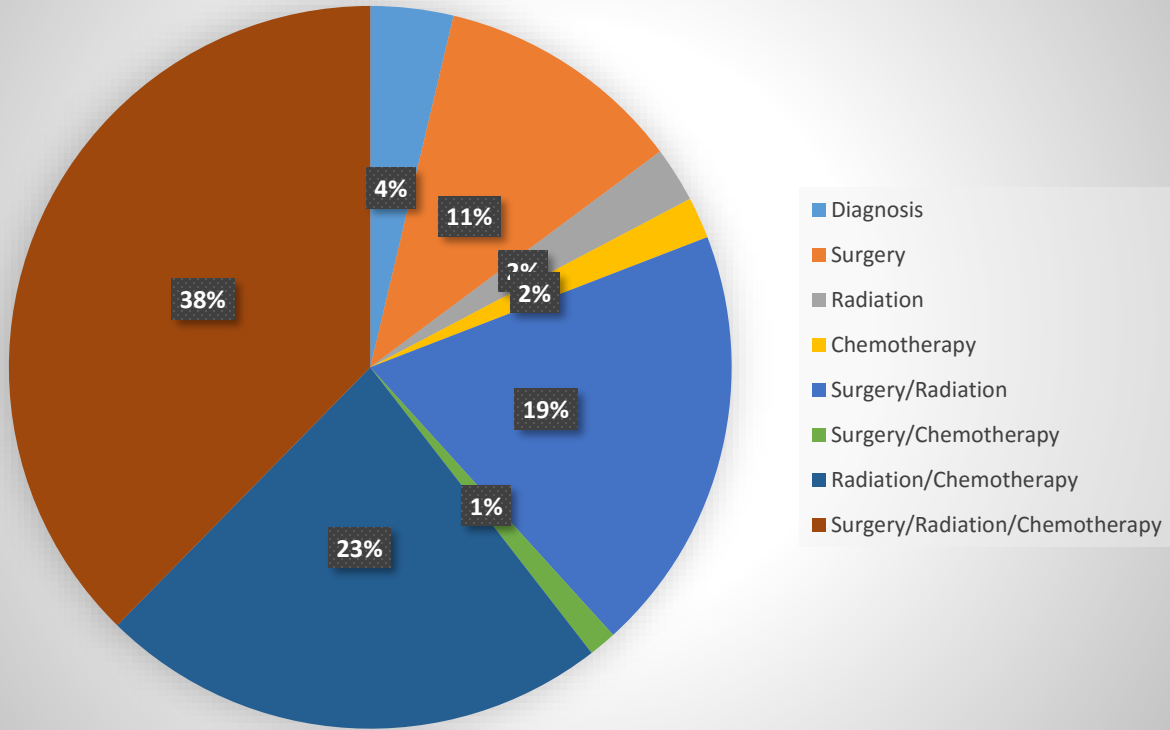
Cancer Stage



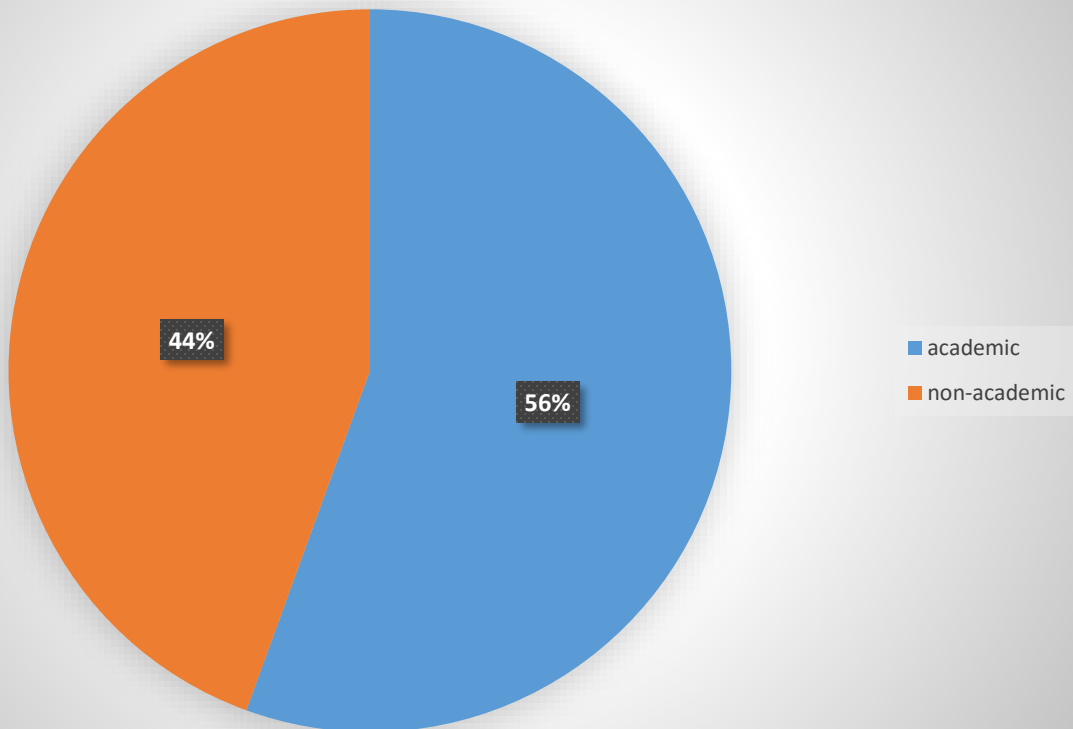
HPV Status



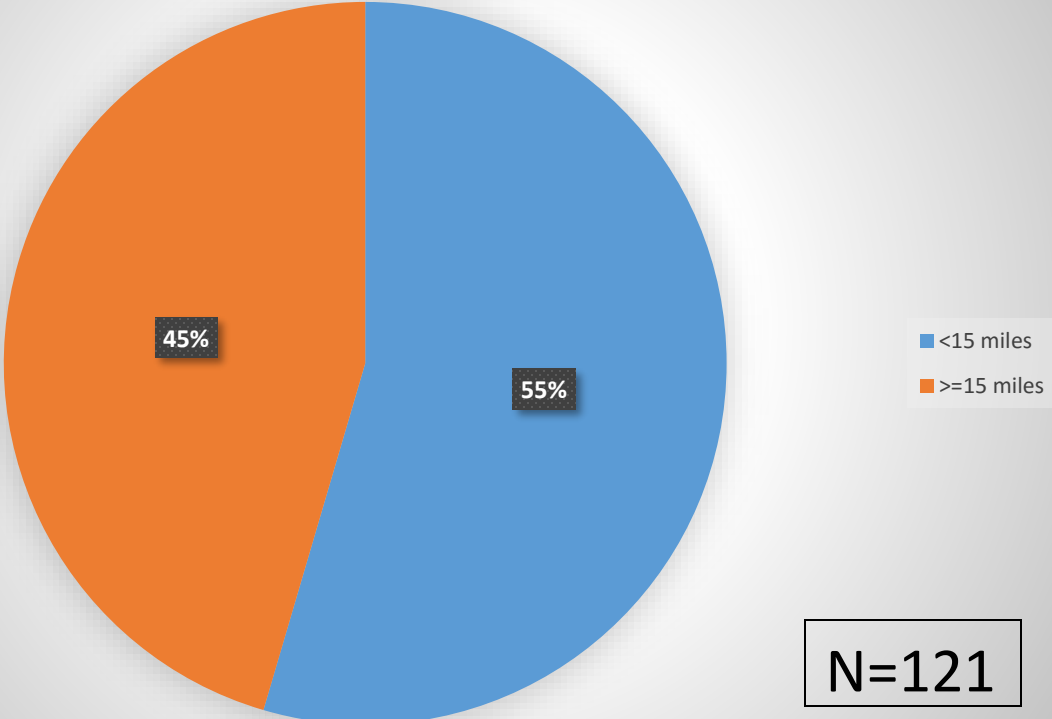
Treatment Types



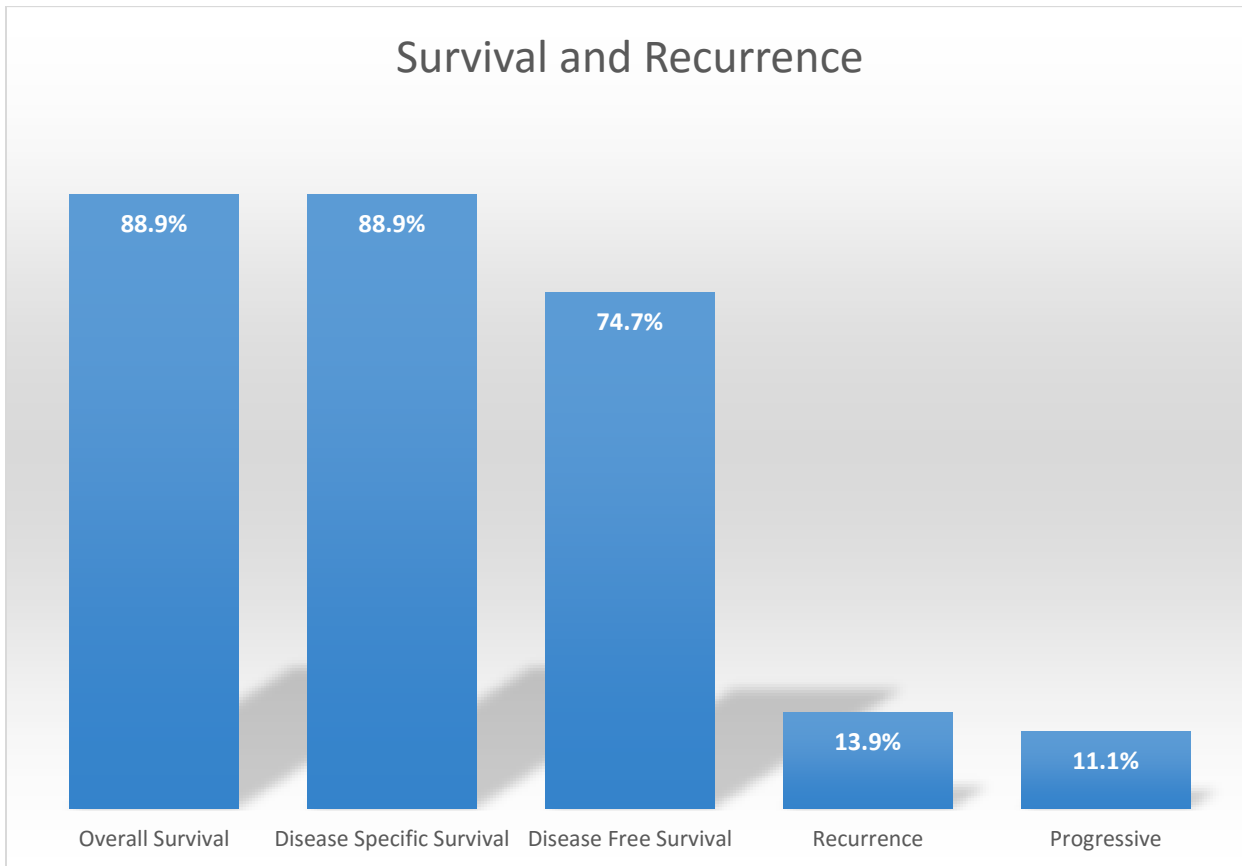
Academic Vs. Non-academic



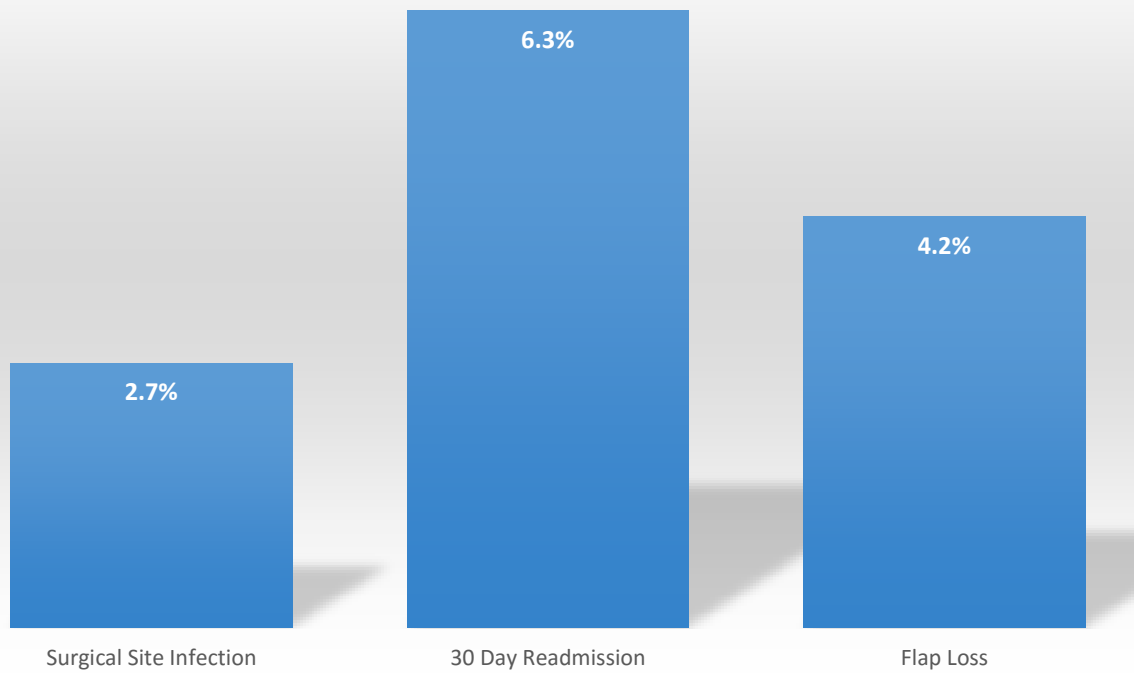
Distance from Radiation Therapy Site



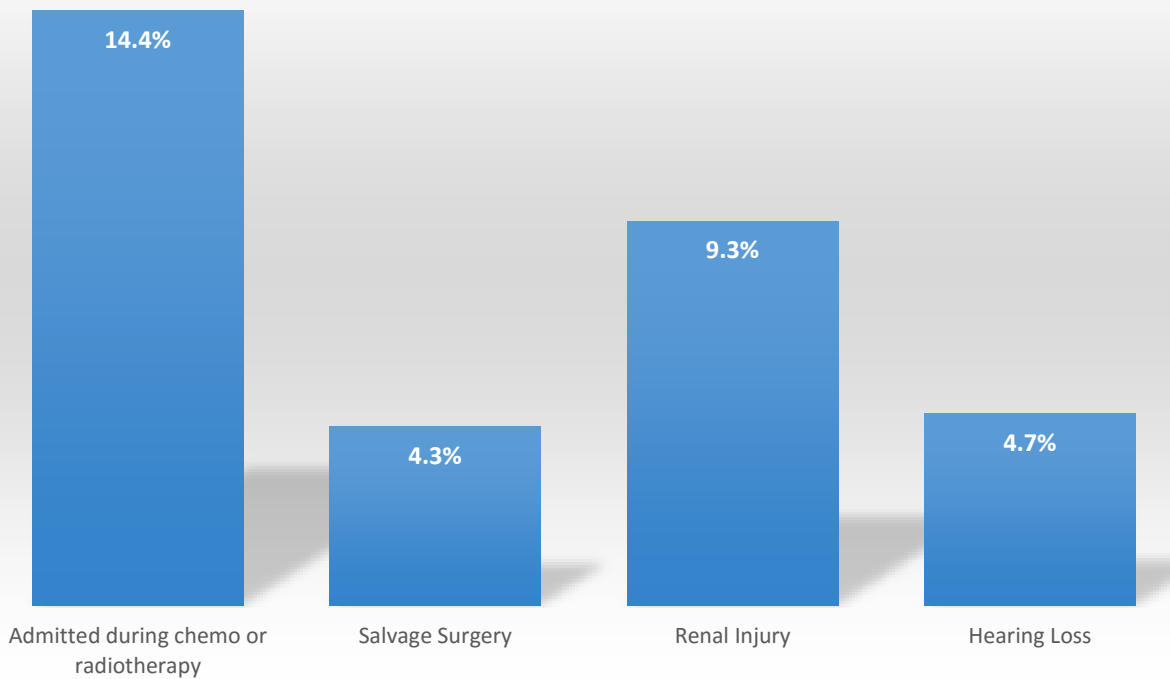
Outcomes Data



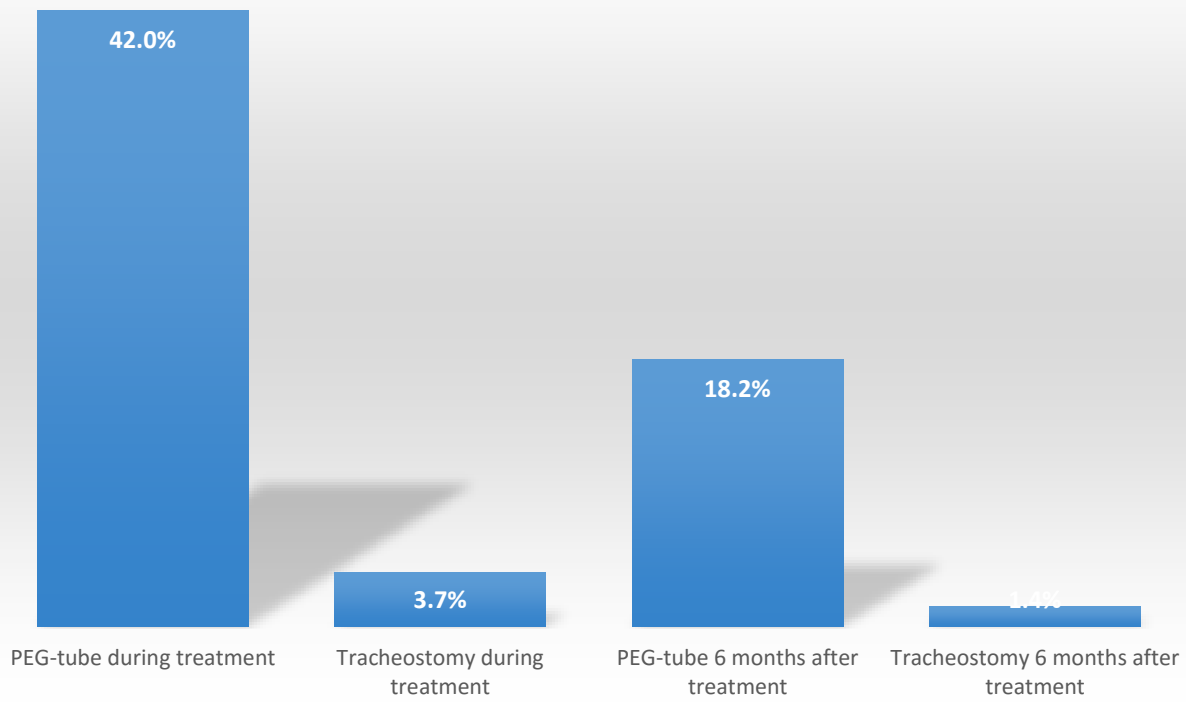
Surgical Complications



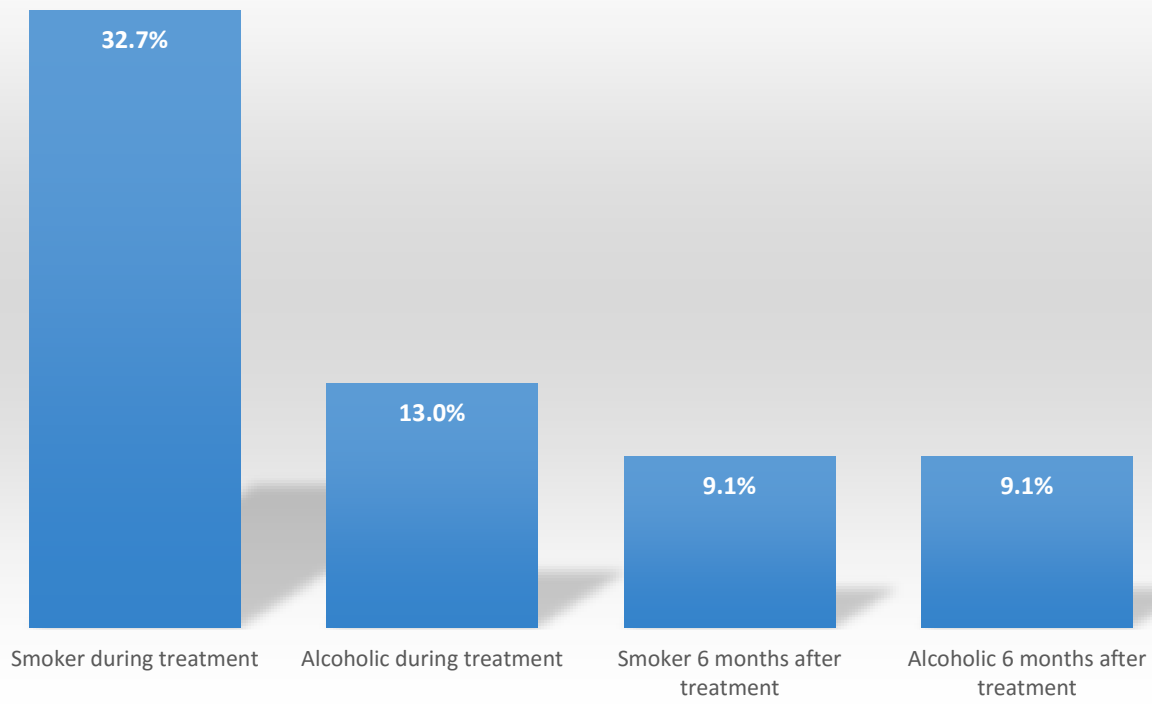
ChemoXRT Complications



Functional Characteristics



Habits



Based on this data, it was decided to focus on four independent variables, academic vs. non-academic treatment, distance from radiation treatment site, HPV status, and insurance type. The outcomes data was then analyzed for mean values across those variables. They are shown in the table below, with the number of patients of each type at the bottom:

	Closer than 15 miles	Greater than 15 miles	HPV Positive	HPV Negative	Academic	Non-academic	Private	Medicare	Medicaid	Uninsured	Other
Overall Survival	90.9%	96.4%	92.6%	69.2%	88.9%	88.9%	92.4%	78.3%	92.3%	100.0%	95.0%
Disease Specific Survival	90.9%	96.4%	92.6%	69.2%	88.9%	88.9%	92.4%	78.3%	92.3%	100.0%	95.0%
Disease Free Survival	84.8%	74.5%	78.7%	53.8%	74.4%	75.0%	79.7%	60.9%	92.3%	50.0%	80.0%
Recurrence Rate	4.9%	21.2%	12.0%	26.3%	16.9%	9.8%	13.3%	21.6%	0.0%	0.0%	11.1%
Surgical Site Infection	1.5%	1.8%	1.5%	3.8%	1.1%	2.8%	1.3%	4.3%	0.0%	0.0%	0.0%
Flap Loss	0.0%	0.0%	0.7%	0.0%	0.0%	1.4%	1.3%	0.0%	0.0%	0.0%	0.0%
30 Day Readmission	4.2%	5.7%	6.2%	6.7%	7.0%	5.5%	3.4%	10.7%	0.0%	25.0%	6.7%
Admission during ChemoXRT	12.1%	14.5%	14.1%	7.7%	16.9%	8.3%	11.4%	15.6%	23.1%	25.0%	5.0%
Salvage Surgery	3.0%	3.6%	4.4%	3.8%	4.4%	4.2%	3.8%	2.2%	0.0%	0.0%	15.0%
Renal Damage	14.8%	9.1%	13.6%	0.0%	11.8%	11.3%	9.5%	21.2%	0.0%	0.0%	6.3%
Hearing Loss	1.9%	4.5%	1.0%	16.7%	2.9%	3.8%	3.2%	0.0%	14.3%	0.0%	6.3%
G tube during treatment	54.5%	34.5%	39.0%	57.7%	45.6%	37.5%	34.2%	45.7%	46.2%	50.0%	60.0%
Trach during treatment	3.0%	1.8%	2.2%	11.5%	4.4%	2.8%	2.5%	6.5%	7.7%	0.0%	0.0%
G tube after treatment	25.0%	14.0%	17.1%	25.0%	19.5%	16.7%	9.6%	28.9%	9.1%	25.0%	35.3%
Trach after treatment	0.0%	2.0%	0.8%	5.0%	2.6%	0.0%	0.0%	5.3%	0.0%	0.0%	0.0%
Smoker during treatment	36.4%	25.5%	26.5%	65.4%	28.9%	37.5%	25.3%	45.7%	38.5%	25.0%	30.0%
Alcoholic during treatment	10.6%	16.4%	12.5%	15.4%	10.0%	16.7%	8.9%	19.6%	23.1%	25.0%	5.0%
Smoker after treatment	10.0%	10.0%	7.3%	20.0%	10.4%	7.6%	8.2%	7.9%	18.2%	0.0%	11.8%
Alcoholic after treatment	6.7%	12.0%	8.9%	10.0%	9.1%	9.1%	8.2%	13.2%	9.1%	0.0%	5.9%
N value	66	55	136	26	90	72	79	46	13	4	20

Univariate analysis was conducted for the independent variables found in the table above against the functional outcomes that were documented through tumor registry:

	Gender	Age	Insurance	Stage	HPV status	Treatment type	Academic Center	Treatment Distance
OS	0.824	0.007	0.06	0.999	0.002	0.002	0.738	0.998
DSS	0.824	0.007	0.06	0.999	0.002	0.002	0.738	0.998
DFS	0.993	0.029	0.029	0.154	0.006	0.003	0.885	0.766
Recurrence	0.808	0.416	0.265	0.999	0.102	0.999	0.286	0.041
SSI	0.552	0.844	0.941	0.999	0.331	0.375	0.546	0.998
Flap Loss	0.999	0.594	0.998	0.999	0.999	0.996	0.999	1
30 day readmission	0.497	0.734	0.139	0.999	0.943	0.368	0.733	0.965
Admission during chemoXRT	0.593	0.173	0.112	0.297	0.663	0.207	0.079	0.523
Salvage	0.96	0.097	0.035	0.999	0.998	0.998	0.942	0.258
Renal damage	0.999	0.461	0.273	0.999	0.999	1	0.832	0.757
Hearing Loss	0.403	0.724	0.045	0.999	0.023	1	0.647	0.582
G tube treatment	0.731	0.195	0.104	0.236	0.081	0.298	0.341	0.267
Trach during treatment	0.936	0.524	0.289	0.999	0.038	0.999	0.642	0.998
G tube after treatment	0.915	0.064	0.348	0.525	0.397	0.056	0.695	0.743
Trach after treatment	0.998	0.685	0.999	0.999	0.195	0.81	0.997	0.997
Smoker during	0.831	0.011	0.021	0.803	0	0.03	0.247	0.275
Alcoholic during	0.444	0.998	0.091	0.878	0.689	0.618	0.635	0.55
Smoker after	0.409	0.998	0.999	0.999	0.08	0.999	0.58	0.562
Alcoholic after	0.402	0.999	0.999	0.924	0.879	0.999	0.977	0.73

In the results shown above, any values found to be approaching significance ($p < 0.2$) are highlighted in yellow, while any values that were found to be significant ($p < 0.05$) are highlighted in green.

Multivariate analysis was then conducted for Insurance type, HPV status, Academic vs Non-academic center, and treatment distance for patients treated with radiation. For each of these variables, gender, age, stage, and treatment type were controlled for. The results are presented below, with significant variables highlighted in green.

	Overall Survival	Disease Specific Survival	Disease Free Survival	Recurrence Rate	Surgical Site Infection	30 Day Readmission	Admission during ChemoXRT	Salvage Surgery	Renal Damage	Hearing Loss	Gtube during treatment	Trach during treatment	Gtube after treatment	Trach after treatment	Smoker during treatment	Alcoholic during treatment	Smoker after treatment	Alcoholic after treatment	
Insurance	0.778	0.778	0.12	0.115	0.079	0.999	0.295	0.743	0.998	0.233	0.33	0.783	0.673	0.073	0.997	0.29	0.027	0.306	0.102
HPV	0.024	0.024	0.015	0.096	0.407	0.999	0.869	0.44	0.998	0.999	0.021	0.164	0.067	0.563	0.325	0.001	0.473	0.041	0.79
Academic	0.845	0.845	0.934	0.194	0.668	0.999	0.522	0.092	0.997	0.94	0.658	0.481	0.57	0.784	0.997	0.188	0.336	0.411	0.973
Radiation Distance	0.998	0.998	0.686	0.023	0.998	0.999	0.901	0.449	0.258	0.819	0.568	0.33	0.998	0.817	0.996	0.305	0.48	0.508	0.754

In the data above, Insurance type is found to be significant for alcoholic during treatment. This was found to be significant when comparing private insurance against Medicare patients.

Patient Reported Outcomes

There were 55 patients who completed the survey. Other patients could not be reached despite repeated attempts, or declined to participate. The mean time since treatment complete was 32.27 ± 6.71 months. The data was broken down similarly to above, based on Treatment distance, HPV status, Academic vs Non-academic center, and distance to radiation treatment site.

	Closer than 15 miles	Greater than 15 miles	HPV Positive	HPV Negative	Academic	Non-academic	Private	Medicare	Medicaid	Uninsured	Other
Pain	0.0%	9.8%	5.9%	25.0%	7.8%	6.4%	5.1%	14.4%	2.8%	0.0%	4.2%
Swallowing	17.8%	18.2%	14.9%	54.2%	19.2%	15.5%	13.6%	32.2%	2.8%	8.3%	8.3%
Senses Problems	27.3%	14.4%	16.3%	50.0%	20.7%	15.9%	16.2%	30.0%	0.0%	16.7%	8.3%
Speech Problems	18.7%	13.1%	12.2%	72.2%	15.8%	17.7%	9.1%	32.6%	7.4%	38.9%	11.1%
Trouble with social eating	22.3%	12.1%	15.2%	66.7%	22.0%	14.4%	13.9%	35.6%	5.6%	16.7%	0.0%
Trouble with Social Contact	6.4%	3.6%	4.3%	25.0%	8.7%	1.5%	4.0%	12.0%	0.0%	0.0%	3.3%
Less Sexuality	15.2%	12.9%	12.7%	0.0%	15.2%	6.8%	8.1%	14.4%	5.6%	0.0%	75.0%
Teeth	28.8%	18.2%	22.2%	8.3%	25.3%	15.2%	25.3%	22.2%	0.0%	0.0%	0.0%
Opening Mouth	12.1%	25.8%	16.3%	25.0%	17.2%	16.7%	18.2%	13.3%	0.0%	0.0%	66.7%
Dry Mouth	60.6%	56.1%	54.9%	50.0%	48.5%	63.6%	59.6%	55.6%	11.1%	50.0%	33.3%
Sticky Saliva	31.8%	24.2%	24.2%	58.3%	28.3%	24.2%	23.2%	44.4%	11.1%	0.0%	0.0%
Coughing	30.3%	28.8%	24.2%	41.7%	22.2%	30.3%	23.2%	33.3%	0.0%	16.7%	50.0%
Felt ill	12.1%	12.1%	8.5%	25.0%	15.2%	1.5%	5.1%	20.0%	0.0%	33.3%	0.0%
Pain Killers	36.4%	27.3%	29.4%	50.0%	33.3%	27.3%	24.2%	46.7%	33.3%	0.0%	50.0%
Nutritional Supplements	31.8%	27.3%	23.5%	75.0%	30.3%	22.7%	24.2%	33.3%	33.3%	50.0%	0.0%
Feeding Tube	4.5%	4.5%	0.0%	75.0%	6.1%	4.5%	0.0%	20.0%	0.0%	0.0%	0.0%
Weight Loss	13.6%	4.5%	9.8%	50.0%	21.2%	0.0%	9.1%	26.7%	0.0%	0.0%	0.0%
Weight Gain	22.7%	31.8%	27.5%	25.0%	21.2%	36.4%	27.3%	26.7%	33.3%	0.0%	50.0%
N Value	22	22	51	4	33	22	33	15	3	2	2

Univariate analysis was then conducted on patient reported outcomes, once they had been transformed into standardized metrics, as detailed in the methods section.

	Gender	Age	Insurance	Stage	HPV status	Treatment type	Academic Center	Treatment Distance
Pain	0.039	0.194	0.304	0.231	0.002	0.389	0.852	0.366
Swallowing	0.607	0.045	0.054	0.934	0.003	0.557	0.589	0.759
Senses Problems	0.384	0.025	0.25	0.003	0.026	0.792	0.024	0.028
Speech Problems	0.332	0.115	0.003	0.591	0.748	0.941	0.839	0.314
Trouble with Social Eating	0.641	0.255	0.081	0.773	0.157	0.947	0.151	0.046
Trouble with Social Contact	0.469	0.506	0.494	0.268	0.001	0.598	0.009	0.459
Less Sexuality	0.991	0.032	0.006	0.107	0.049	0.51	0.07	0.418
Teeth	0.092	0.053	0.543	0.38	0.07	0.841	0.045	0.028
Opening Mouth	0.05	0.475	0.182	0.589	0.217	0.568	0.674	0.02
Dry Mouth	0.594	0.499	0.17	0.566	0.574	0.008	0.009	0.959
Sticky Saliva	0.684	0.174	0.122	0	0.107	0.635	0.188	0.542
Coughing	0.383	0.131	0.462	0.566	0.142	0.525	0.145	0.536
Felt Ill	0.032	0.74	0.082	0.02	0.172	0.564	0	0.815
Pain Killers	0.007	0.216	0.625	0.647	0.403	0.979	0.634	0.518
Nutritional Supplements	0.324	0.417	0.439	0.999	0.058	0.519	0.538	0.741
Feeding Tube	0.496	0.472	1	0.999	0.997	0.983	0.809	1
Weight Loss	0.776	0.232	0.671	0.081	0.045	0.167	0.998	0.317
Weight Gain	0.571	0.217	0.973	0.999	0.916	0.966	0.221	0.5

Multivariate analysis was then conducted for insurance type, HPV status, radiation treatment distance, and academic vs non-academic center while controlling for age, gender, stage, and treatment types. The results are presented below, with significant variables highlighted in green.

	Pain	Swallowing	Senses Problems	Speech Problems	Trouble with social eating	Trouble with Social Contact	Less Sexuality	Teeth	Opening Mouth	Dry Mouth	Sticky Saliva	Coughing	Felt Ill	Pain Killers	Nutritional Supplements	Feeding Tube	Weight Loss	Weight Gain
Insurance	0.02	0.007	0.434	0.075	0.008	0.153	0.796	0.893	0.986	0.049	0.008	0.675	0.004	0.223	0.96	0.998	0.997	0.879
HPV	0.276	0.004	0.046	0	0.004	0.026	0	0.46	0.09	0.628	0.123	0.387	0.382	0.893	0.119	0.995	0.029	0.752
Academic	0.784	0.686	0.88	0.429	0.272	0.045	0.187	0.711	0.972	0.154	0.732	0.372	0.031	0.873	0.44	0.873	0.998	0.203
Radiation Distance	0.801	0.832	0.066	0.391	0.205	0.061	0.579	0.347	0.06	0.657	0.426	0.529	0.818	0.671	0.682	0.969	0.497	0.679

In the data above, Insurance type was found to be significant for a number of factors.

For all factors except dry mouth, the data presented was significant for private

insurance vs Medicare only. For dry mouth, it was found to be significant when comparing private insurance to Medicaid patients.

Conclusion

National Data

Patients diagnosed with a head or neck cancer often have a difficult and protracted course of treatment before them. Many patients seek additional information about their prognosis, as well as how their particular institution performs. In this study, systemic analysis of what information was available to patients at the NCI designated Cancer Centers across the country was obtained. In addition, it was shown that it is feasible to construct an informational book that would provide data in accordance with American Association of Head and Neck Surgery guidelines.

In the analysis of the 62 cancer centers across the United States, it was shown that there was minimal data regarding their cancer center's structural, process, and outcomes metrics that was available to the public. Cancer centers that provide any quality and outcomes metrics accessible to patients should be commended, but this study shows that there is great opportunity to improve transparency, reporting, and data to patients. The United Kingdom, and parts of Canada have much more sophisticated means of measuring and publicly reporting outcomes to guide decision-making and policy with the goal of optimizing H&N cancer care across the country. This paper proposes a system whereby H&N cancer programs at the 62 NCI-designated cancer centers could voluntarily but systematically, report a particular set of H&N specific

structural, process, and outcome metrics for public consumption. The initial goal would be for benchmarking and transparency, with the ultimate goal being to elevate the quality and outcomes of head and neck cancer care at each of these sites and possibly throughout the country.

Yale Data

In the analysis of Yale data, it was shown using tumor registry data was both reliable and feasible for a number of metrics. The registry data was able to isolate patients who had head and neck cancer, as well as provide comprehensive data on a number of metrics. In addition to general demographic data, the tumor registry was able to provide detailed information regarding key process metrics, as well as some morbidity and mortality information. However, many of the outcomes metrics that are most relevant to head and neck cancer patients were not catalogued by the tumor registry, and had to be found by chart review.

The outcomes books demonstrated that the demographic data regarding head and neck patients was in line with national statistics regarding patients. In addition, the functional data regarding survival rates was also in line with national statistics. However, it also showed that there are several areas in which improvements could be made. Most notably, in many of the process metrics related to monitoring and treatment by ancillary staff, there were very few patients who were seen at an appropriate time, whether it was pre-treatment, during treatment, or post-treatment. There is no national data available regarding these metrics, so it is unclear if the program at Yale is an outlier, or if it is in line with other cancer centers. At Yale, steps have already been taken to start

remedying these issues. A smoking cessation specialist has been hired, and physicians are now working more closely with speech pathologists, nutritionists, audiologists, and other ancillary staff to provide more comprehensive care.

Oropharyngeal Patients

The demographic data for the oropharyngeal patients analyzed were in line with national data, with a higher rate of cancer among males, usually between 55 and 75. There was also a much higher rate of HPV positive cancers as well as late stage cancers, which is again in line with national data. The outcomes data for one year survival, as well as recurrence rates were also in line with national data. Much of the other data could not be compared to national data, because it does not exist, to our knowledge.

The data analysis demonstrated many different effects, but was also notable for the areas in which it did not demonstrate a difference. The data demonstrated that rates of alcoholism were higher for Medicare patients compared to patients with private insurance. This could demonstrate that patients on Medicare need to be monitored more carefully for alcoholic tendencies and treated as soon as possible, so that it interferes with their treatment as little as possible. The HPV positive patients demonstrated improved overall survival, disease specific survival, and disease free survival, which is consistent with national data regarding survival rates. It also demonstrated smaller rates of hearing loss when treated with cisplatin. This could indicate that patients with HPV negative cancer need to be monitored more carefully during chemotherapy to make sure they are receiving adequate hydration and other preventative measures to limit the toxicity of cisplatin. Finally, HPV negative patients

were much more likely to be smokers during and after treatment. As almost all oropharyngeal cancers are caused by either HPV or smoking, it seems clear that patients who had an HPV negative cancer would be more likely to be smokers. Interestingly, academic vs non-academic center demonstrated no difference in any functional outcome metric, demonstrating that care in terms of these metrics is equivalent. Finally, the analysis also demonstrated that recurrence rates in oropharyngeal patients were higher for patients that lived over 15 miles away. This may indicate that patients who live further away from their treatment sites may miss more appointments, or are unable to get proper follow-up as much as patients who live closer to their treatment site. However, further analysis must be conducted.

Patient Reported Outcomes

Patient reported outcomes showed differences in outcomes in several different areas.

Private insurance patients were much less likely than Medicare patients to suffer from high rates of pain, swallowing difficulty, trouble with social eating, sticky saliva, and feeling ill. These factors can be monitored more closely for Medicare patients, to alleviate the issues they have with their treatment. The data also demonstrated that private practice patients were much more likely to have dry mouth compared to Medicaid patients. Dry mouth is a problem many patients suffer from after radiation treatment, and should be monitored for in all patients. The patients who were HPV positive had noticeably better patient reported outcomes in a number of metrics, including swallowing, senses problems, speech problems, social eating, social contact, and weight loss. As with the issues HPV negative patients had in terms of functional

outcomes, they can be monitored for these issues more closely. The one area in which HPV positive patients did worse was in terms of decreased sexuality. This could be due to a number of factors that were not accounted for, such as whether one group was more likely to have a partner or engage in sexual behavior prior to treatment.

Patient reported outcomes demonstrated that distance to radiation treatment site did not have significant impact on quality of life. However, in various categories, patients who received some of their treatment at non-academic centers had better quality of life. This could indicate that long term outcomes when there is adjuvant therapy at non-academic centers are superior to outcomes when treatment is exclusively at academic centers. However, other possibilities include that the sample size was insufficient or that there were other confounding factors that were not controlled for.

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