

# Head and Neck Cancer Management in North Carolina: Updates for 2020

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## Disclosures

None.

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**Historically**

**2020**

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## Case

Ramses T. Heel is a 55 year old white male who presents for follow up. You initially met him three weeks ago after he discovered a painless neck mass while shaving. He has noted "on and off" sore throat for the last 2 months but thought it was allergies. He denies any other symptoms including pain with swallowing, shortness of breath or weight loss.

His past medical history (PMH) is significant for asthma and well controlled hypertension on lisinopril. He has a 5 pack year smoking history during college (1980s) and drinks alcohol socially. His family history is significant for breast cancer (mother and older sister). He travels to China yearly for business for the last 10 years.

You ordered a CT neck, which showed a 3cm mass and subsequently referred him to ENT. Endoscopic evaluation reveals a 1 cm right tonsillar mass. An ultrasound guided FNA was performed in office. Pathology returned positive for squamous cell carcinoma. Additional diagnostic testing is pending.

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## Learning Objectives

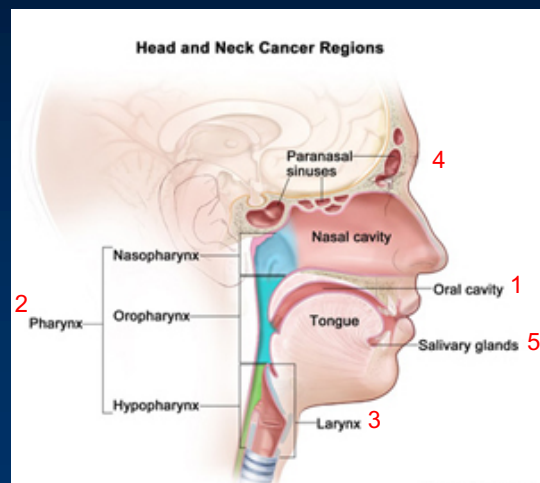
- Understand key risk factors and critical anatomy associated with head and neck cancers
- Distinguish differences in biology, prognosis, and treatment between HPV associated head and neck cancer and non-HPV associated head and neck cancer
- Recognize and familiarize findings from seminal head and neck cancer clinical trials in the last 2 years



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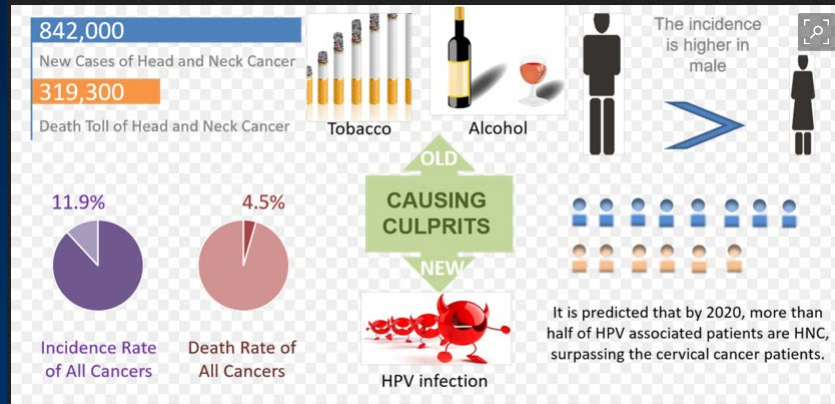
## Head and Neck Cancer Anatomy

- Pathology: SCC
- 5 main anatomical locations
- Location is influenced by risk factor



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# Statistics and Epidemiology



ACS Facts and Figures, 2018; Advanced Science News, 2017



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# HNSCC TNM Staging is Complex

Change	7th Ed. (2010)	8th Ed. (2017)	
		Oral Cavity	HPV- Oropharynx / HPV+ Oropharynx
T-stage	<p><b>T0:</b> no primary</p> <p><b>T1:</b> size ≤2cm</p> <p><b>T2:</b> size 2-4cm</p> <p><b>T3:</b> size &gt;4cm</p> <p><b>T4:</b></p> <ul style="list-style-type: none"> <li>o T4a: moderately advanced (extrinsic tongue muscle involvement constituted T4a)</li> <li>o T4b: very advanced</li> </ul>	<ul style="list-style-type: none"> <li>• <b>T0</b> deleted</li> <li>• <b>T1:</b> size ≤2cm and DOI ≤5mm</li> <li>• <b>T2:</b> size ≤2cm and DOI 5-10mm or size 2-4cm and DOI ≤10mm</li> <li>• <b>T3:</b> size &gt;4cm or &gt;10mm DOI</li> <li>• <b>T4a</b> extrinsic tongue muscle infiltration now deleted</li> </ul>	<ul style="list-style-type: none"> <li>• <b>T0</b> deleted</li> <li>• <b>T0</b> if proven p16+ disease without evidence of primary tumor</li> <li>• All locally advanced combined to T4</li> </ul>
N-stage	<p><b>N0:</b> no LN involved</p> <p><b>N1:</b> single ipsi LN ≤3cm in size</p> <p><b>N2:</b></p> <ul style="list-style-type: none"> <li>o N2a: single ipsi LN, 3-6cm in size</li> <li>o N2b: multiple ipsi LNs, all ≤6cm in size</li> <li>o N2c: any bi or ctr LNs, all ≤6cm in size</li> </ul> <p><b>N3:</b> any LN &gt;6cm in size</p>	<p><b>Clinical N-stage</b></p> <ul style="list-style-type: none"> <li>• <b>N1-N2</b> is same as previous and ENE(-)</li> <li>• <b>N3</b> now with subcategories:                             <ul style="list-style-type: none"> <li>o N3a is previous N3 (size &gt;6cm) and ENE(-)</li> <li>o N3b is any ENE(+), either clinical or radiographic</li> </ul> </li> </ul>	
		<p><b>Pathological N-stage</b></p> <ul style="list-style-type: none"> <li>• Microscopically evident ENE(+) LNs results in upstaging</li> </ul>	
Stage grouping	Clinical or pathological TNM used for same grouping system	Same as previous	
			<p><b>Separate clinical and pathological TNM groupings</b></p> <ul style="list-style-type: none"> <li>• <b>N1:</b> &lt;4 LNs involved</li> <li>• <b>N2:</b> &gt;4 LNs involved</li> <li>• <b>N3</b> deleted</li> </ul>



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## Rate of metastatic disease at initial presentation for common cancers

Site	Metastatic Rate (%)	Source
Breast Cancer	6-10%	MBCN.org 2016
Colorectal Cancer	25%	Engstrand. BMC Cancer. 2018
Cervical Cancer	13%	Li. J Gynecol Oncol. 2016
NSCLC	25-40%	ACS 2017
Pancreatic Cancer	30-50%	ACS 2018
Prostate Cancer	5%	ACS 2018



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## HNSCC rarely presents as metastatic disease

Site	Total in SEER	Number Metastatic at Presentation	Percentage	95% CI
Lip	5,975	20	0.33%	0.20-0.52%
Oral Cavity	16,385	320	1.95%	1.75-2.18%
Oropharynx	17,783	729	4.10%	3.81-4.40%
Hypopharynx	1,866	128	6.86%	5.75-8.10%
Supraglottis	8,114	270	3.33%	2.95-3.74%
Glottis	13,085	87	0.66%	0.53-0.82%
Subglottis	356	12	3.37%	1.75-5.81%
Sinus	1,068	69	6.46%	5.06-8.11%
Nasopharynx	2,610	177	6.78%	5.85-7.81%



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## Non-metastatic HNSCC

- Stage at diagnosis: early stage (40%) and locally advanced (LA), 50%)
- Prognosis for LA-HNSCC remains poor
- Treatment options:
  1. Primary surgery followed by post-operative RT  $\pm$  chemotherapy
  2. Concurrent chemoradiation therapy (cCRT)



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## HPV-ASSOCIATED HNSCC



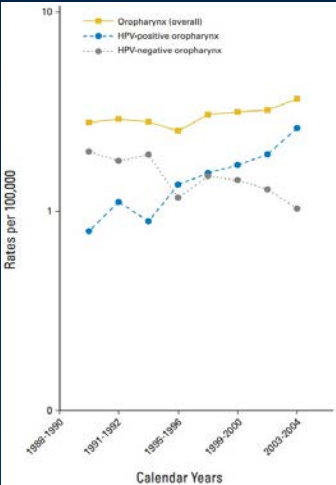
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## HPV and the rise of oropharynx cancer in the US

VOLUME 29 · NUMBER 32 · NOVEMBER 10 2011

JOURNAL OF CLINICAL ONCOLOGY

ORIGINAL REPORT



**↑28% in all OPSCC**  
2.6→3.6 cases/100k

**↑225% in HPV+ OPSCC**  
0.8→2.6 cases/100k

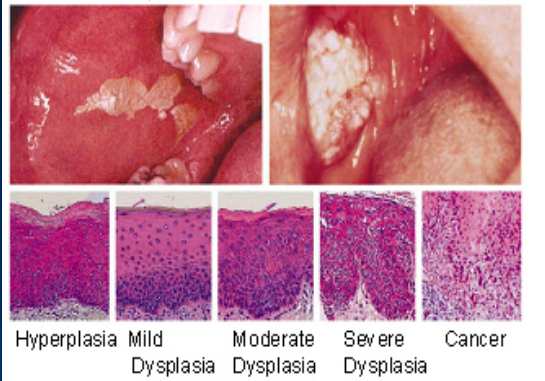
**↓50% in HPV- OPSCC**  
2.0→1.0 cases/100k

Chatruvedi et al, J Clin Oncol, 29(32), 2011

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## What is HPV?

- >100 types of HPV have been classified to date
  - HPV 16 is most commonly associated with OPSCC
  - Sometimes HPV 18, 31 or 33
  - Rarely other “high risk” types
- Also causes gynecological, anal, penile cancers
- HPV DNA is detected in 65% of OPSCC (tonsil & base of tongue)

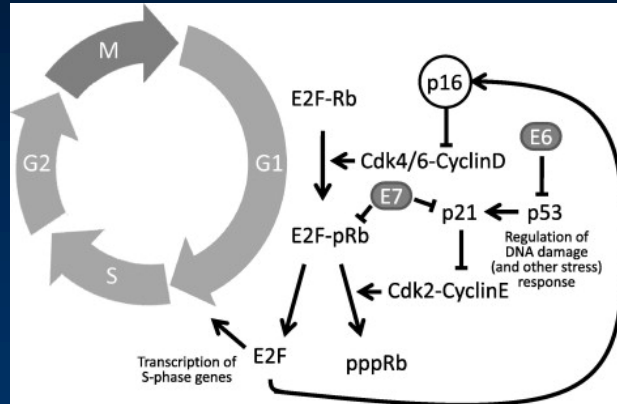


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## Viral oncogenes and p16 expression

- E6/E7 viral oncoproteins
  - E6 inactivates p53
  - E7 inactivates Rb
- Over expression of E2F leading to p16 expression
- >80% malignant cells positive by p16 IHC correlates with HPV+



Chan PK et al, *Crit Rev Clin Lab Sci* 49:117, 2012;  
 Darragh TM et al, *Arch Pathol Lab Med* 136:1266, 2012

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## How to test for HPV?

Base of Tongue/Tonsil/Posterior Pharyngeal Wall/Soft Palate  
 WORKUP

• Tumor human papillomavirus (HPV) testing by p16 immunohistochemistry (IHC) required<sup>a</sup>

- H&P<sup>b,c</sup> including a complete head and neck exam; mirror and fiberoptic examination as clinically indicated
- Biopsy of primary site or fine-needle aspiration (FNA) of the neck
- CT with contrast and/or MRI with contrast of primary and neck
- As clinically indicated:
  - ▶ Preanesthesia studies
  - ▶ FDG-PET/CT
  - ▶ Chest CT<sup>d</sup> (with or without contrast)
  - ▶ Dental evaluation,<sup>e</sup> including Panorex
  - ▶ Nutrition, speech and swallowing evaluation/therapy, and audiogram<sup>f</sup>
  - ▶ EUA with endoscopy<sup>g</sup>

Multidisciplinary consultation as clinically indicated

p16-negative

p16 (HPV)-positive

Tests for HPV status

- p16 IHC
- HPV ISH
- HPV PCR

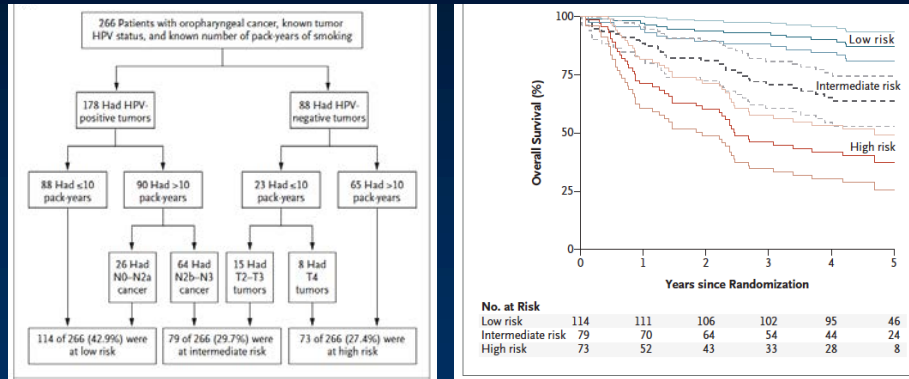


**NCCN Guidelines Version 3.2019**  
**Cancer of the Oropharynx**

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## RTOG 0129: Risk Stratification in Oropharynx Cancer



	Low Risk	Intermediate Risk	High Risk
3 year OS	93%	71%	46%

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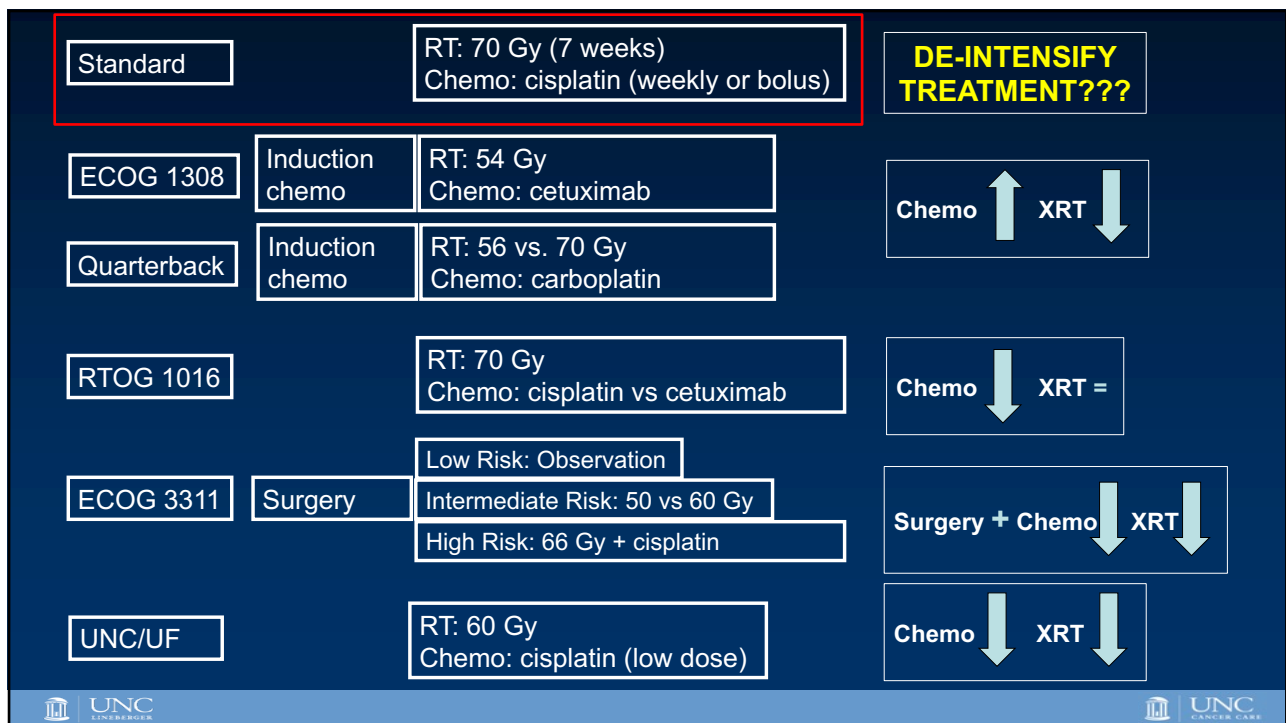
## HPV and HNSCC prognosis

- 87% are HPV positive HNSCC are non-smokers and light drinkers
- Higher sensitivity to chemoradiation
- Independent predictor for overall survival
- Superior survival regardless of stage at diagnosis

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# Treatment of HPV-associated HNSCC

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## Are All HPV-Associated OPSCC the same?

**Phase II study of N=80 patients**

- Stage III/IV HPV-associated OPSCC
- Regardless of smoking status

E1308: Phase II Trial of Induction Chemotherapy Followed by Reduced-Dose Radiation and Weekly Cetuximab in Patients With HPV-Associated Resectable Squamous Cell Carcinoma of the Oropharynx— ECOG-ACRIN Cancer Research Group

**Neoadjuvant chemotherapy (3 cycles, every 21 days)**

- Cisplatin 75mg/m<sup>2</sup>
- Paclitaxel 90 mg/m<sup>2</sup>
- Cetuximab 400 mg/m<sup>2</sup> (cycle 1 day 1), then 250mg/m<sup>2</sup> weekly

↓

**Response to induction chemotherapy**

- Primary site = manual and endoscopic
- Nodal sites = palpation

→ 70% had cCR at primary site (56 patients)

↓

51 pts with cCR received cetuximab + 54 Gy  
 8 pts with <cCR received cetuximab + 54 Gy  
 9 pts w/o IC response received cetuximab + 70 Gy (SOC)

→ **OUTCOMES?**

J Clin Oncol 34. © 2016

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Cohort	2-Year PFS (95% CI)	2-Year OS (95% CI)
All patients (N = 80)	0.78 (0.67 to 0.86)	0.91 (0.82 to 0.96)
cCR to IC, RRD 54 Gy (n = 51)	0.80 (0.65 to 0.89)	0.94 (0.84 to 0.99)
All cCR/PR/SD to IC, RRD = 54 Gy (n = 62)	0.81 (0.69 to 0.89)	0.93 (0.83 to 0.97)
SRD <sup>15</sup>	0.67 (0.38 to 0.85)	0.87 (0.56 to 0.96)
Subsets cCR to IC, treated on RRD (n = 51)		
Cohort	0.90 (0.71 to 0.97)	0.97 (0.79 to 0.995)
Smoker > 10 pk-yr <sup>21</sup>	0.65 (0.41 to 0.82)	0.90 (0.66 to 0.97)
Smoker ≤ 10 pk-yr, and < T4N2c <sup>41</sup>	0.95 (0.71 to 0.99)	0.95 (0.71 to 0.99)
Smoker > 10 pk-yr or T4 or N2c <sup>30</sup>	0.69 (0.49 to 0.83)	0.93 (0.75 to 0.98)
Non-T4a (n = 45)	0.84 (0.69 to 0.92)	0.95 (0.83 to 0.99)
T4a <sup>6</sup>	0.50 (0.11 to 0.80)	0.83 (0.27 to 0.97)
N2c <sup>15</sup>	0.73 (0.44 to 0.89)	0.93 (0.61 to 0.99)
Non-N2c (n = 36)	0.82 (0.65 to 0.92)	0.94 (0.79 to 0.99)

Abbreviations: cCR, complete clinical response; IC, induction chemotherapy; pk-yr, pack-year; OS, overall survival; PFS, progression-free survival; PR, partial response; RRD, reduced radiation dose; SD, stable disease; SRD, standard radiation dose.

Median f/u = 35 months



**Key Study Findings:**

1. Outcomes were good with IC strategy and de-intensification of CRT
2. All HPV+ patients with recurrences occurred in those with >10 pack years smoking history

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## Key Takeaways:

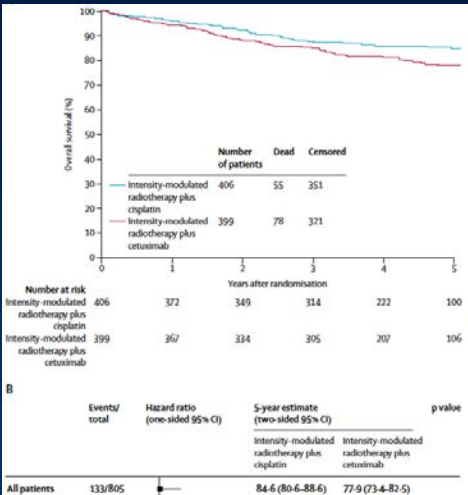
1. Risk factors matter for prognosis
2. Patients with HPV associated OPSCC **who smoke <10 pack years** are lowest risk.

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## Does the type of systemic therapy matter? 70 Gy + Cetuximab vs. Cisplatin, HPV-associated OPSCC

### RTOG 1016



	Number of patients	Dead	Censored
Intensity-modulated radiotherapy plus cisplatin	406	55	351
Intensity-modulated radiotherapy plus cetuximab	399	78	321

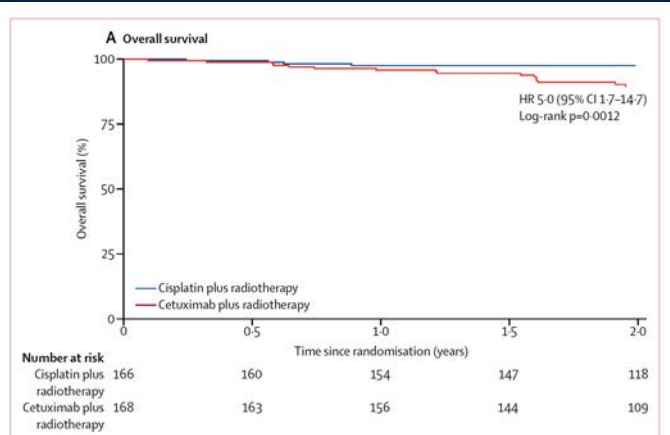
  

Number at risk	Years after randomisation					
	0	1	2	3	4	5
Intensity-modulated radiotherapy plus cisplatin	406	372	349	314	222	100
Intensity-modulated radiotherapy plus cetuximab	399	367	334	305	207	106



  

Events/total	Hazard ratio (one-sided 95% CI)	5-year estimate (two-sided 95% CI)		p value
		Intensity-modulated radiotherapy plus cisplatin	Intensity-modulated radiotherapy plus cetuximab	
All patients	133/805	84.6 (80.6-88.6)	77.9 (73.4-82.5)	

### De-ESCALaTE:



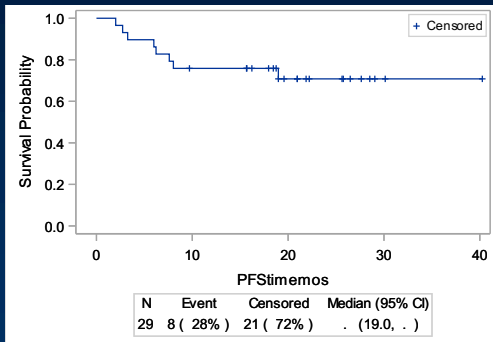
Number at risk	Time since randomisation (years)				
	0	0.5	1.0	1.5	2.0
Cisplatin plus radiotherapy	166	160	154	147	118
Cetuximab plus radiotherapy	168	163	156	144	109

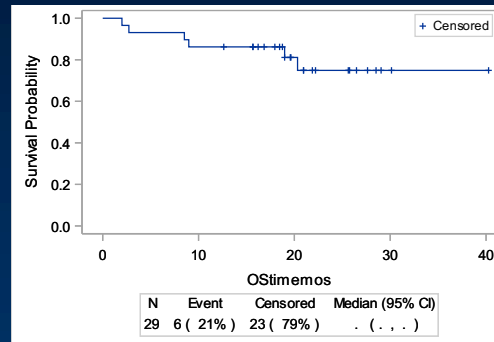
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## What about Radiation + Immunotherapy?

1 Year PFS = 76%



1 Year OS = 86%



Weiss J, Sheth S, et al. Concurrent definitive immunoradiotherapy for patients with Stage III-IV Head and Neck Cancer with cisplatin contraindication. *Clinical Cancer Research*. 2020. In Press.

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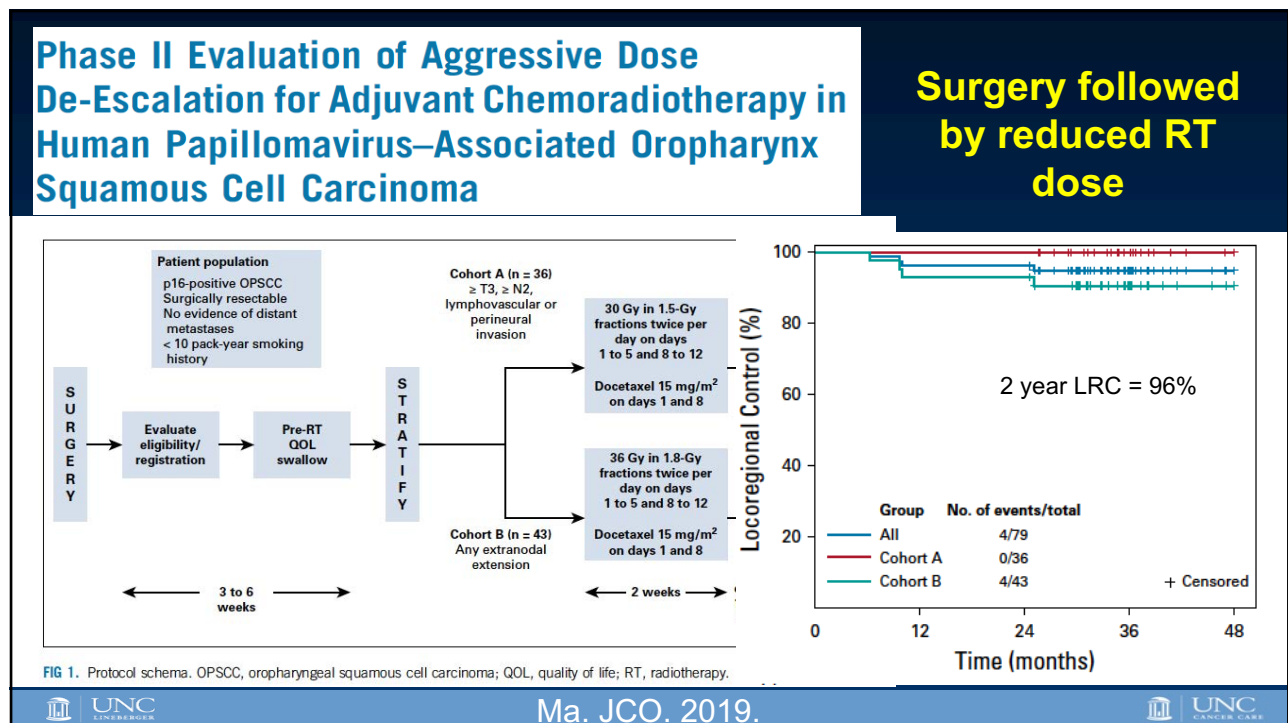
### Key Takeaway:

In patients with HPV+ LA-OPSCC receiving curative therapy, **cisplatin + radiation therapy** remains the standard of care

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# What about treatment options involving surgery?

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# Is surgery an option?

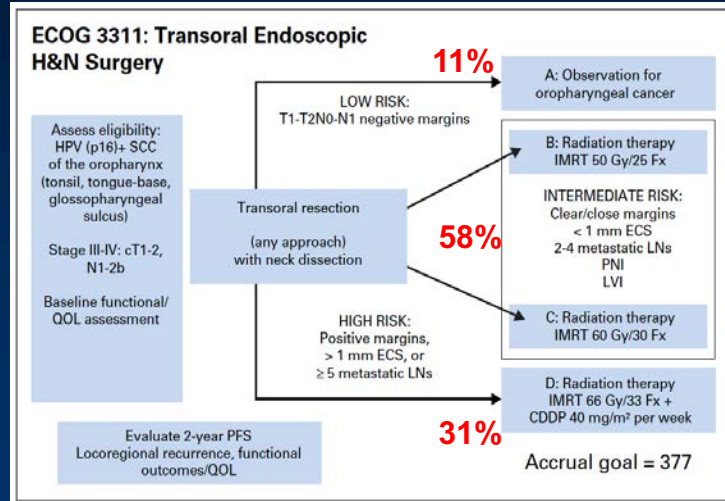
Yes.

TORS = Trans-oral robotic surgery

- Minimally invasive
- Less risks

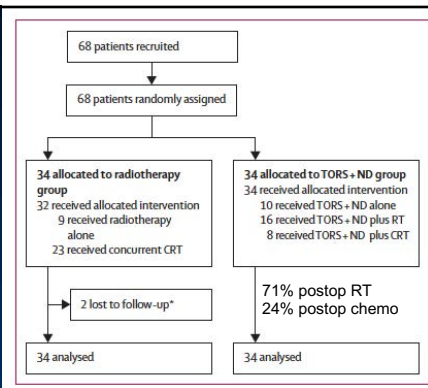
ECOG 3311:

- Study open since 2013
- Enrolled 511 pts as of 8/1/2018
- Key results this month!?



*J Clin Oncol 33:3285-3292.*

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## Radiotherapy versus transoral robotic surgery and neck dissection for oropharyngeal squamous cell carcinoma (ORATOR): an open-label, phase 2, randomised trial

Primary endpoint: Dysphagia @ 1 year

	1 year				Clinically meaningful decline*		
	RT group	TORS + ND group	Effect estimate (95% CI)	p value†	RT group	TORS + ND group	p value
<b>Total (primary endpoint)</b>	86.9 (11.4)	80.1 (13.0)	6.7 (0.2 to 13.2)	0.042	7/27 (26%)	11/27 (41%)	0.25
Global	89.6 (15.1)	79.3 (22.6)	10.3 (0.2 to 20.4)	0.046	6/27 (22%)	14/27 (52%)	0.024
Emotional	88.8 (12.0)	81.3 (12.5)	7.4 (0.9 to 14.0)	0.027	5/27 (19%)	13/27 (48%)	0.021
Functional	89.9 (11.5)	86.5 (12.0)	3.4 (-2.9 to 9.6)	0.28	7/27 (26%)	9/26 (35%)	0.49
Physical	83.1 (14.1)	75.3 (16.5)	7.9 (-0.3 to 16.0)	0.058	12/27 (44%)	16/27 (59%)	0.28
Composite (total score excluding global score)	86.7 (11.4)	80.2 (13.1)	6.5 (0.0 to 13.1)	0.049	6/27 (22%)	11/27 (41%)	0.14

Data are presented as mean (SD) unless otherwise stated. RT=radiotherapy. TORS + ND=transoral robotic surgery and neck dissection. \*Defined as a decrease of at least 10 points. †p values adjusted for stratification by p16 status (post-hoc analysis): total (p=0.054), global (p=0.071), emotional (p=0.040), functional (p=0.29), physical (p=0.064), and composite (p=0.062).


Table 2: Quality-of-life scores at 1 year for the MD Anderson Dysphagia Inventory

*Lancet Oncol 2019*

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**Key Takeaway:**  
Surgery (TORS) and radiation therapy are both good options for LA-OPSCC.



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**How do we treat HPV associated HNSCC at UNC?**



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## Can we dose reduce both chemo and RT?

### Version 1: De-intensified Chemoradiotherapy

1. 60 Gy RT for 6 weeks (*instead of 70 Gy for 7 weeks*)
2. Cisplatin 30mg/m<sup>2</sup> for 6 weeks (*instead of 40mg/m<sup>2</sup> for 7 weeks*)

N=44  
Median f/u = 34 months (88% ≥ 2 years)

**Primary endpoint (IJROBP 2015):**  
pCR rate = 86%

**Secondary endpoints (Cancer 2018):**  
 3 year PFS = 100%  
 3 year OS = 95%  
 Global QoL returned to baseline  
 Swallowing returned to baseline  
 Dry mouth continues to improve > 1 year

**Phase 2 Trial of De-intensified Chemoradiation Therapy for Favorable-Risk Human Papillomavirus–Associated Oropharyngeal Squamous Cell Carcinoma**

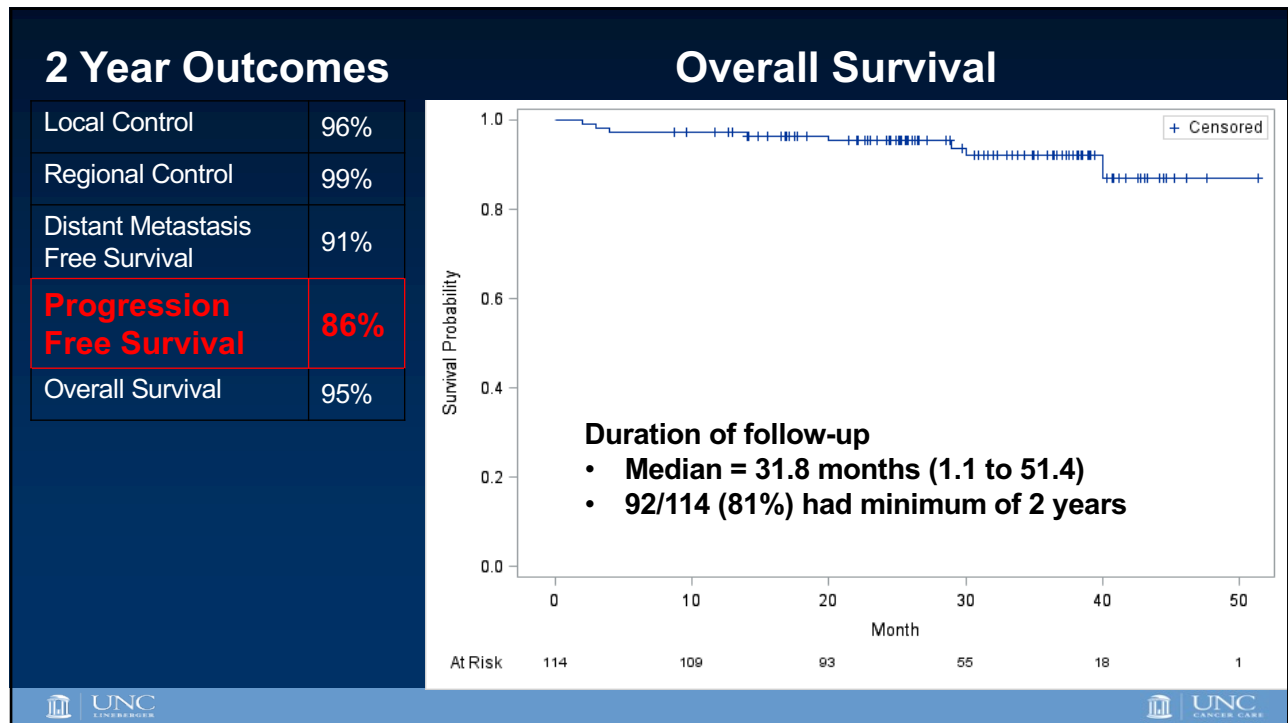
Int J Radiation Oncol Biol Phys, Vol. 93, No. 5, pp. 976–985, 2015

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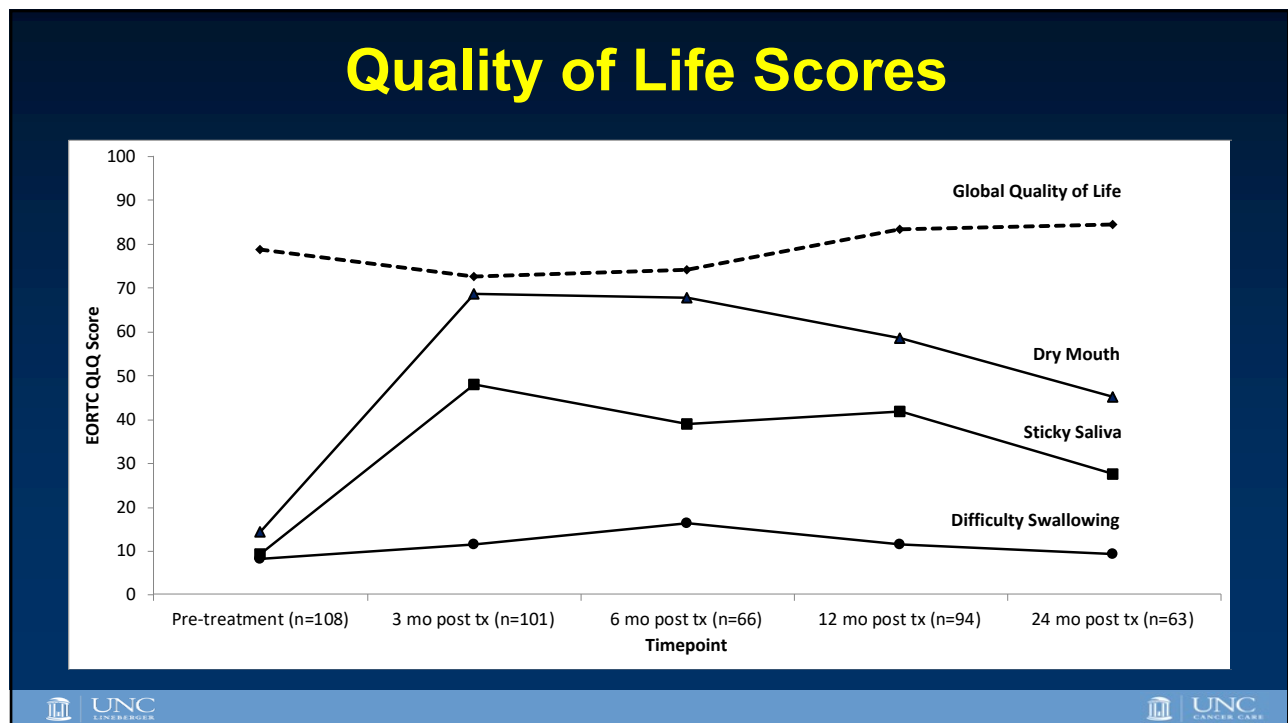
## Version 2: Patient Characteristics

	N=114	%	
Age (mean)	62 (37-87)		
Male	96	84%	
Caucasian	104	91%	➤ 100% received 60 Gy
Married	90	79%	
<b>Tobacco</b>			➤ <b>Chemotherapy:</b>
<b>Never</b>	<b>54</b>	<b>47%</b>	➤ 89/114 (78%) received chemo
<b>&lt;= 10 pack years</b>	<b>38</b>	<b>33%</b>	➤ 57/89 (64%) received 6 doses cisplatin
<b>&gt;10 pack years</b>	<b>22</b>	<b>19%</b>	➤ 10/89 (11%) received cetuximab
T1-T2 Stage	96	84%	
N0-1 Stage	96	84%	➤ 11 patients had neck dissection (4 pathologically positive)
HPV/p16 status			
HPV+/p16+	46	40%	
HPV-/p16+	12	11%	
HPV unk/p16+	56	49%	

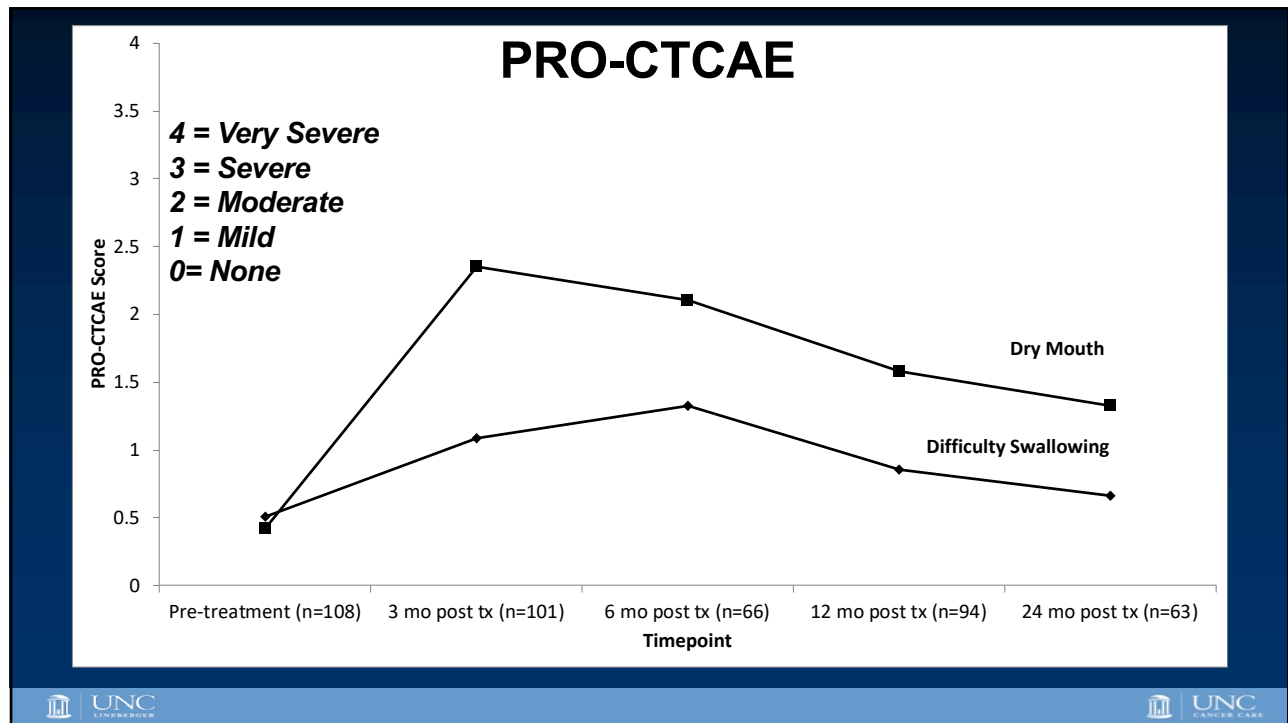
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## Phase II Trial of De-Intensified Chemoradiotherapy for Human Papillomavirus–Associated Oropharyngeal Squamous Cell Carcinoma



Bhishamjit S. Chera, MD<sup>1,2</sup>; Robert J. Amdur, MD<sup>3</sup>; Rebecca Green, MSW<sup>1</sup>; Colette Shen, MD, PhD<sup>1,2</sup>; Gaorav Gupta, MD, PhD<sup>1,2</sup>; Xianming Tan, PhD<sup>2</sup>; Mary Knowles, ANP<sup>1</sup>; David Fried, PhD<sup>1</sup>; Neil Hayes, MPH, MD<sup>4</sup>; Jared Weiss, MD<sup>1,2</sup>; Juneko Grilley-Olson, MD<sup>1,2</sup>; Shetal Patel, MD, PhD<sup>1,2</sup>; Adam Zanation, MD<sup>1</sup>; Trevor Hackman, MD<sup>1</sup>; Jose Zavallos, MPH, MD<sup>5</sup>; Jeffrey Blumberg, MD<sup>1</sup>; Samip Patel, MD<sup>1</sup>; Mohit Kasibhatla, MD<sup>6</sup>; Nathan Sheets, MD<sup>7</sup>; Mark Weissler, MD<sup>1</sup>; Wendell Yarbrough, MMHC, MD<sup>1,2</sup>; and William Mendenhall, MD<sup>3</sup>

Journal of Clinical Oncology®

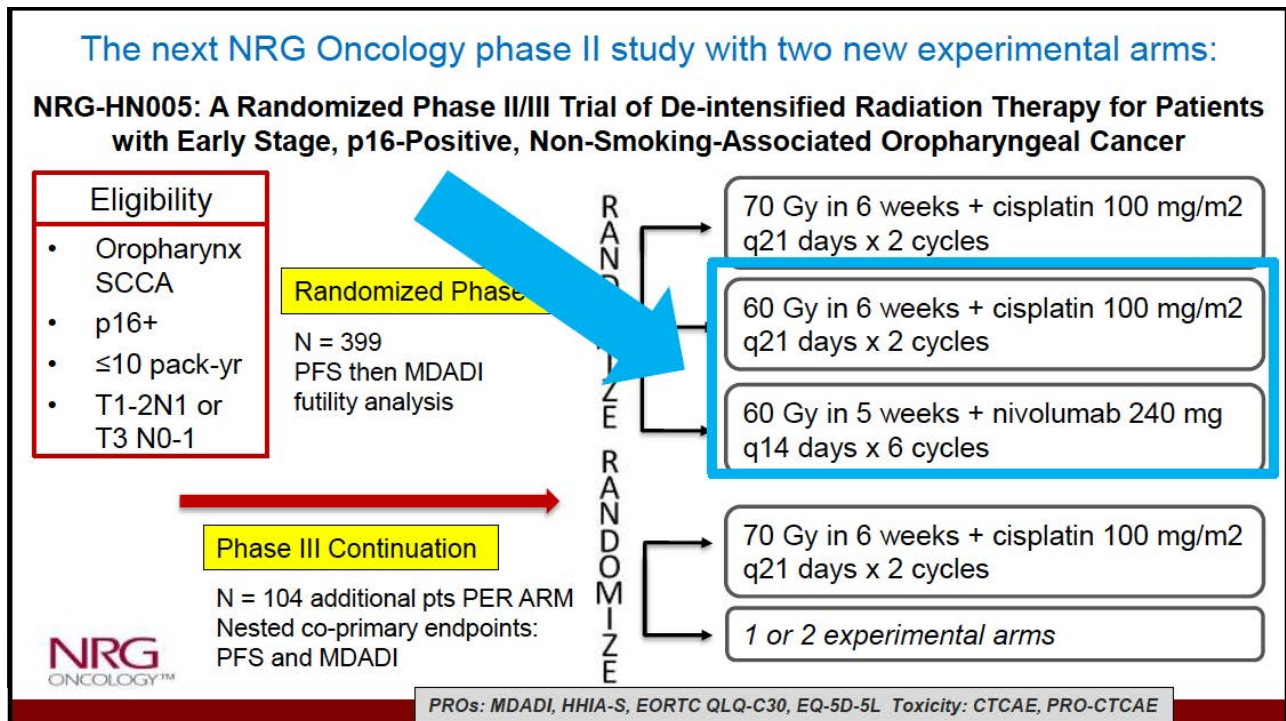
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**Lots of data.**

**How will the field move forward?**

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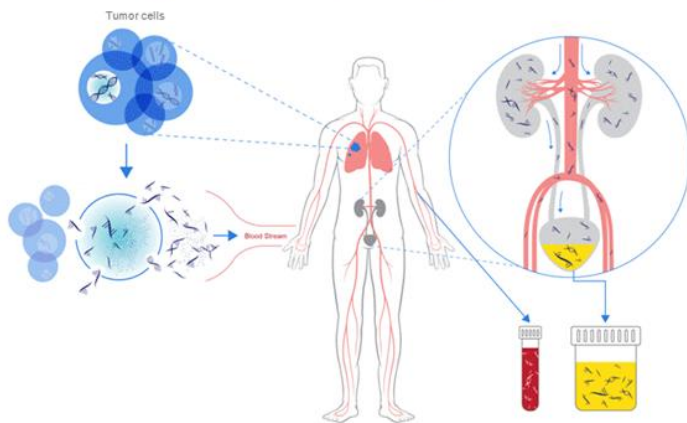
# Biomarker strategies in HNSCC




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## Liquid Biomarkers



### Circulating Tumor DNA (ctDNA)



**Main Advantages of ctDNA**

- Captures intratumor heterogeneity
- Systemic overview of cancer
- Frequent sampling options for monitoring applications
- Different analyte options depending on clinical context

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## ctDNA as a circulating biomarker of treatment response for HPV-related HNSCC

Since 2016, our UNC group has prospectively analyzed ctHPVDNA

- 3 clinical trials (LCCC 1121,1413,1612)
- ~160 patients, >1500 blood samples to date

The diagram shows a timeline starting with 'Simulation Enrollment' at day -7. 'CRT' (Cancer Radiation Therapy) begins at day 0 and continues through days 14, 21, 28, 35, and 42. 'Blood sampling time points' are indicated by red arrows at days -7, 0, 7, 14, 21, 28, 35, 42, and ~120.

**Ultimate goal of ctDNA:**

1. Guide therapeutic intensity
2. Earlier detection of disease recurrence

Chera. JCO. 2020

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## Multi-analyte digital PCR (dPCR) assay for ctHPVDNA

The plot shows a strong linear relationship between HPV16 copies (x-axis, 1 to 10,000) and dPCR HPV16 counts (y-axis, 1 to 10,000). The regression equation is  $Y = 0.9736 \cdot X + 3.65$  with  $R^2 = 0.99$ .

- Standardized multi-step analytical protocol to optimize specificity and sensitivity
- Distinguishes fragmented ctDNA from native viral genomes
- Detects ctHPV16, 18, 31, 33, and 35 (*more high-risk strains coming*)
- **Linear:** absolute quantification over 5 orders of magnitude (5-50,000 copies)
- **Precise:** High reproducibility
- **Sensitive:** Detects as few as 6 copies of HPV16 with ~80% sensitivity

ctHPVDNA

**POSITIVE**

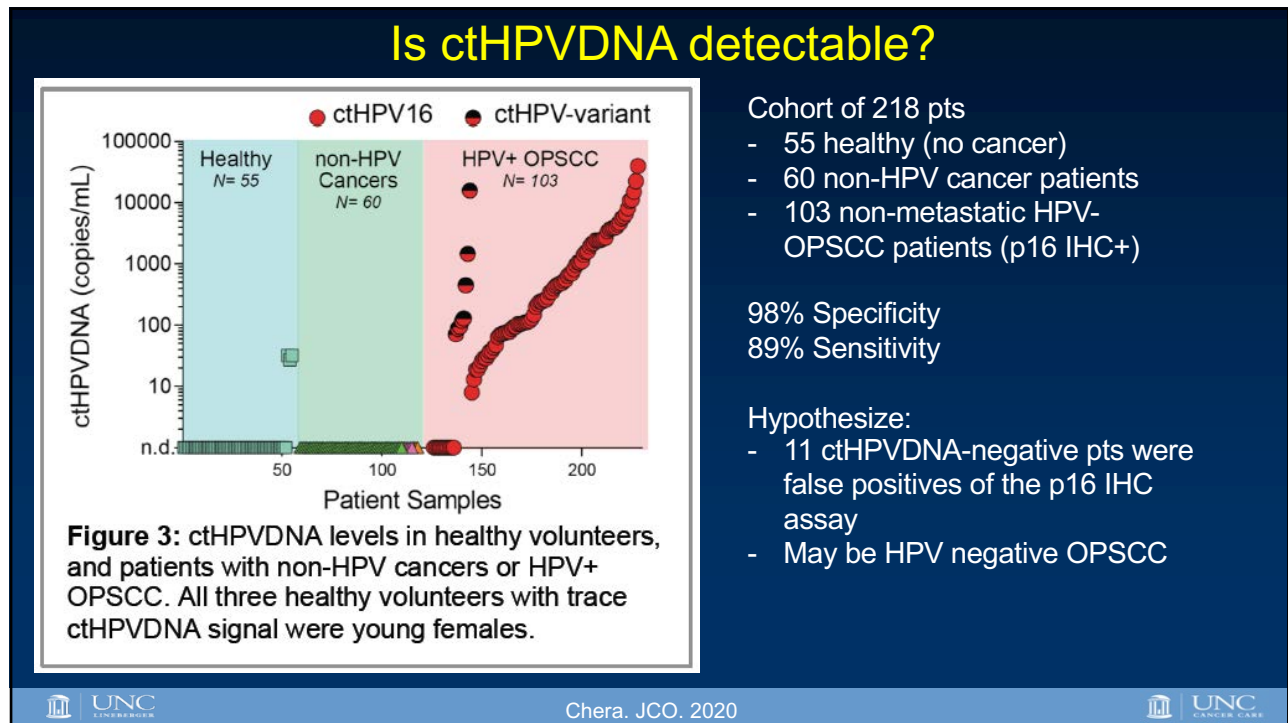
Native HPV genome

**NEGATIVE**

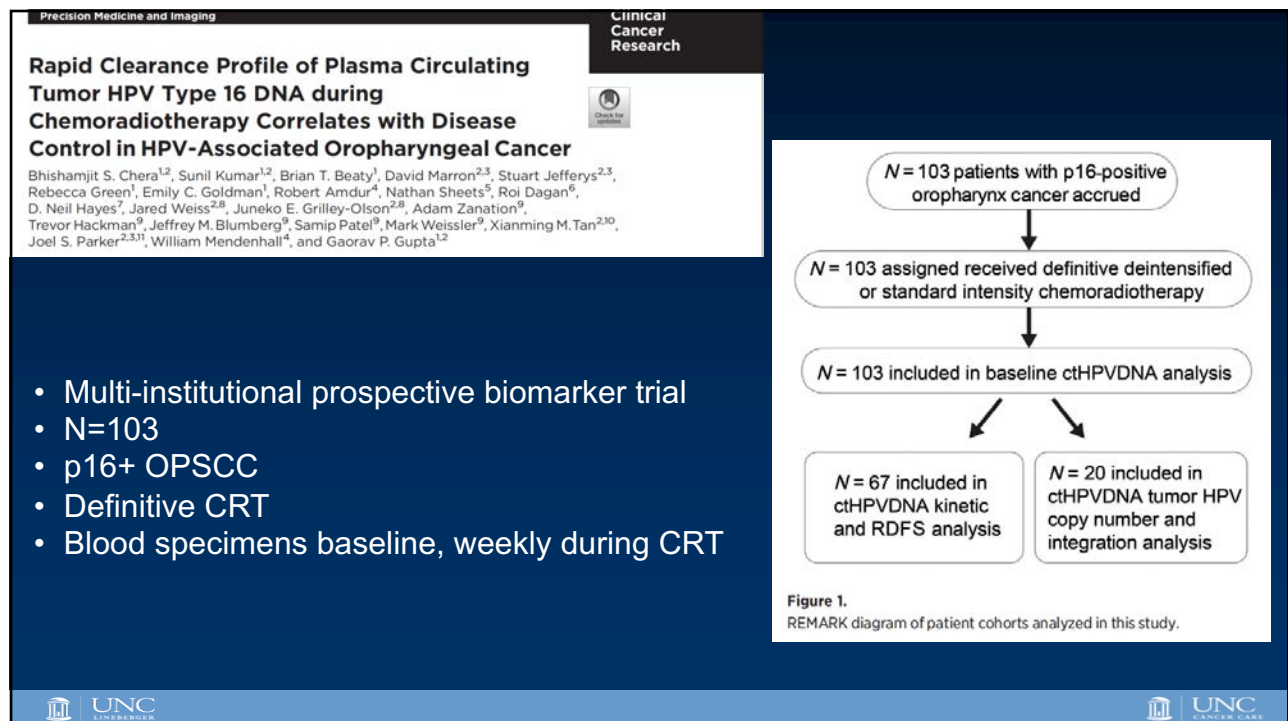
Chera. JCO. 2020

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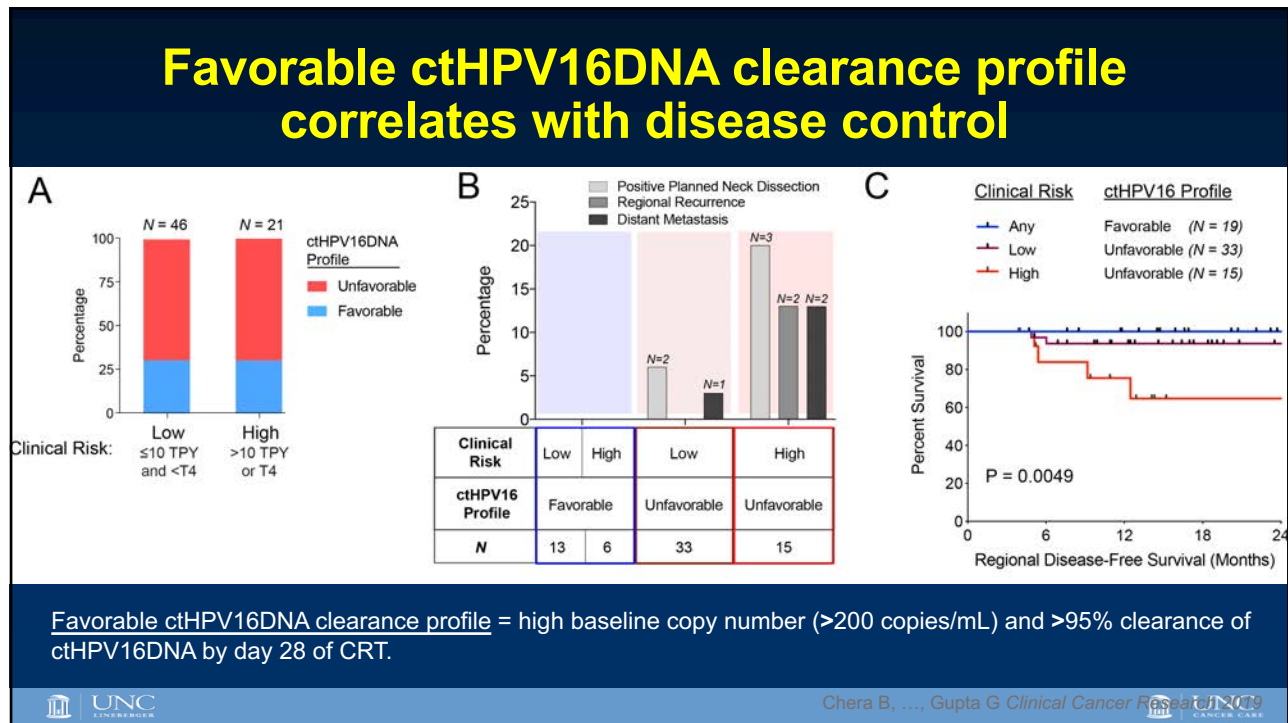




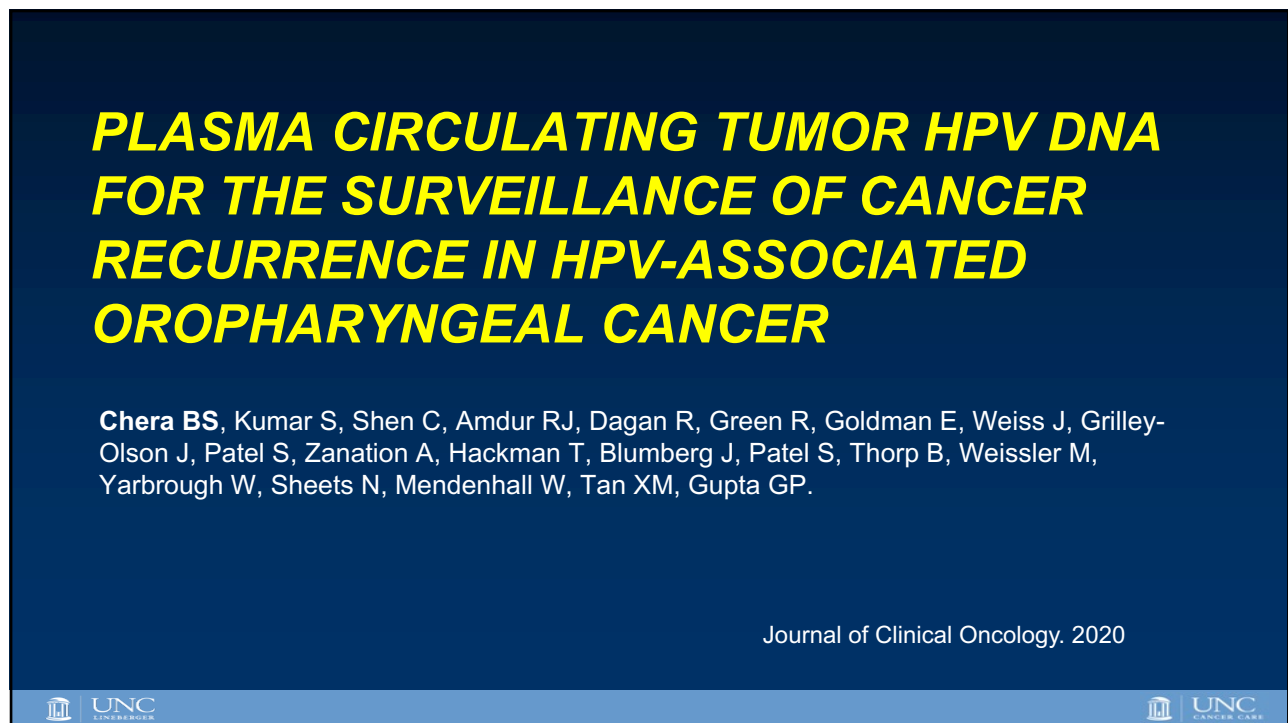
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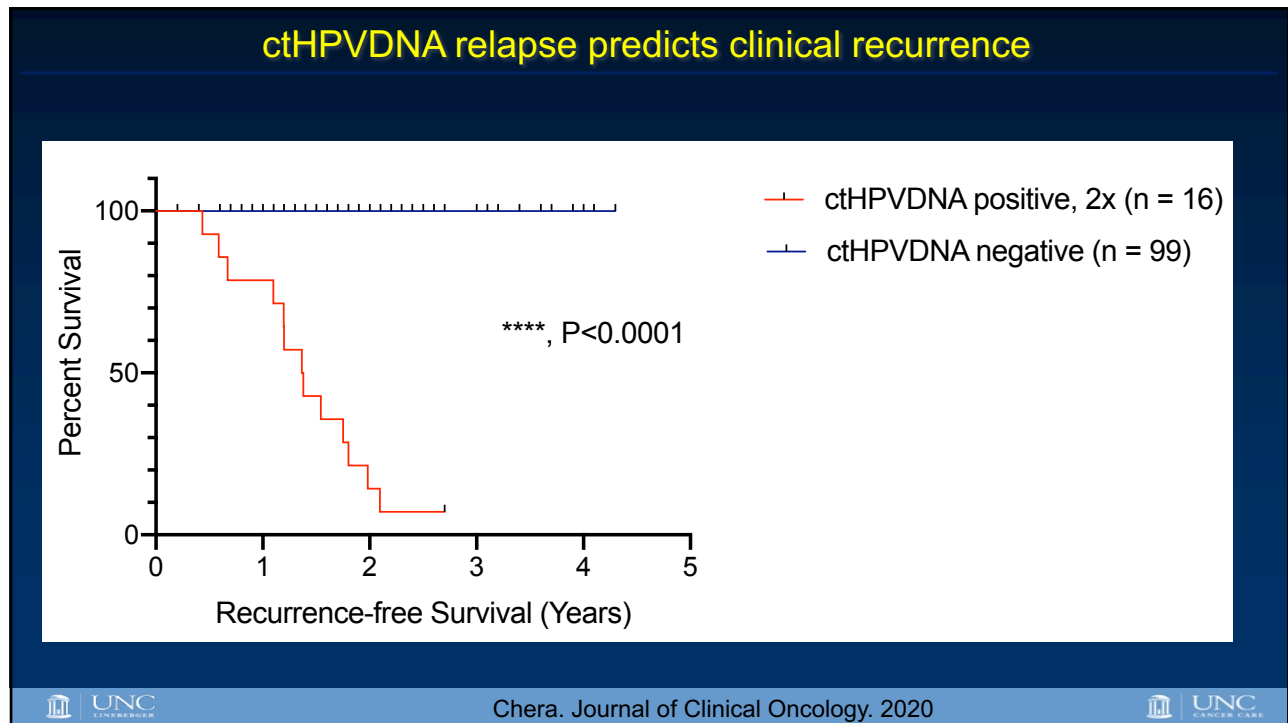
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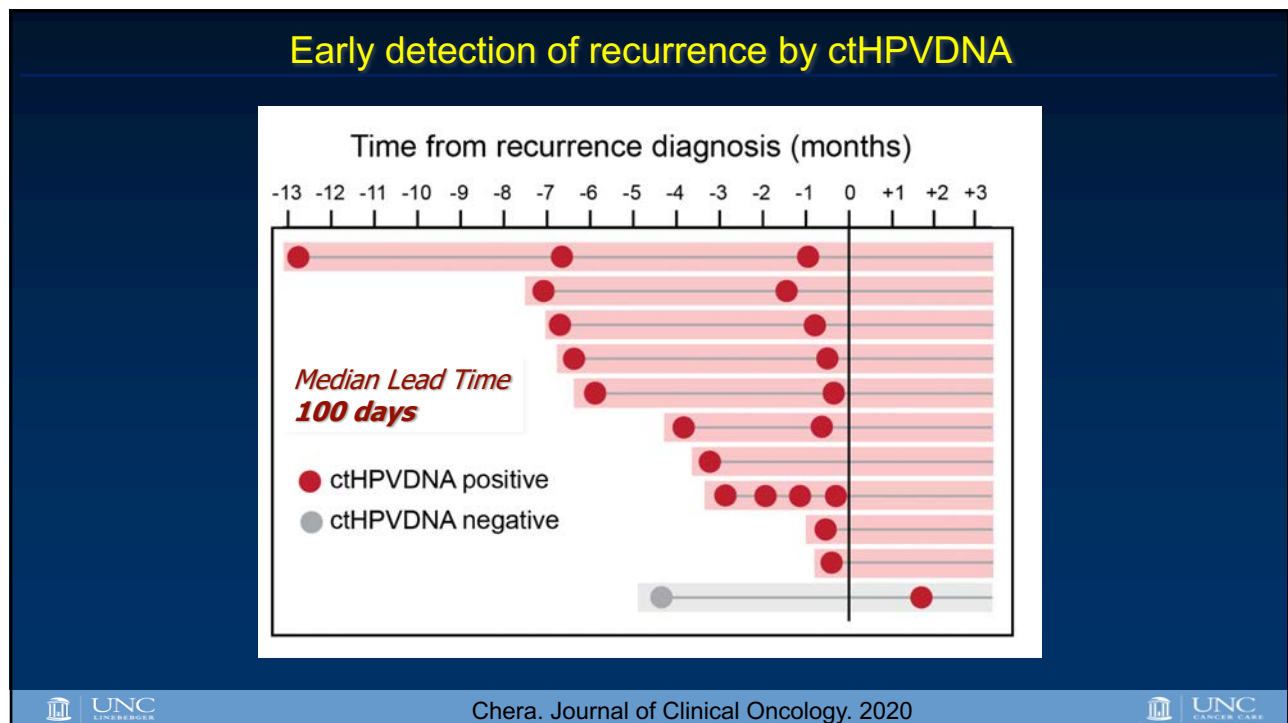
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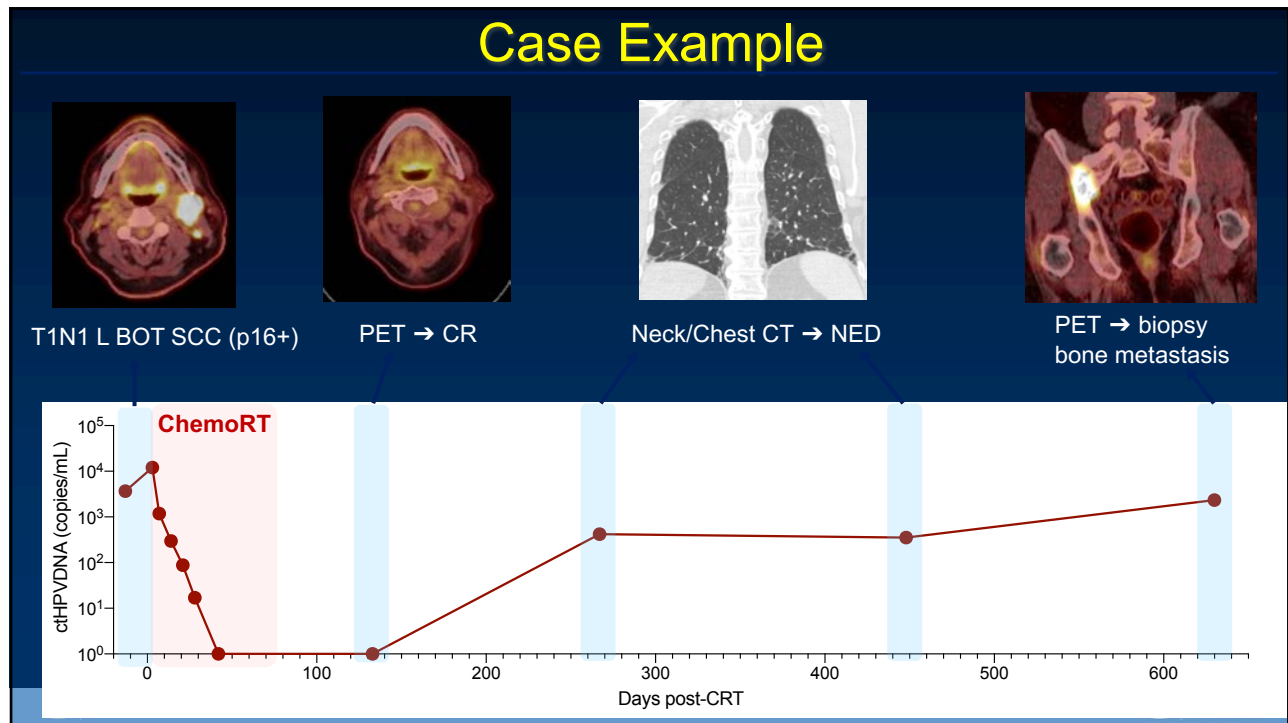
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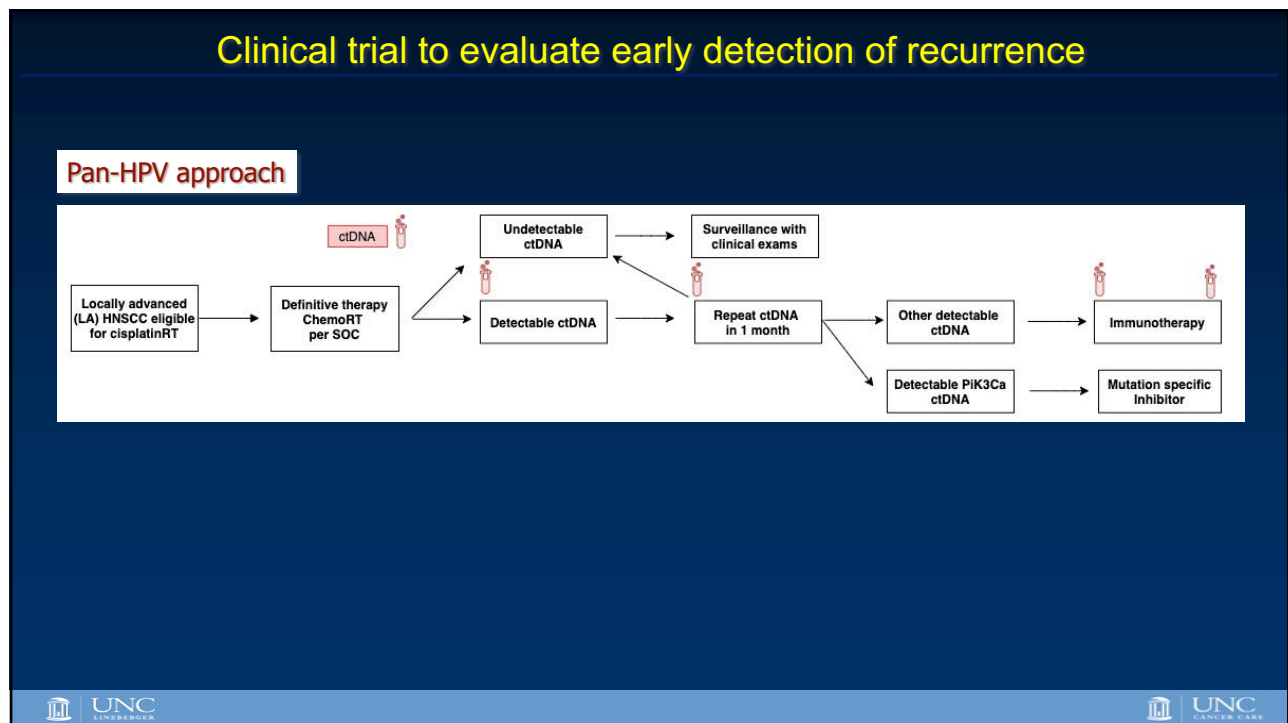
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## Key Takeaways for ctHPVDNA

- Plasma ctHPVDNA surveillance testing has high NPV and PPV for early detection of cancer recurrence
- ctHPVDNA based surveillance may reduce the overall cost of post-treatment surveillance in patients who remain ctDNA negative
  - Less radiographic scans
- Prospective evaluation in a clinical trial is needed. Efforts are underway

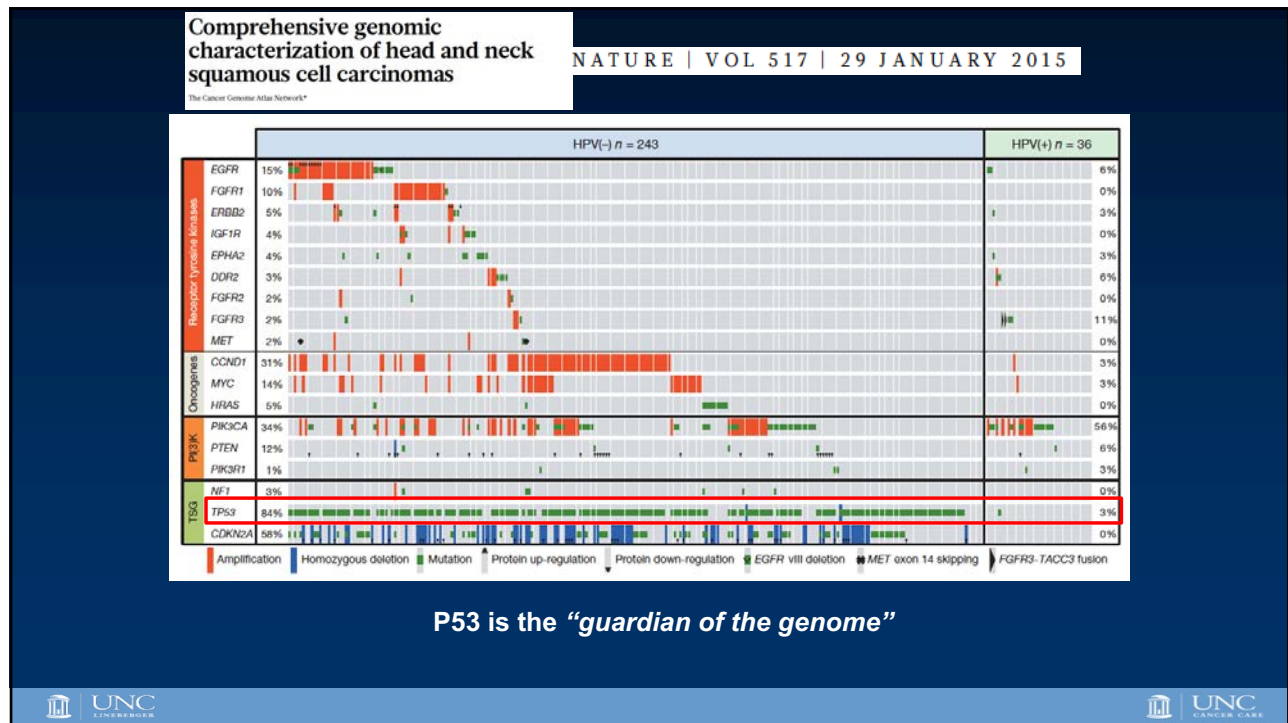


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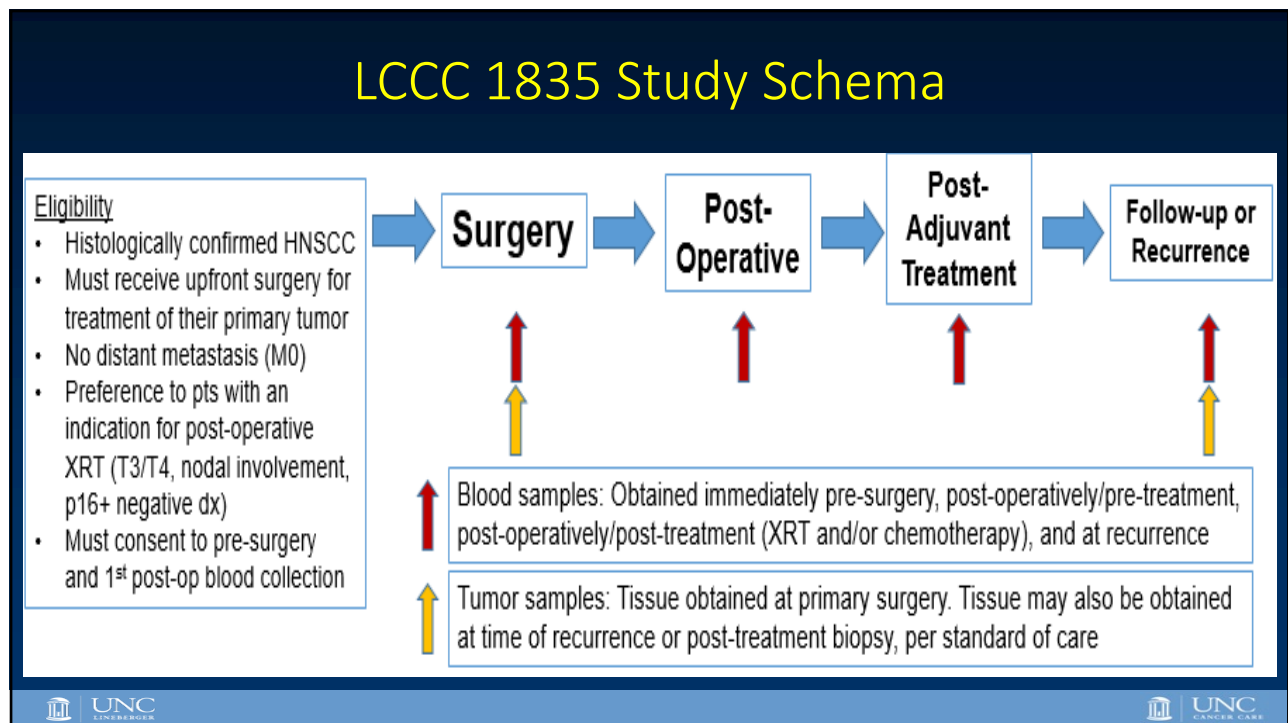
**What about ctDNA in  
HPV negative patients?**



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## LCCC 1835 Study Aims

Aim 1: To estimate the feasibility of detecting ctDNA in pre-operative plasma

- Targeted NGS sequencing on surgically excised tumor tissue
- Design and validate tumor-specific mutation (TSM) assays for detection by digital droplet PCR

Aim 2: To estimate the feasibility of detecting ctDNA in post-operative plasma and explore associations with outcomes

- Quantify changes in plasma ctDNA following surgical resection
- Investigate the correlation of pathological risk factors and disease-free survival




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**Past**







**2020**



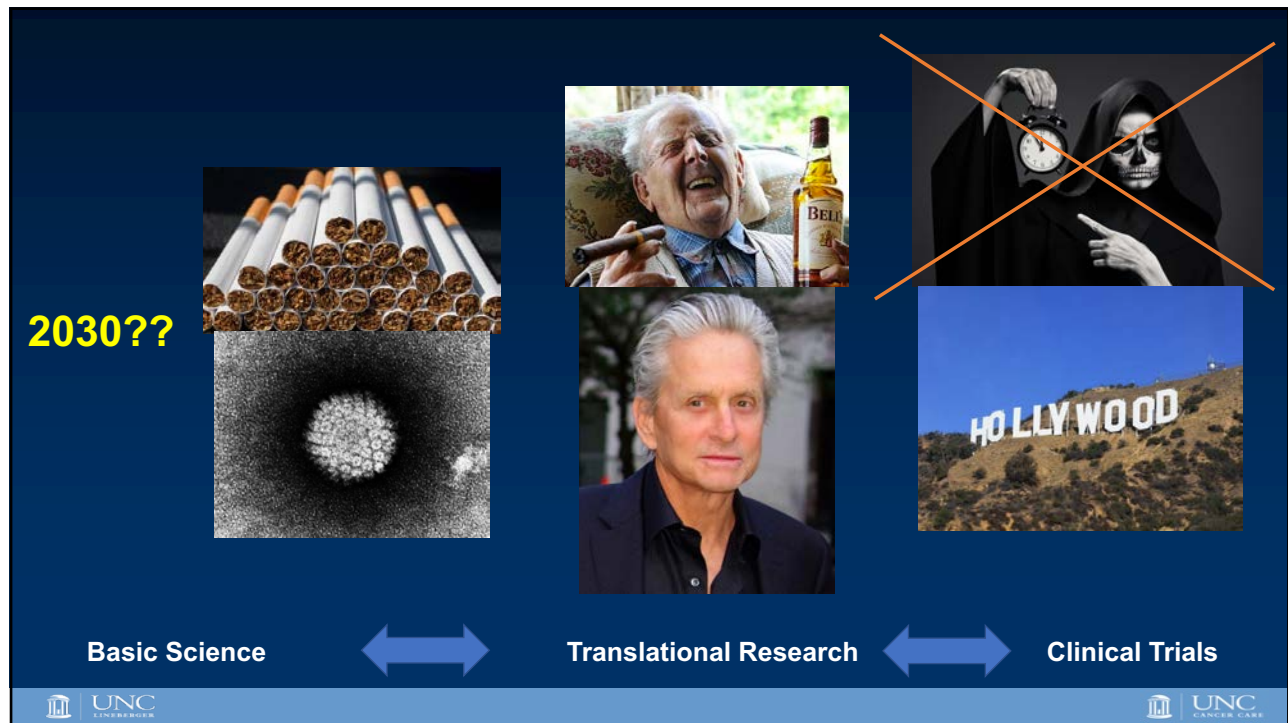






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## Case Revisited


Ramses Heel is a 55 year old presents who presented with a painless neck mass. PMH of hypertension and asthma. Family history of breast cancer (mother and older sister). Admits to a 5 pack year smoking history during college and social alcohol use currently. He travels to China yearly for business for the last 10 years. Your order an neck ultrasound and CT scan which shows a 3cm neck mass. FNA positive for squamous cell carcinoma.

**Your patient asks what caused his cancer?**

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# Conclusions

1. Head and neck cancers are common
  - Location of cancer may suggest associated risk factor
  - The incidence of oropharynx due to HPV is rising
  
2. HPV associated cancers are lower risk compared to smoking related HNSCC
  - Treatment deintensification will be come standard of care (when *not* if)
  - How to “best” de-intensify is still an active area of investigation
  
3. Biomarkers are important for cancer diagnosis, treatment, and surveillance
  - Testing for ctHPVDNA may soon become part of standard practice. How to use this assay to guide treatment decisions is being studied
  - ctDNA based on gene mutational status is also being studied for non-HPV associated HNSCC



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**Our Patients**



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# Thank you!

Questions?

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