

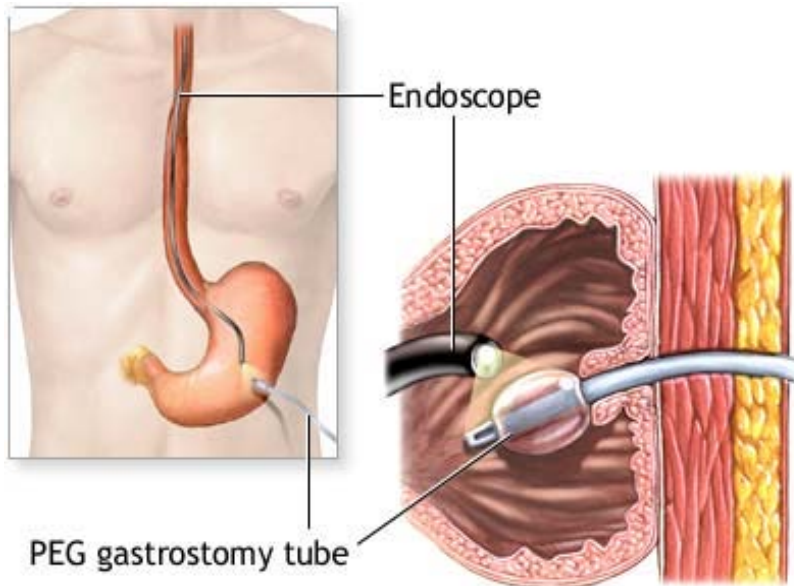


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Use of Gastrostomy in Head & Neck Cancer: A Review of the Evidence



Irene Karam, MD

PGY-4 Radiation Oncology Resident

BCCA Annual Cancer Conference

December 1st, 2011

- No conflicts of interest to declare with the current work



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Objectives

- Review of basics
- Outline the indications for G-tube placement
- Discuss the benefits and risks of prophylactic feeding tubes
- Determine the impact of G-tube use on QOL, swallowing and outcome
- Discuss the BCCA experience



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Introduction

- Head and neck cancer patients develop difficulties with oral intake due to irradiation of mucous membranes and salivary glands
- Recent gains in local control and survival from altered fractionation RT and concurrent chemoRT lead to higher rates of swallowing dysfunction
- Potential toxicities include:
 - Xerostomia, mucositis and taste loss
 - Lead to physical/emotional inability to eat
 - Effects are magnified for patients on concurrent chemoRT

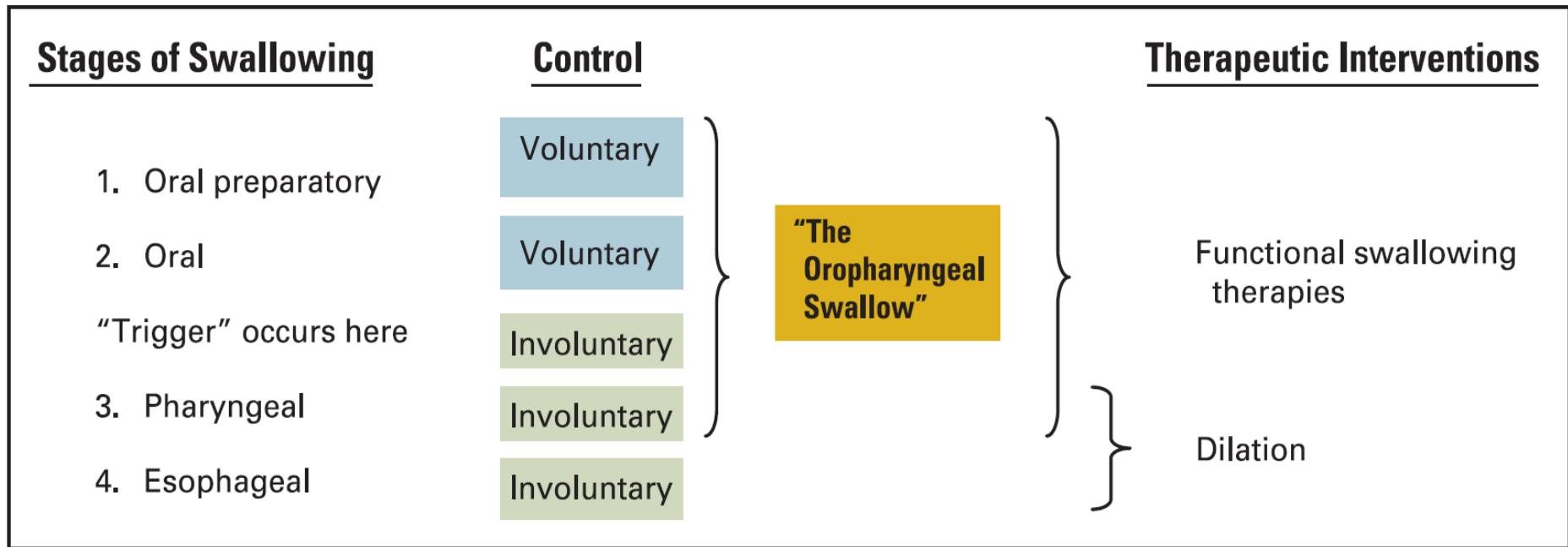


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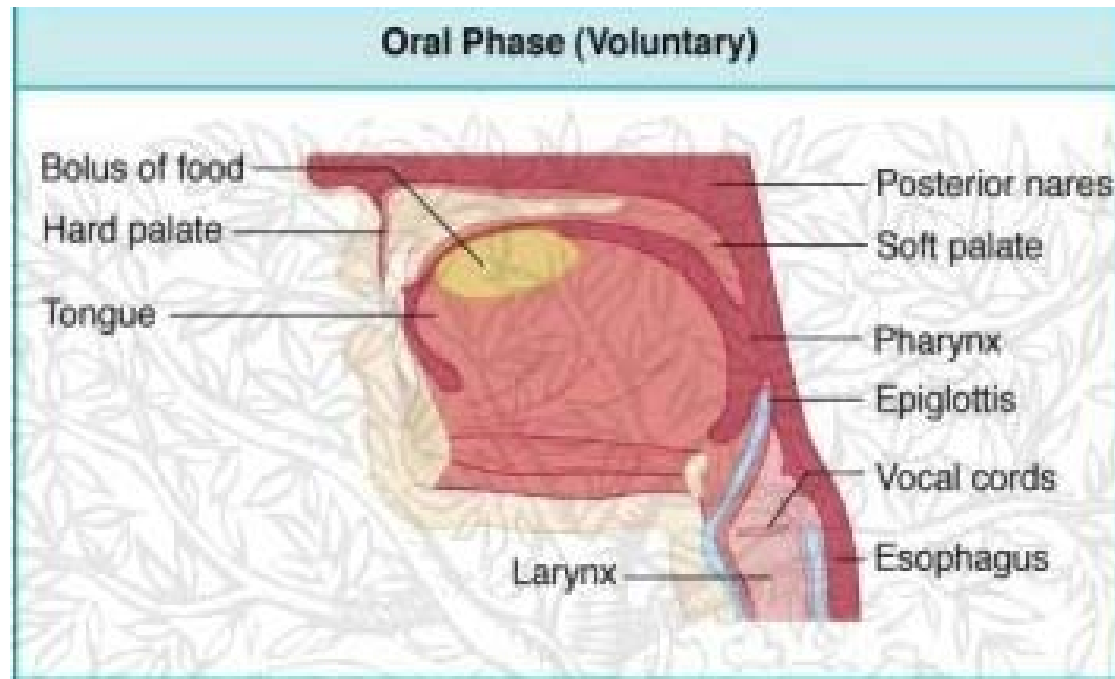
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Stages of Swallowing



Oral Phase (Voluntary)

- Oral preparatory phase
 - Processing of bolus to make it swallowable
- Oral propulsive phase
 - Propelling of food from oral cavity into oropharynx
- Contractions of tongue and muscles of mastication
- Trigger of the involuntary swallowing reflex
- Cerebellum controls output for :
 - **CN V** (trigeminal)
 - **CN VII** (facial)
 - **CN XII** (hypoglossal)
- Duration of sequence
 - Swallows of solid foods:
~5-10 sec



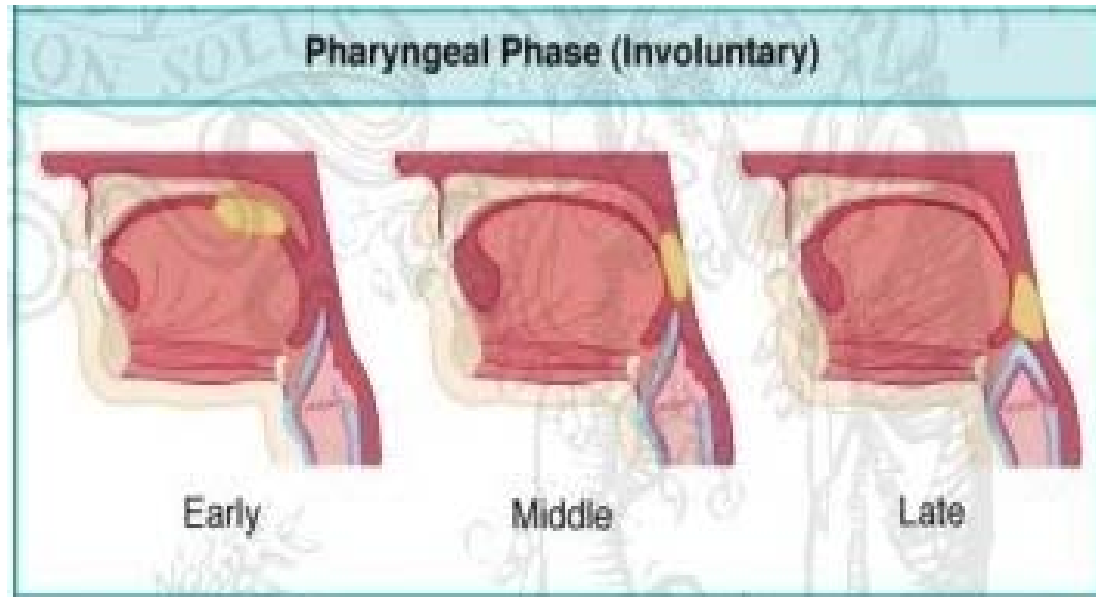
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Pharyngeal Phase (Involuntary)

- Soft palate elevates
- Tongue pushes backward to meet the posterior pharyngeal wall
 - Creates driving pressure
- Adduction of vocal cords and laryngeal excursion
 - Leading to epiglottic closure
- Relaxation of cricopharyngeus muscle
- Forward movement of larynx/hyoid to open the cricopharyngeal inlet (UES)
- Motor and sensory tracts from:
 - **CN IX** (glossopharyngeal)
 - **CN X** (vagus)
- Lasts ~ 1 sec



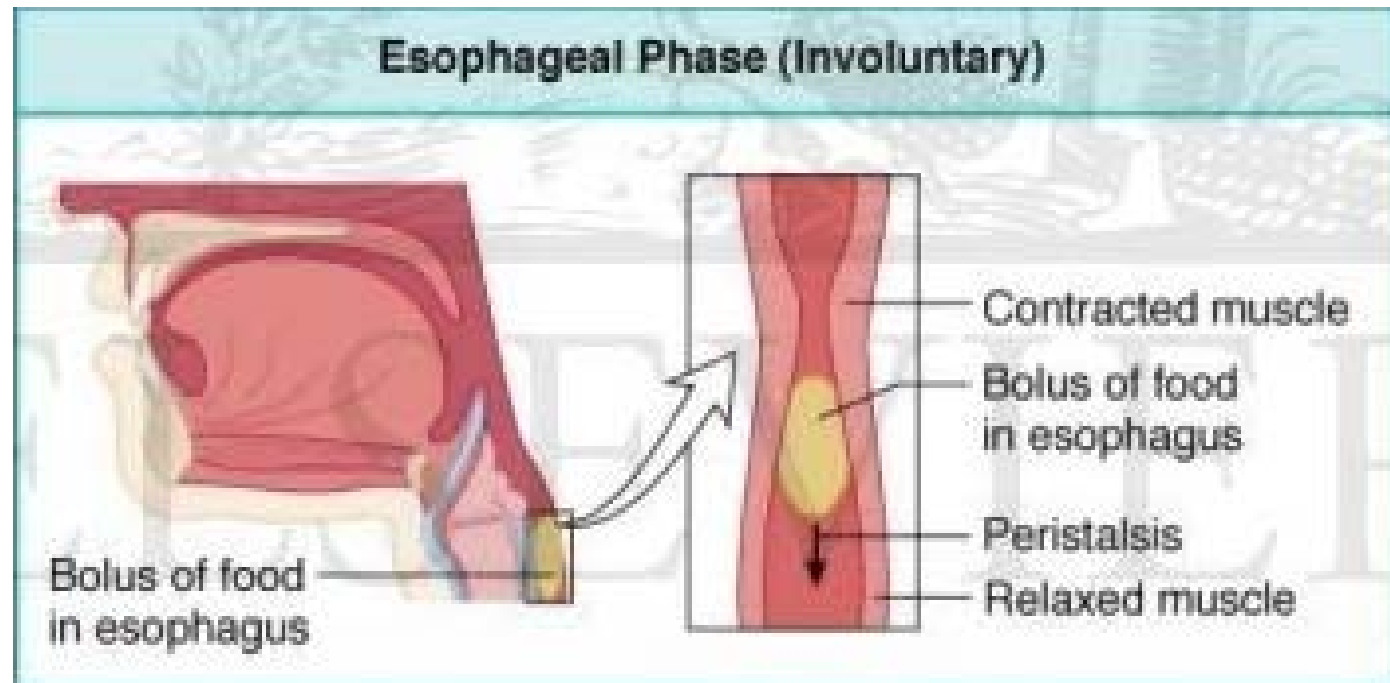
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Esophageal Phase

- Bolus propelled downward by peristaltic movement
- Relaxation of lower esophageal sphincter (LES)
- Controlled by the medulla
- ~ 8-20 sec to drive bolus into stomach



Acute Mucositis

- Dose-limiting toxicity of chemoRT
- Associated with long-term dysphagia
- Thick, ropery oropharyngeal secretions are associated with high-grade mucositis
- Secretions interfere with swallowing, cause gagging and regurgitation and predispose to aspiration
- Increased risk for prolonged mucosal ulceration leading to scarring and organ dysfunction



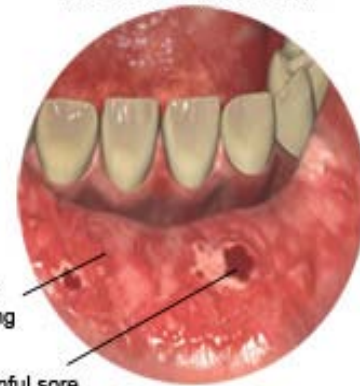
Normal, healthy mouth

Mild oral mucositis



Redness and swelling

Moderate oral mucositis



Redness and swelling

Painful sore



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Rosenthal *et al.* JCO 2006

Enteral Feeding

- Effect of RT on swallowing may vary, but:
 - Up to one half will develop significant dysphagia
- ~60% of patients require enteral feeding in the form of NG tubes or G tubes
- Use of G-tubes has been increasing due to low complication rates and easy availability
 - Indications remain variable
 - Long-term effects on swallowing function and QOL are not well understood
 - Cost benefit of G-tube is unknown



Indications for G-tube Placement

- Guidelines based on expert opinions vary
- Lack of consistency in the decision-making about the indications for placing G-tubes
- Large series arrive at different conclusions
- No randomized controlled trials



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Indications for G-tube Placement

- **European Society for Clinical Nutrition and Metabolism Guidelines** (Clin. Nutr., 2005)
 - “G-tubes should be considered for those patients whose nutritional intake is likely to be qualitatively or quantitatively inadequate for 2-3 weeks.”
- **National Institute for Health and Clinical Excellence Guidelines** (London, 2006)
 - “G-tube feeding should be considered in people likely to need long-term (4 wks or more) enteral tube feeding.”



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Indications for G-tube Placement

- **Canadian Oncology Nutrition Clinical Practice Guidelines (2009)**
 - “Prophylactic feeding tube insertion should be seriously considered for individuals initially presenting with one or more of the following:”
 - Significant weight loss (>5% in 1 mo or >10% in 6 mo)
 - BMI < 18.5
 - Dysphagia
 - Anorexia
 - Dehydration
 - Pain or any other symptoms that interfere with the ability to eat



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Factors Associated with G-tube Placement

- **Cheng *et al.* Arch Otolaryngol Head Neck Surg 2006**
 - Multicenter retrospective study
 - 98 patients dependent on enteral tube feeding for >1 mo
 - Independent variables associated with G-tube placement:
 - Oropharynx/ hypopharynx tumors ($p = 0.01$)
 - Tumour stage III/IV ($p = 0.03$)
 - Flap reconstruction ($p = 0.004$)
 - Current tracheostomy ($p < 0.001$)
 - Chemotherapy ($p < 0.001$)
 - Increased age (per decade) ($p = 0.02$)



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Any Benefits to Prophylactic G-tubes?

CLINICAL INVESTIGATION

Head and Neck

EVALUATING THE ROLE OF PROPHYLACTIC GASTROSTOMY TUBE PLACEMENT PRIOR TO DEFINITIVE CHEMORADIOTHERAPY FOR HEAD AND NECK CANCER

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Chen *et al.*, 2010

- Retrospective review of 120 patients treated with chemoRT for Stage III/IV head and neck cancer between 2002-2009
 - Median RT dose: 70 Gy
- **Prophylactic GT:** 70 patients
- **No GT:** 50 patients
 - **Reactive GT:** 16/50 patients (at median 33 days)

Table 1. Clinical and disease characteristics

Characteristic	GT (%)	No GT (%)
Primary tumor size		
Oropharynx	37 (53)	29 (58)
Nasopharynx	16 (23)	12 (24)
Larynx/hypopharynx	12 (17)	7 (14)
Unknown primary	5 (7)	2 (8)
T-stage		
T0	5 (7)	2 (8)
T1	6 (9)	11 (22)
T2	11 (16)	11 (22)
T3	20 (29)	10 (20)
T4	28 (40)	16 (32)
N-stage		
N0	8 (11)	6 (12)
N1	17 (24)	17 (34)
N2	31 (44)	21 (42)
N3	14 (20)	6 (12)
Racial distribution		
Caucasian	42 (60)	29 (58)
Hispanic	10 (14)	6 (12)
Black	9 (13)	9 (18)
Asian	9 (13)	6 (12)
Age		
<50 years	33 (47)	17 (33)
>50 years	37 (53)	33 (66)
Baseline body weight (pounds)		
<150	12 (17)	6 (12)
150–200	33 (43)	19 (38)
>200	25 (36)	25 (50)
KPS		
90–100	55 (79)	38 (76)
80	10 (14)	10 (20)
70	5 (7)	2 (4)
RT technique		
IMRT	36 (51)	31 (62)
Non-IMRT	34 (49)	19 (38)

Chen et al. IJROBP 2010 - Results

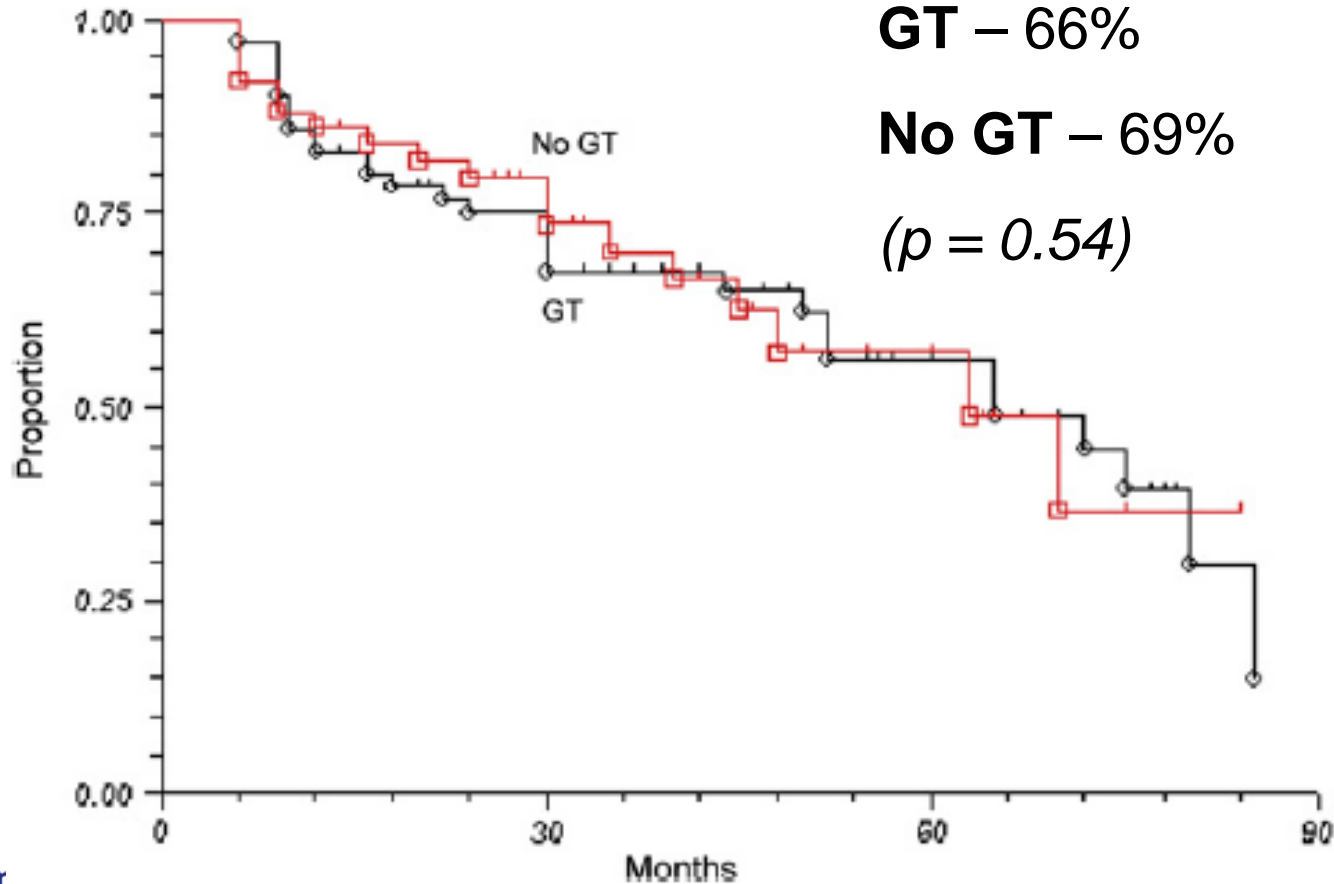
Overall Survival

3 year OS:

GT – 66%

No GT – 69%

(p = 0.54)



Chen et al. IJROBP 2010 - Results

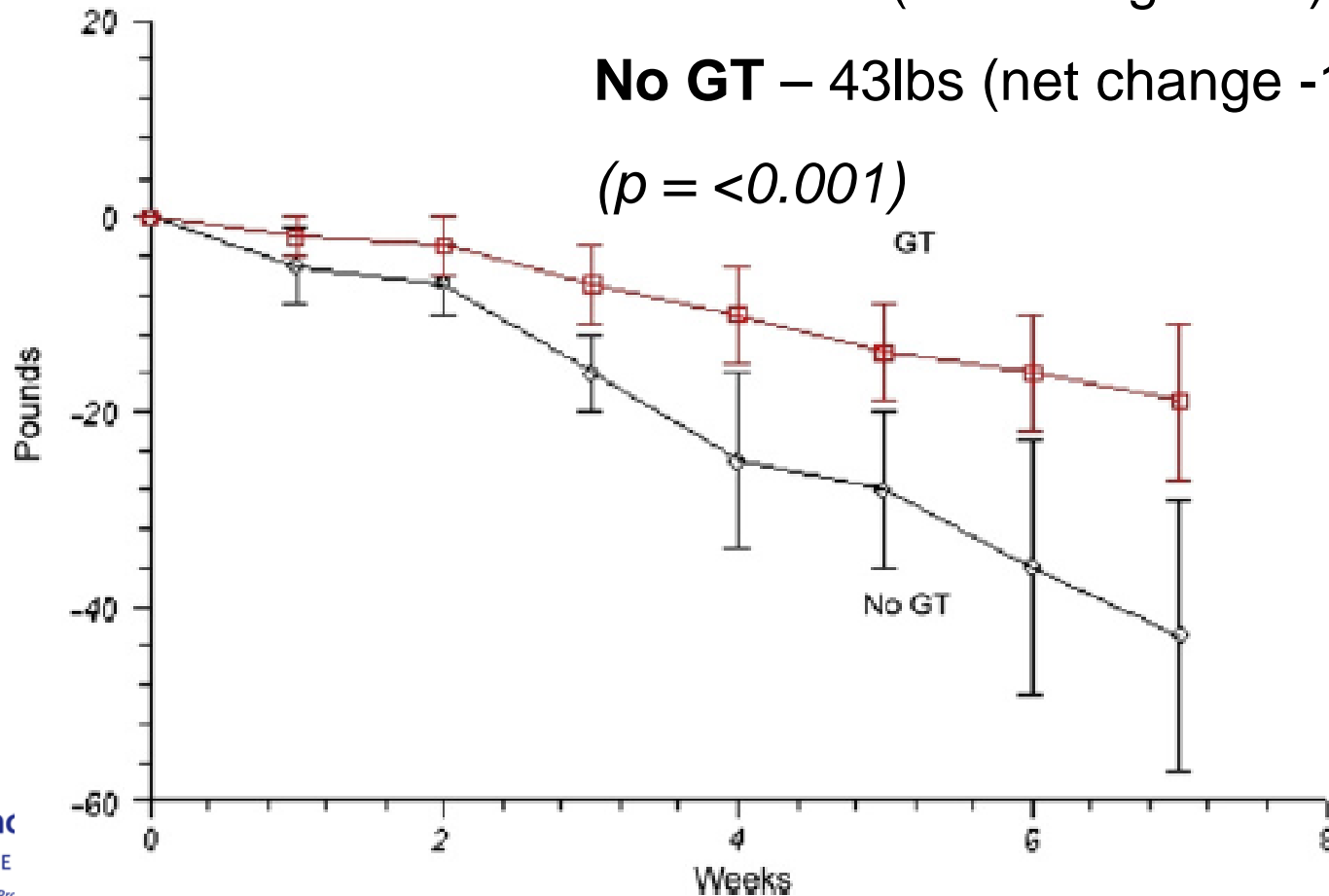
Mean Weight Loss

Average weight loss:

GT – 19lbs (net change -8%)

No GT – 43lbs (net change -14%)

($p = <0.001$)



Chen et al. IJROBP 2010 - Results

Acute Toxicity

Table 2. Grade 3+ acute toxicity among patients treated by chemoradiotherapy

Characteristic	GT (%)	No GT (%)
Hematologic	41 (59)	31 (62)
Mucositis	30 (43)	19 (38)
Xerostomia	16 (23)	12 (24)
Skin desquamation	15 (21)	11 (22)
Hoarseness	7 (10)	3 (6)



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Chen et al. IJROBP 2010 - Results

- **Late toxicity**
 - **High-grade dysphagia**
 - At 3 mo follow-up
 - Prophylactic GT- 46%
 - No GT – 27%
 - $P= 0.01$
 - **GT duration**
 - At 3, 6 and 12 mo
 - Prophylactic GT – 60%, 41%, 21%
 - Reactive GT – 14%, 8%, 0%
 - $P < 0.001$
 - **Need for esophageal dilatation due to strictures**
 - Prophylactic GT – 30%
 - No GT – 6%
 - $P < 0.001$



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Chen et al. IJROBP 2010 - Results

- Prophylactic GT placement
 - **Pros**
 - Prevents acute weight loss
 - Need for IV hydration
 - **Cons**
 - Associated with significantly higher rates of late esophageal toxicity
 - Increased rates of grade 3 dysphagia
 - Increased GT dependence
 - No change in OS



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Other Trials

- **Allen et al. IJROBP 2007**
 - Prospective trial of 46 patients with unresectable HNSCC
 - T3/T4, N3 disease
 - Concurrent cisplatin/5-FU and accelerated RT
 - **Prophylactic PEG:** 22 patients (if pharynx included in high-dose treatment volume)
 - **Reactive PEG:** 9 patients
 - **PEG within 3 wks post -Tx:** 5 patients



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Other Trials

- **Bahl *et al.* IJROBP 2004**
 - PMH experience
 - Retrospective review of 75 patients treated with chemoRT for locally advanced NPC between 1998 – 2002 as per INT 0099 protocol
 - **Prophylactic PEG:** 23 patients
 - **Reactive PEG:** 17 patients
 - **No PEG:** 35 patients



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Comparison of Results

	n	% Weight loss		Length of G-tube dependence		High-grade dysphagia		Mucositis		Esophageal strictures	
		GT	NGT	GT	NGT	GT	NGT	GT	NGT	GT	NGT
<i>Chen et al. 2010</i>	120	8% Mean	14% Mean	60% (3 mo)	14% (3 mo)	46%	27%	30%	19%	30%	6%
<i>Allen et al. 2007</i>	46	3.8% Median	7.9% Median	64% (>3 mo)	-	NR	-	NR	-	32%	NR
<i>Bahl et al. 2004</i>	75	18% Mean	14% Mean	145 days	116 days	44%	23%	44%	32%	NR	-

GT – Prophylactic GT

NGT – Reactive or no tube placed



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Do G-tubes have an Impact on Outcomes?

- **Rabinovitch *et al.* Head & Neck 2006**
 - Subset analysis of RTOG 90-03
 - RTOG 90-03
 - Phase III prospective randomized trial evaluating 4 definitive RT fractionation schedules in patients with locally advanced HNSCC
 - 1073 patients analyzed between 1991-1997
 - Prospectively collected data on nutritional support delivered
 - Before treatment (BNS)
 - During treatment (TNS)
 - After definitive XRT



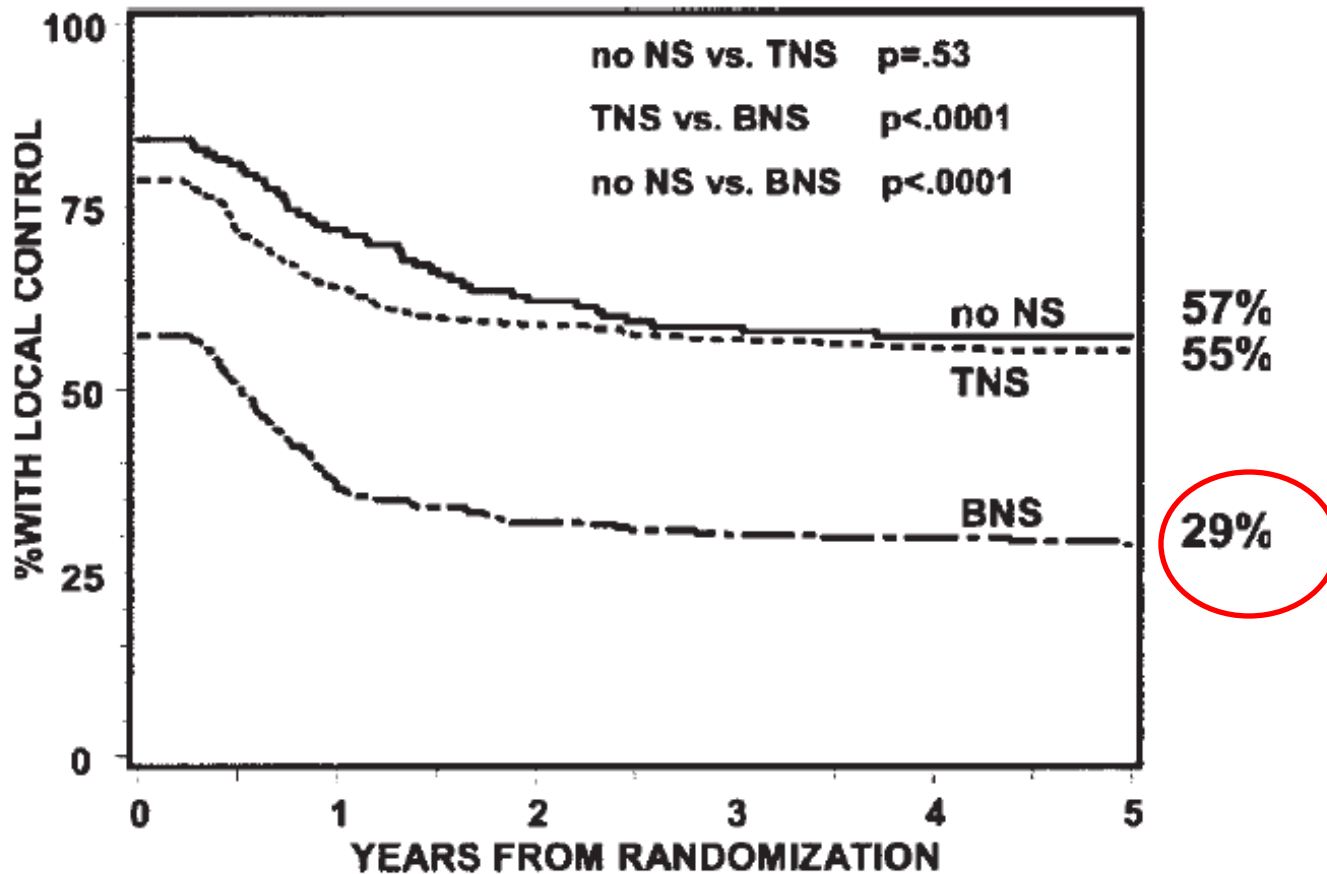
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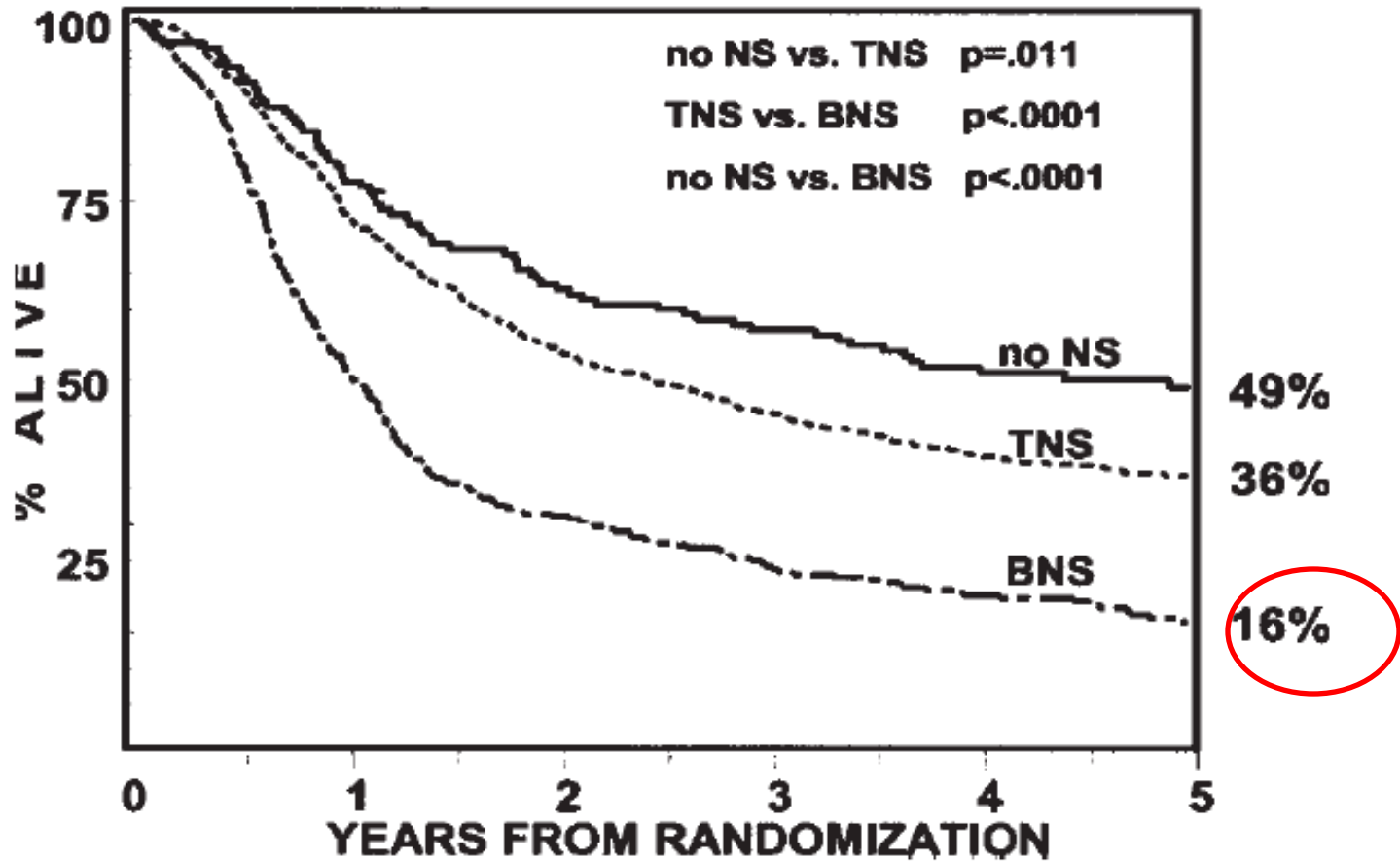
Rabinovitch et al. Head & Neck 2006

Locoregional Control by level of nutrition support



Rabinovitch et al. Head & Neck 2006

Overall Survival by level of nutrition support



Rabinovitch et al. Head & Neck 2006

- Conclusions:
 - “Although nutritional support and appropriate dietary intake benefit the host patient with respect to preserving body mass, minimizing toxicity to therapy and improving QOL”
 - They seem to “similarly benefit the malignancy as well and stimulate tumor growth”
- Study was criticized by **Sanabria et al. Head & Neck 2006** (*letter to the editor*)
 - Confounding factors may influence the conclusion
 - Patients with BNS also had
 - Poorer KPS
 - Higher T, N stage
 - Increased anemia
 - Greater weight loss



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Is G-tube preferable to NG tube?

- **Mekhail *et al.* Cancer 2001**

- Retrospective review of NG-FT vs PEG-FT
- Patients treated with RT or concurrent chemoRT between 1989-1997
- 91 FT placed in 158 patients
 - **NG** – 29 patients
 - **PEG** – 62 patients

TABLE 3
Characteristics of Patients with Feeding Tubes (n = 91)

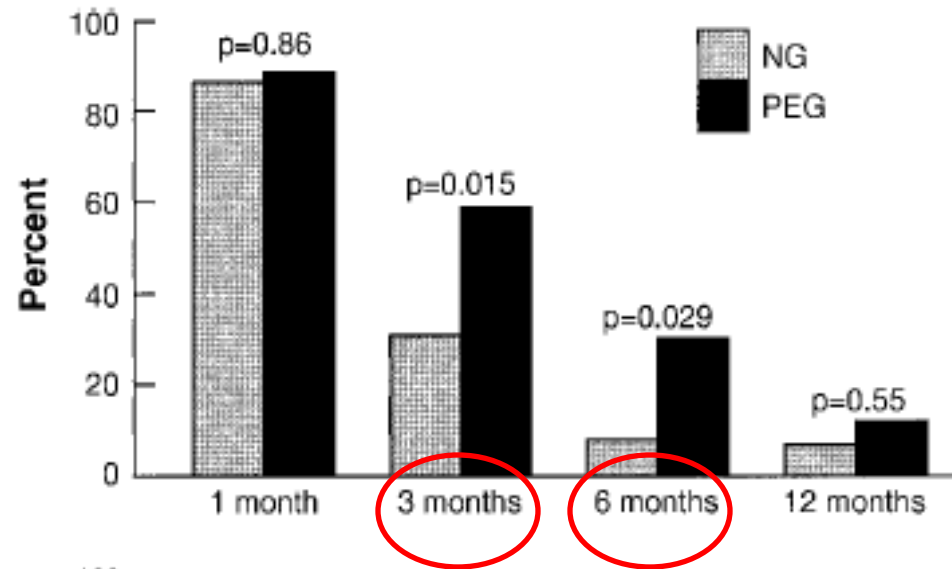
Characteristic	No. of patients (%)		P value
	With NG tube (n = 29)	With PEG tube (n = 62)	
Mean age in yrs (range)	61 (30-75)	59 (24-77)	0.29
Gender			
Male (n = 64)	23 (79.3)	41 (66.1)	—
Female (n = 27)	6 (20.7)	21 (33.9)	0.20
Race			
Black	3 (10.3)	7 (11.3)	—
White	26 (89.7)	55 (88.7)	0.89
Primary site			
Oral cavity (n = 4)	2 (6.9)	2 (3.2)	—
Larynx (n = 29)	6 (20.7)	23 (37.1)	—
Oropharynx (n = 35)	14 (48.3)	21 (33.9)	—
Hypopharynx (n = 23)	7 (24.1)	16 (25.8)	0.34
T (tumor) stage			
1 (n = 7)	3 (10.3)	4 (6.4)	—
2 (n = 21)	8 (27.6)	13 (21.0)	—
3 (n = 26)	9 (31.0)	17 (27.4)	—
4 (n = 37)	9 (31.0)	28 (45.2)	0.61
N (lymph node) stage			
0 (n = 22)	8 (27.6)	14 (22.6)	—
1 (n = 15)	4 (13.8)	11 (17.7)	—
2 (n = 48)	16 (55.2)	32 (51.6)	—
3 (n = 6)	1 (3.4)	5 (8.1)	0.78
Tracheostomy			
Yes (n = 12)	1 (3.4)	11 (17.7)	—
No (n = 79)	28 (96.6)	51 (82.3)	0.06
Treatment			
Radiotherapy (n = 16)	3 (10.3)	13 (21.0)	—
Chemoradiotherapy (n = 75)	26 (89.7)	49 (79.0)	0.22



Mekhail *et al.* Cancer 2001 - Results

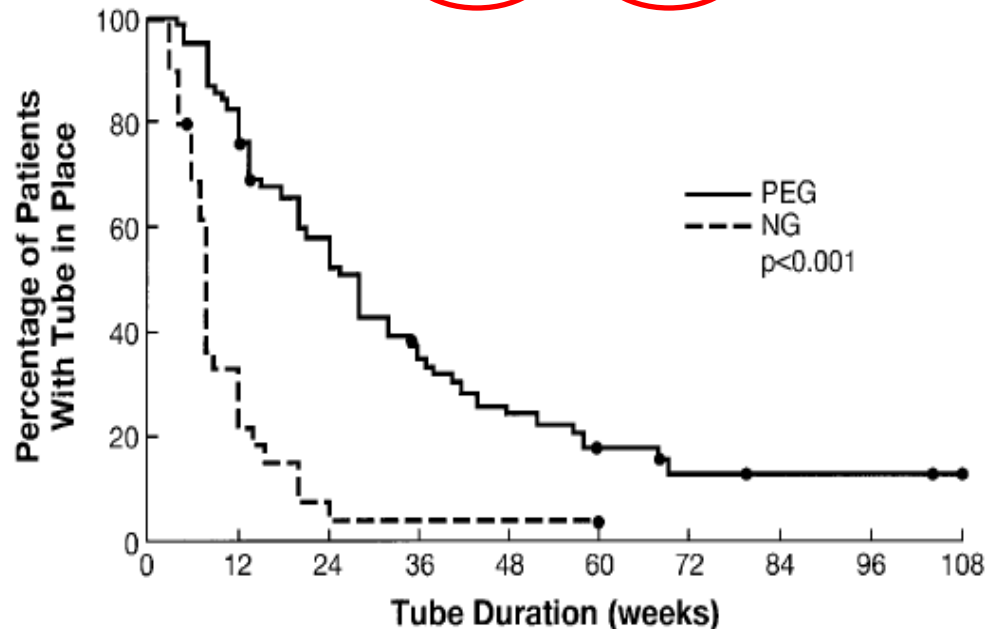
1. Dysphagia

- Persistence of significant dysphagia with PEG tubes vs. NG tubes



2. Feeding tube duration

- Longer in patients with PEG tubes vs. NG tubes
- Median FT duration – 28 wks (PEG) vs. 8 wks (NG)



Mekhail *et al.* Cancer 2001 - Results

3. Need for Pharyngoesophageal dilatation

- 14 of 62 PEG patients (**23%**) vs. 1 of 29 NG patients (**4%**) required dilatation [$p = 0.022$]
- No dilatation in patients who did not require FT
- No dilatation in patients treated with RT alone
- Dilatation required in 15 of 75 patients treated with chemoRT [$p = 0.05$]

Assumption:

- NG-FTs might perform a stenting function serving to limit synechia formation and maintain luminal patency and motivate patients to swallow sooner



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Is G-tube preferable to NG Tube?

- **Corry *et al.* Head & Neck 2009**
 - Prospective nonrandomized study comparing NG-T versus PEG
 - Patients with HNSCC treated with radical RT or concurrent chemoRT
 - 81% received concurrent chemoRT
 - **PEG:** 32 patients
 - **NG:** 73 patients



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Corry *et al.* Head & Neck 2009 - Results

1. Weight loss

- PEG patients sustained significantly less weight loss at 6 wks post-Tx
- Median 0.8 kg gain (PEG) vs 3.7 kg loss (NG) ($p < 0.001$)

2. Dysphagia

- PEG patients experienced more grade 3 dysphagia
- 25% (PEG) vs 8% (NG) ($p < 0.07$)

3. Feeding tube duration

- PEG patients had longer median duration of use
- 146 days (PEG) vs 57 days (NG) ($p < 0.001$)



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G-tubes and Quality of Life

- *Evidence that feeding tubes have an adverse effect on QOL*
- **Rogers et al. Oral Oncol 2007**
 - Looked at patient's experience with long-term G-tube feeding following primary surgery for oral/oropharyngeal cancer
 - Patients with retained G-tubes
 - n = 30, median 34 mo
 - Deficits in all *University of Washington* QOL domains
 - Family life, intimate relationships, social activities, hobbies
 - Versus non-G-tube or ex-G-tube patients
 - n = 20, median 7 mo



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Prevention and Treatment Strategies

- No large, multi-institution, prospective, controlled swallowing intervention series
- Most data is retrospective
- Early therapeutic regimens of swallowing exercises provide best prevention for long-term swallowing
 - Strengthen musculature
 - Increase precision of movements
 - Maintain range of motion
- Studies show less benefit to delayed swallowing therapy
 - Aim for maximal swallowing recovery by 6mo post-CRT



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Prevention and Treatment Strategies

Table 3. Radiation Therapy Swallowing Exercises

Targeted Muscles/Anatomic Structure	Exercise Description
Suprahyoid musculature and larynx	Isometric-isokinetic head lifting in supine positioning to increase hyolaryngeal excursion and upper esophageal sphincter opening
Larynx and true vocal folds	Airway closure and sound production with systematic variation of pitch to move larynx
Base of tongue and posterior pharyngeal wall	Isometric and range of motion

Prevention and Treatment Strategies

- **Feng *et al.* IJROBP 2007 & Eisbruch *et al.* IJROBP 2004**
 - Suggest *minimizing* dose to
 - Pharyngeal constrictor muscles
 - Cricopharyngeal inlet
 - Glottic larynx
 - Supraglottic larynx
 - Using “dose-painting” IMRT
 - May decrease long-term GT dependence and improve QOL



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In Summary

- Practice varies significantly among centres
- Indications for placement of G-tubes are poorly defined despite considerable experience in their use in HNSCC
- No predictive model to identify patients who are at risk of chronic dysphagia and may benefit from a prophylactic G-tube
 - Potential risk for overtreatment
- Significant methodologic flaws with published studies



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In Summary

Prophylactic G-tube:

– Pros

- Less morbidity
- Prevents dehydration
- Prevents weight loss severity

– Cons

- Increase G-tube dependency
- Increase risk grade 3 dysphagia
- Increase need for esophageal dilatation
- Increase risk of complications (cellulitis around insertion site, leakage of G-tube)
- Impacts QOL



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The BCCA Experience



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Use of Percutaneous Gastrostomy Tube Placement in Head and Neck Cancer Patients Treated with Concurrent Chemo- Radiation Therapy

Irene Karam MD, Gavin Wilson, Angela Bowman RD, Frances Wong FRCPC, Robert Olson FRCPC



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What do we do at the BCCA?

- **FVCC**

- Mostly prophylactic approach
- G-tubes are placed prior to concurrent chemo-RT therapy in most patients treated with chemo-RT

- **VCC**

- Mostly therapeutic approach
- G-tubes placed only when needed in most patients treated with chemo-RT



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Question

- For H&N patients receiving concurrent chemoRT, should prophylactic G-tubes be placed?

**Therapeutic
G-tube**

versus

**Prophylactic
G-tube**



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How to answer this Question

- RCT
- Don't have time, resources, etc...
- Therefore, retrospective analyses have been performed
 - Significant epidemiological mistakes have been made...



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How others have tried to answer this Question

**Therapeutic
G-tube**

versus

**Prophylactic
G-tube**

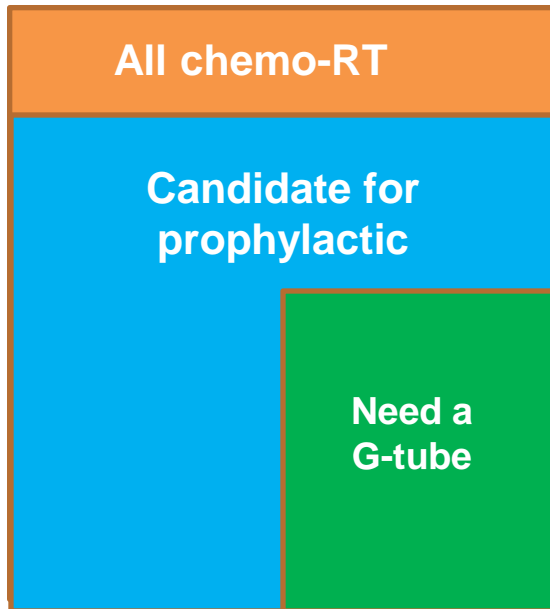


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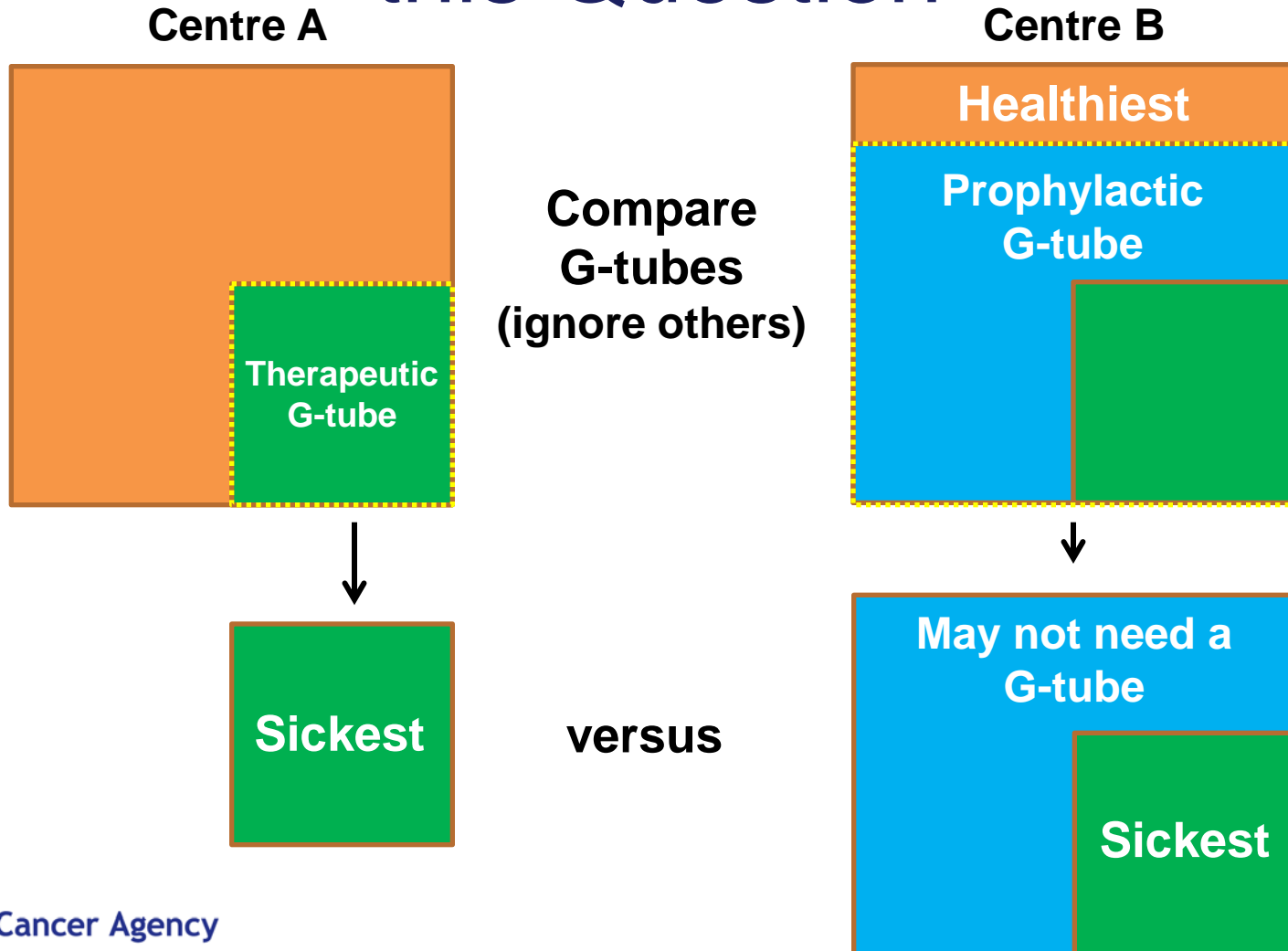
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Not all patients need a G-tube



- ~ 1 / 4 of patients will ultimately need a G-tube
- Can be difficult to place near end of treatment, when patients are sickest
- Therefore, many advocate for selecting patients in advance most likely to get a G-tube
 - Many will never have needed a G-tube

How others have tried to answer this Question

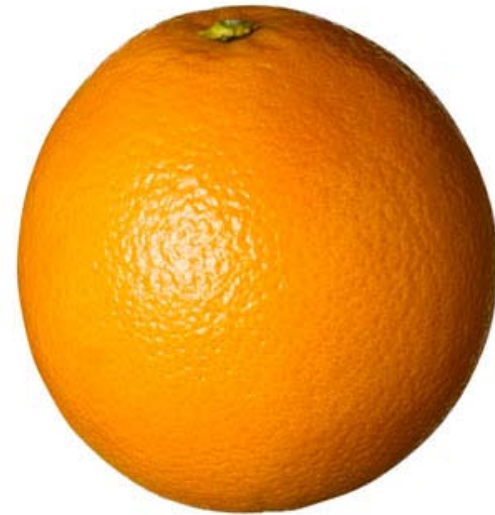


How others have tried to answer this Question



Therapeutic G-tubes

versus



Prophylactic G-tubes

Selection Bias!



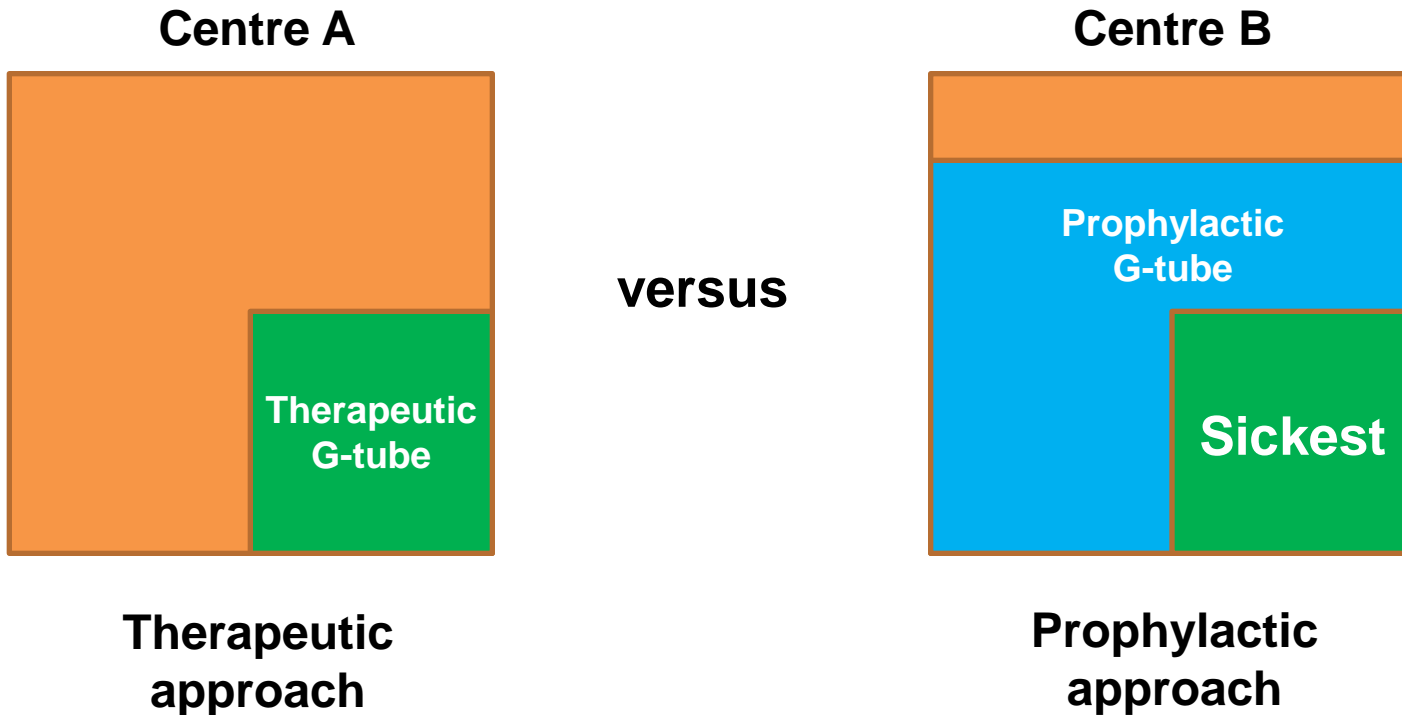
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How we will try to answer this Question

Compare two centres with different G-tube approach, to prevent selection bias



RCT would best...

Purpose

- Retrospective analysis comparing the outcomes of patients treated at a cancer centre that generally prophylactically places G-tubes (FVCC), with a centre that reserves G-tube placement for immediate use (VCC)



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Methods and Materials



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Population-based retrospective chart review

Oncology Reporting System

All H & N patients treated with concurrent chemoRT from **January 2001 to June 2009**

Exclusion criteria:

- NG tube (~15 pts)
- RT alone
- Not H&N primary

VCC
“therapeutic”

n = 269

FVCC
“prophylactic”

n = 165

Results:

Patient and Treatment Characteristics



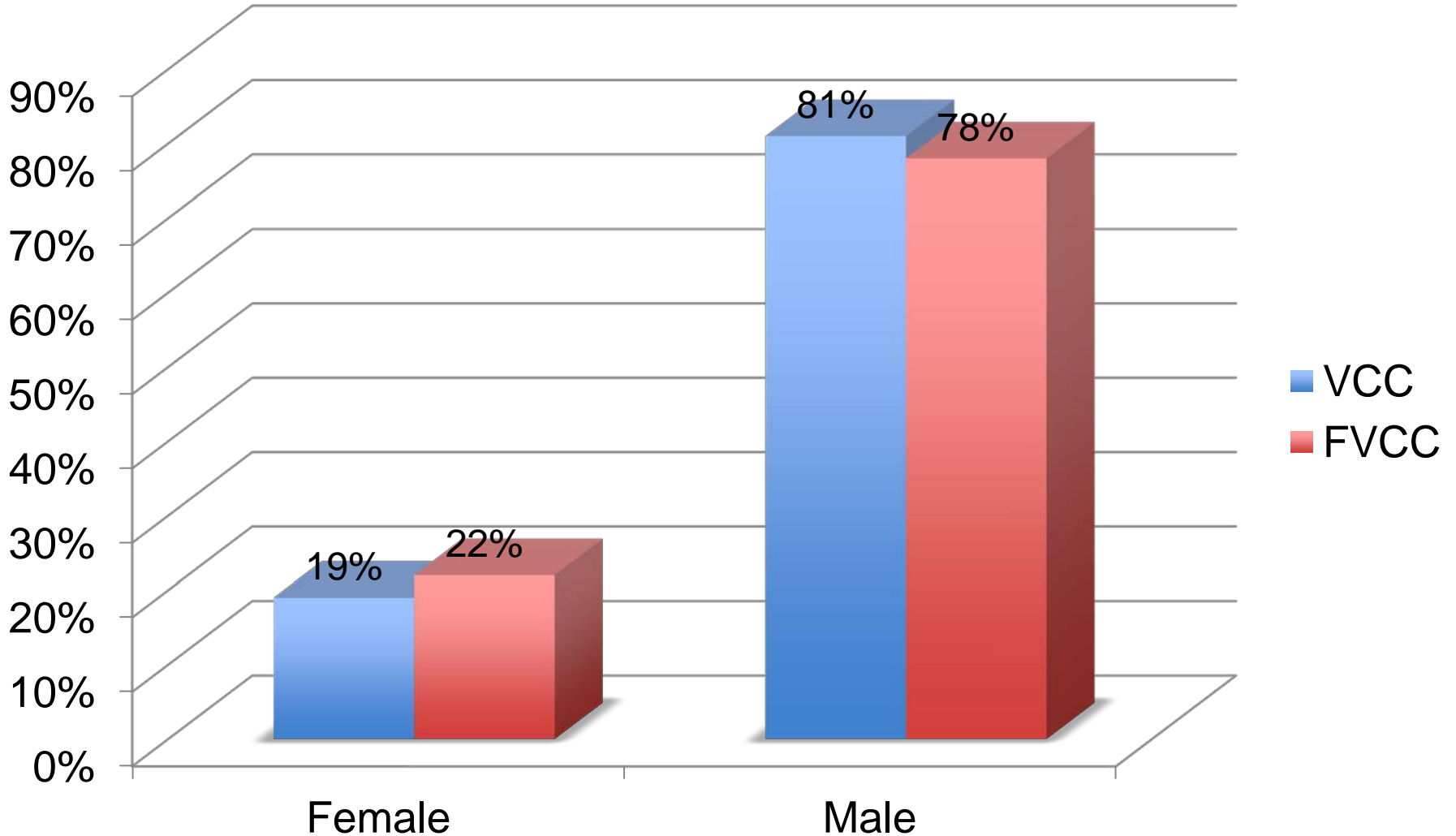
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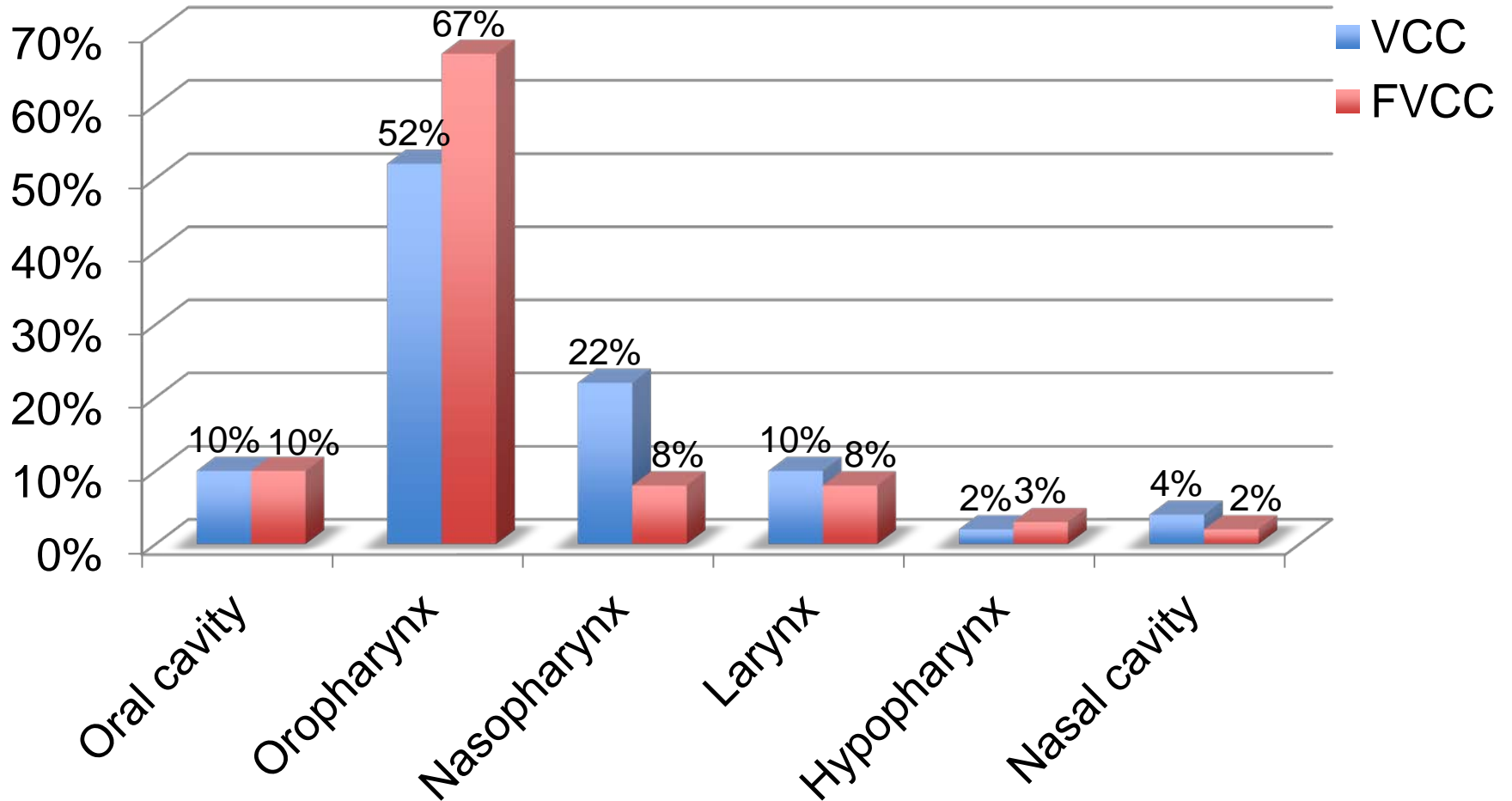
Gender

p-value = 0.537



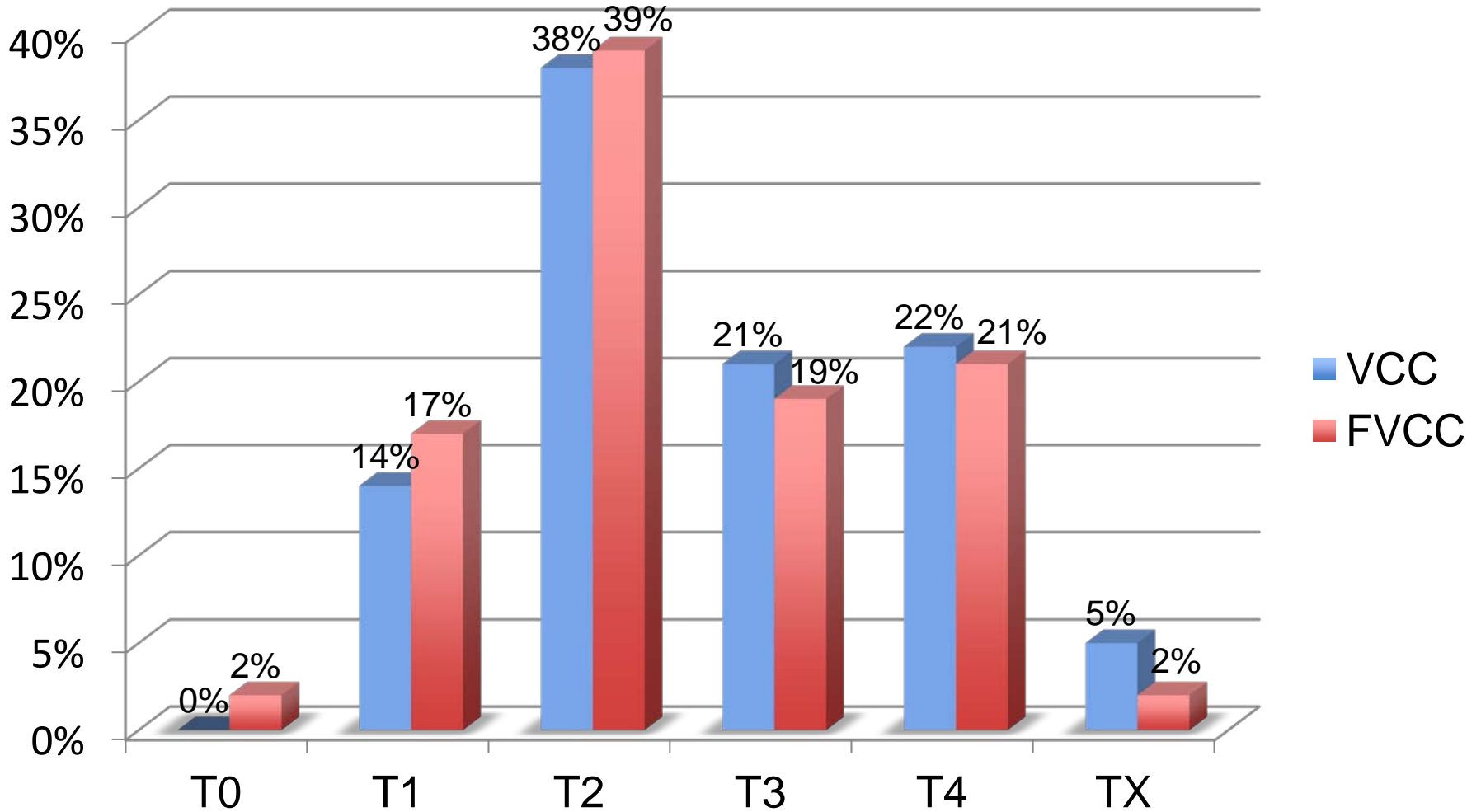
Primary tumor site

p-value = 0.011



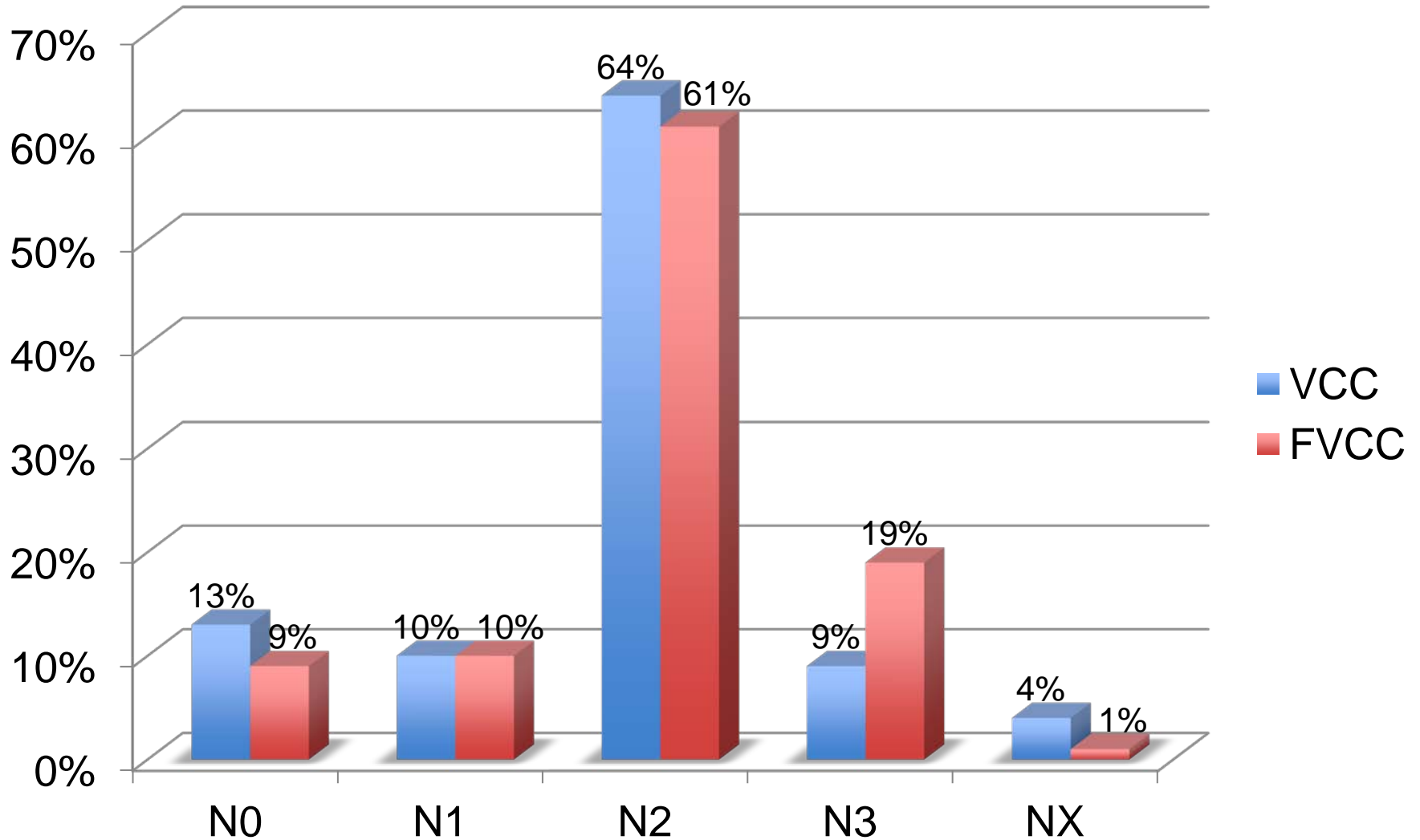
T stage

p-value = 0.021



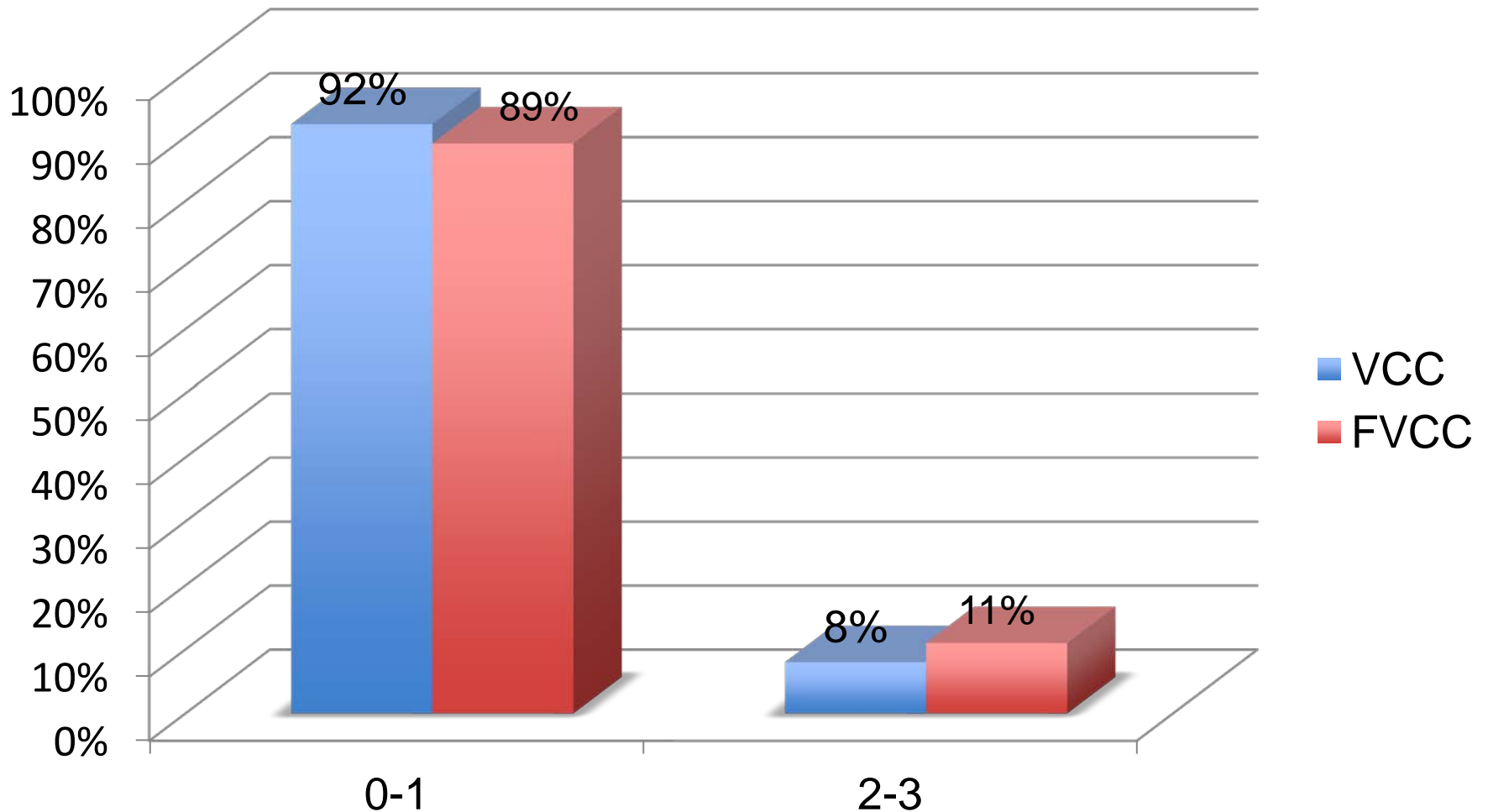
N stage

p-value = 0.002



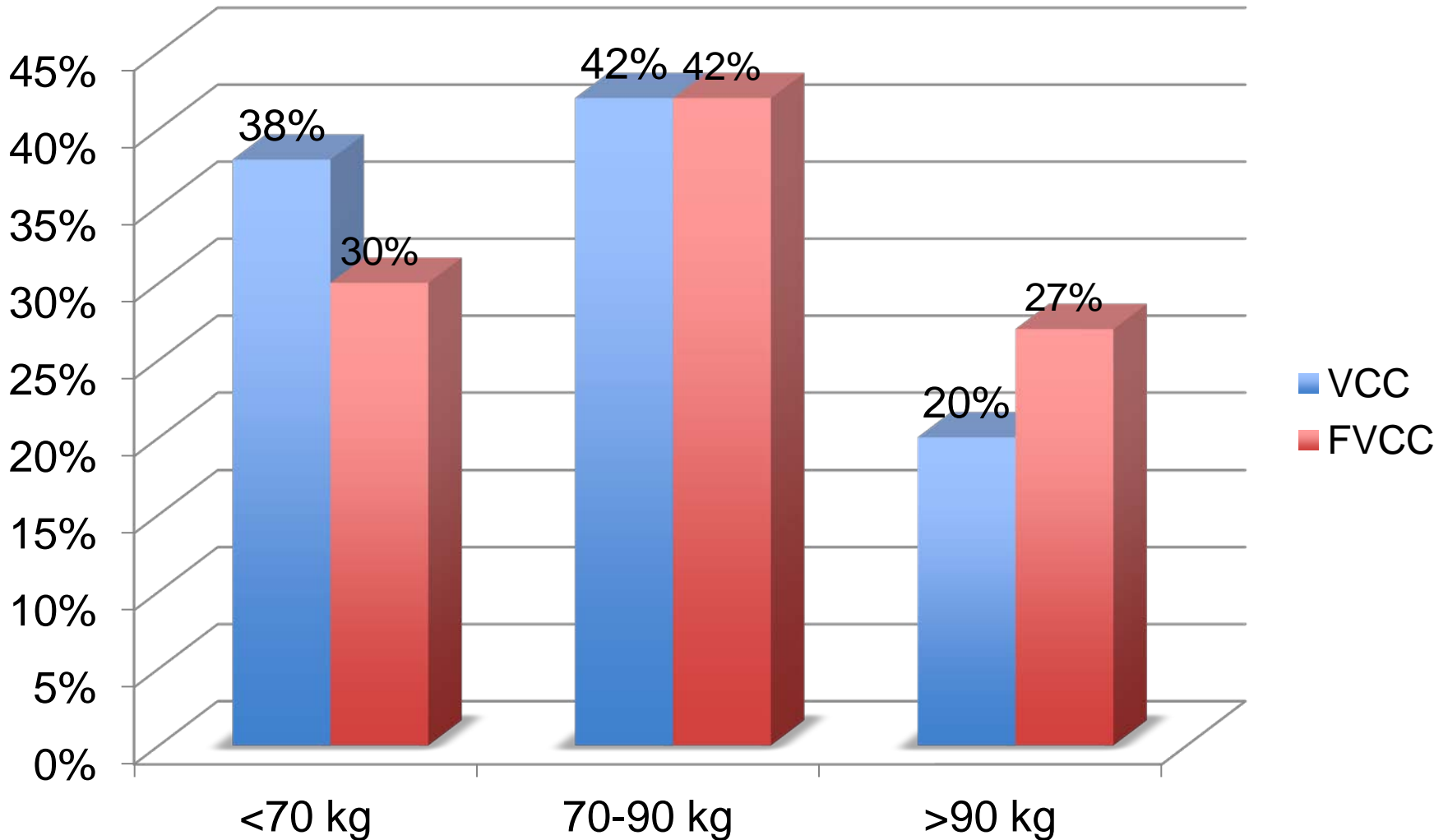
ECOG performance status

p-value = 0.232



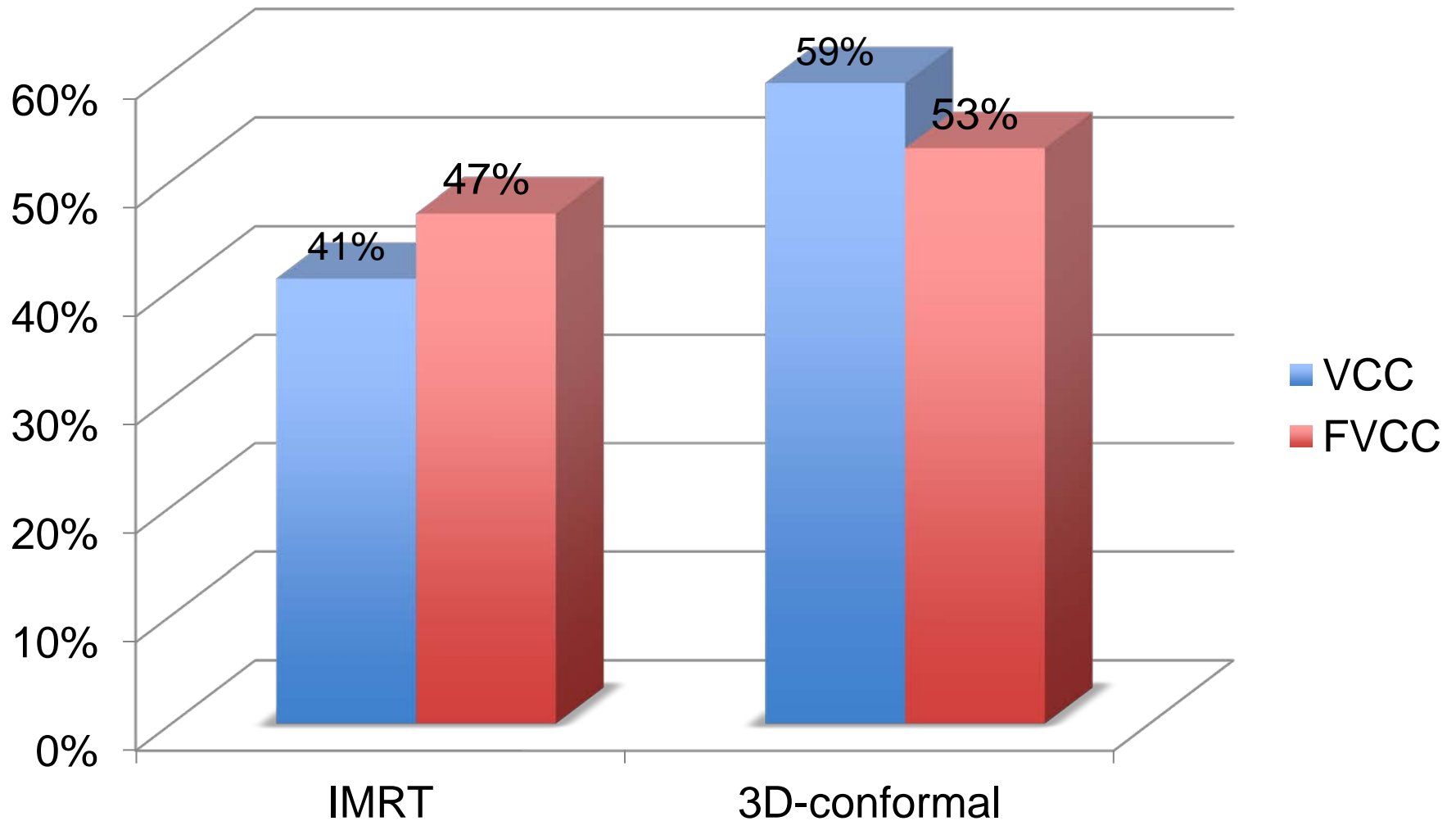
Weight at baseline (kg)

p-value = 0.134



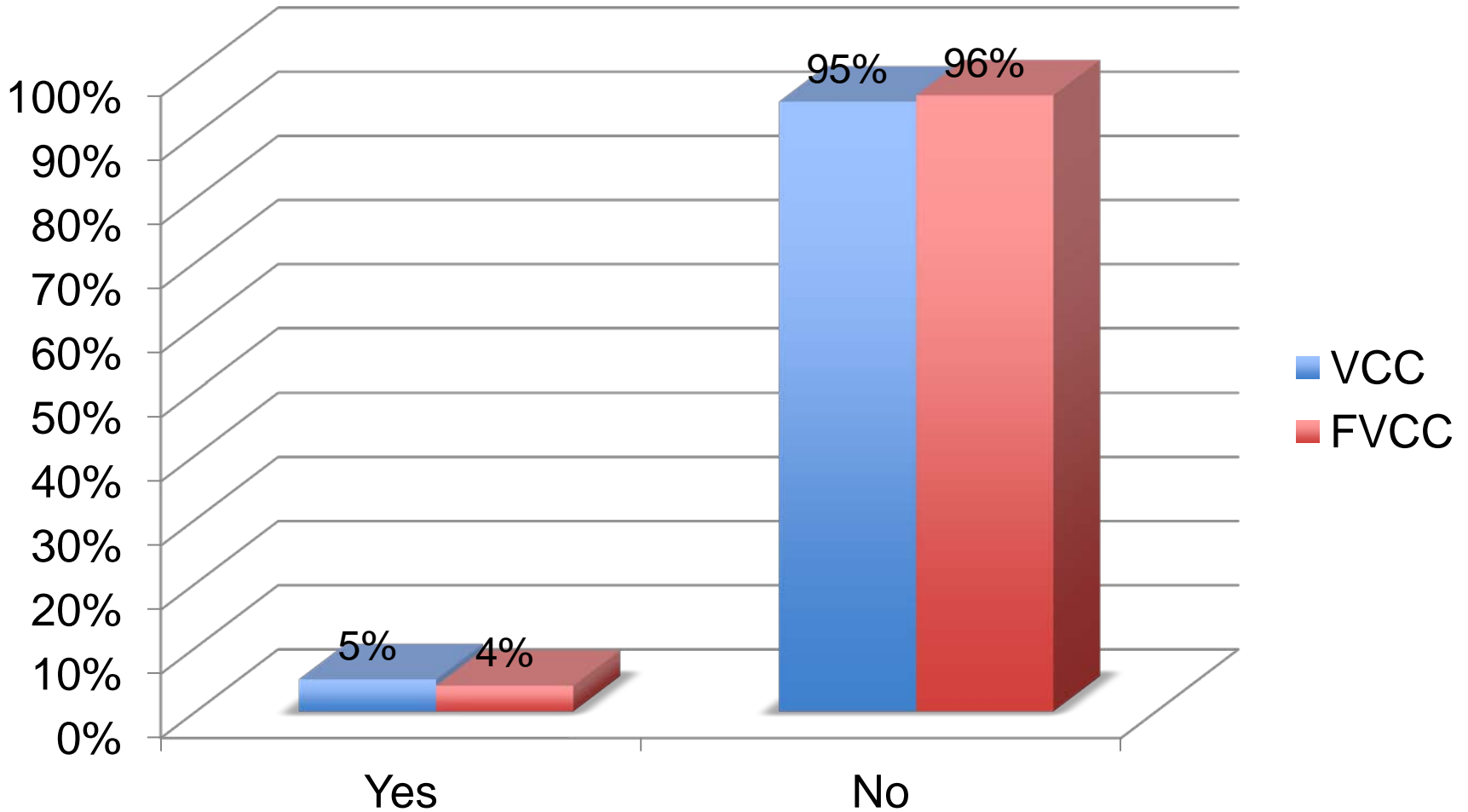
RT technique

p-value = 0.233



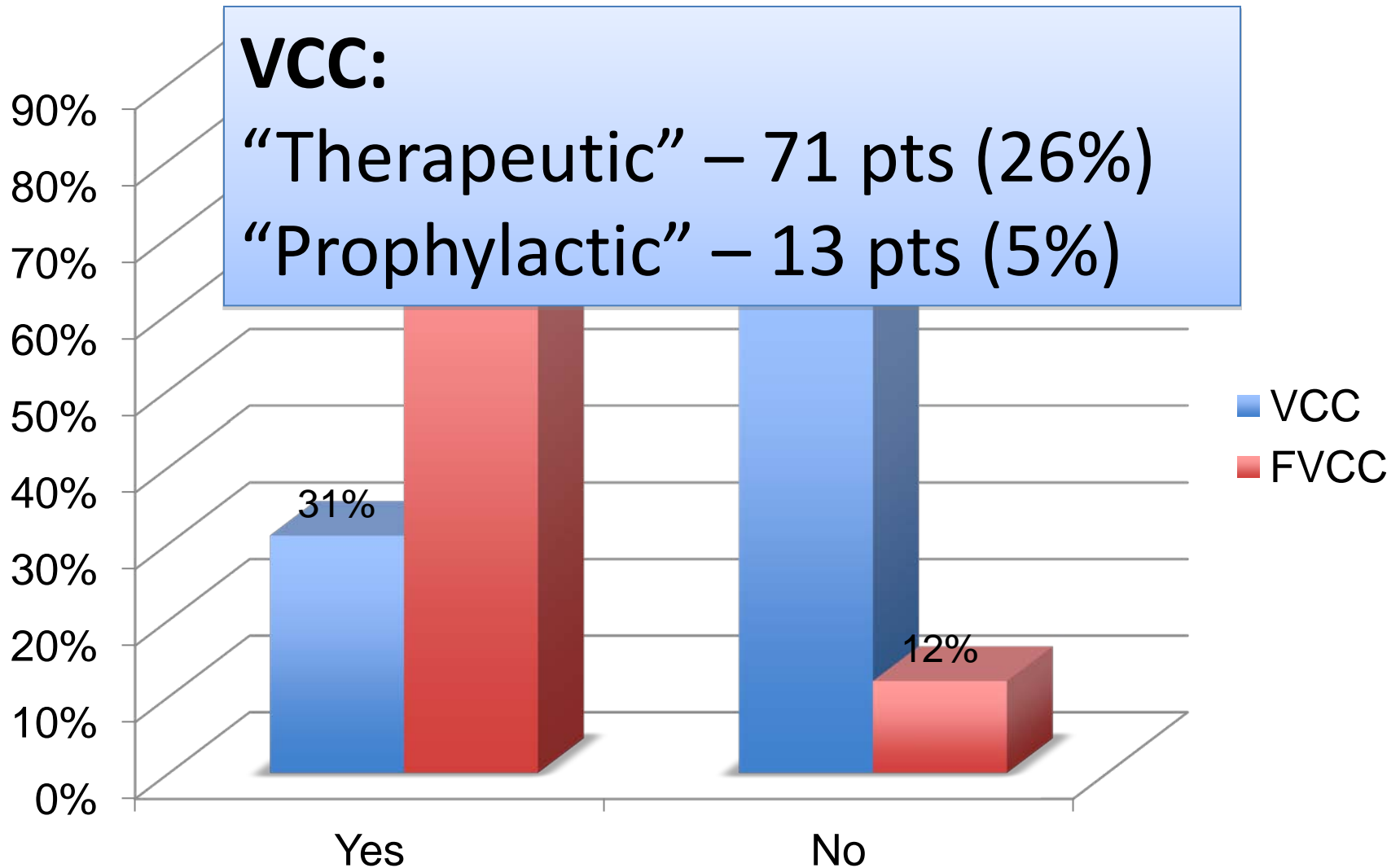
Neck dissection (pre-RT)

p-value = 0.806



G-tube placement

p-value <0.001



Results:

G-tube-related Complications



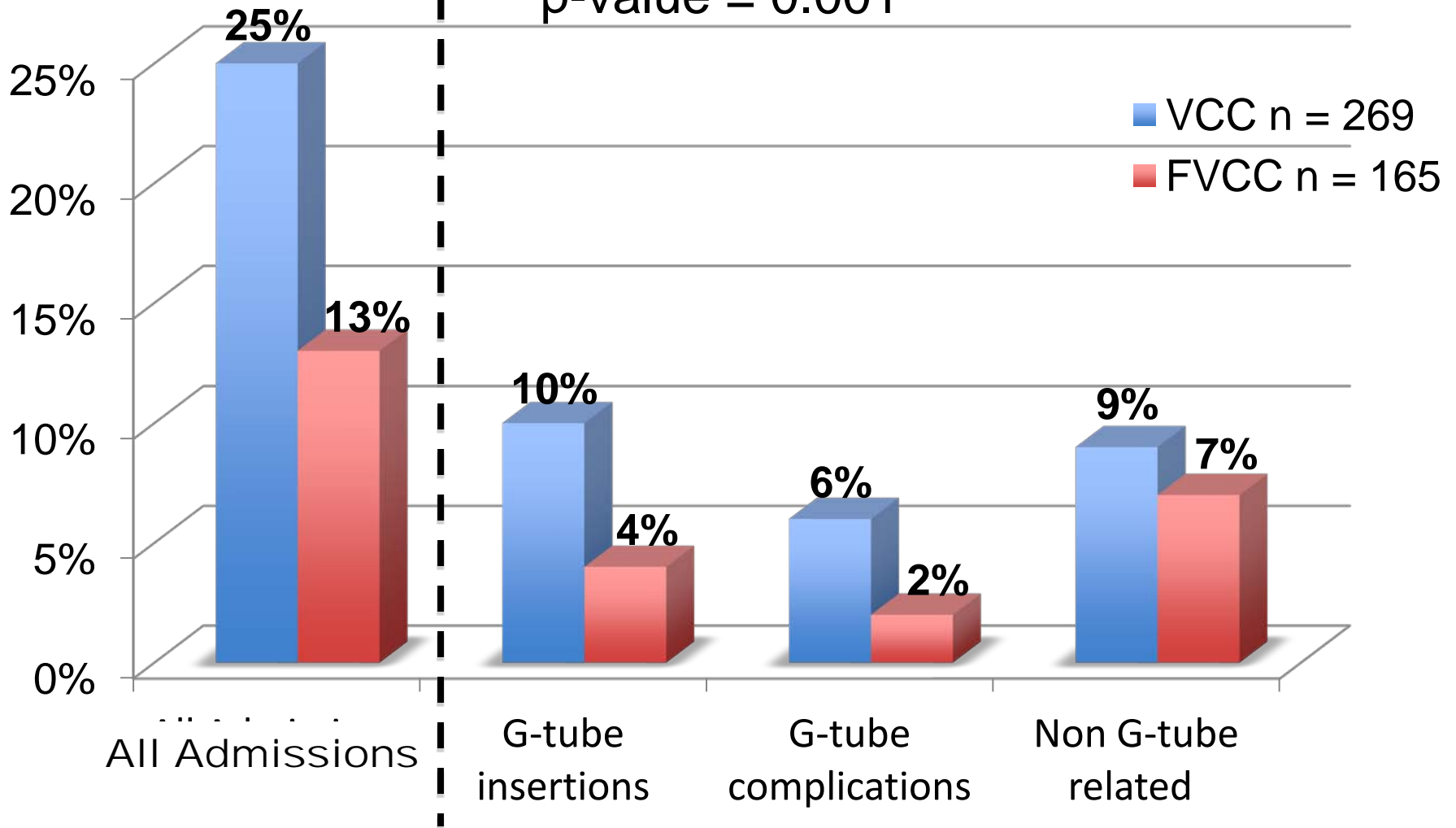
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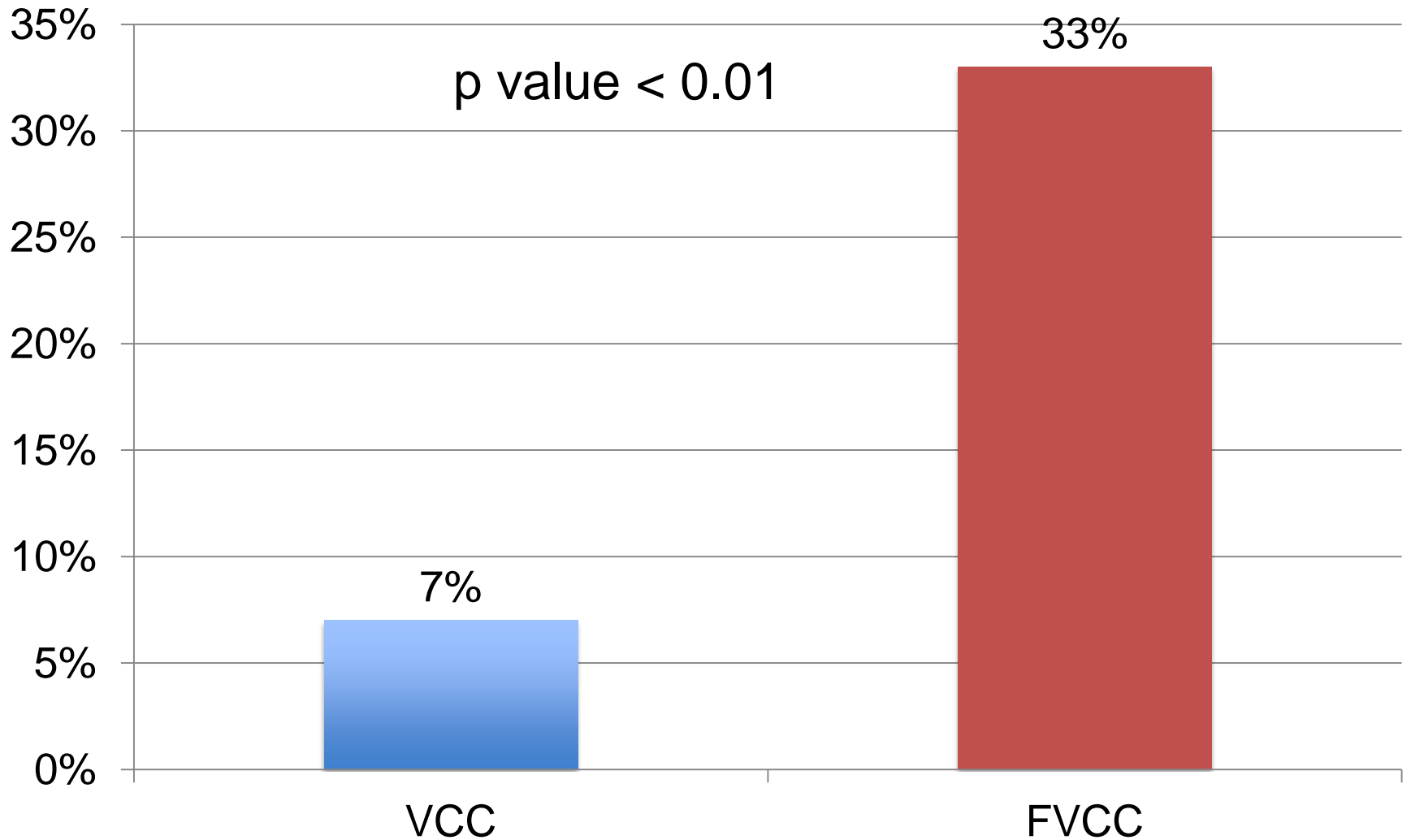
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Admissions for G-tube complications/insertions

p-value = 0.001

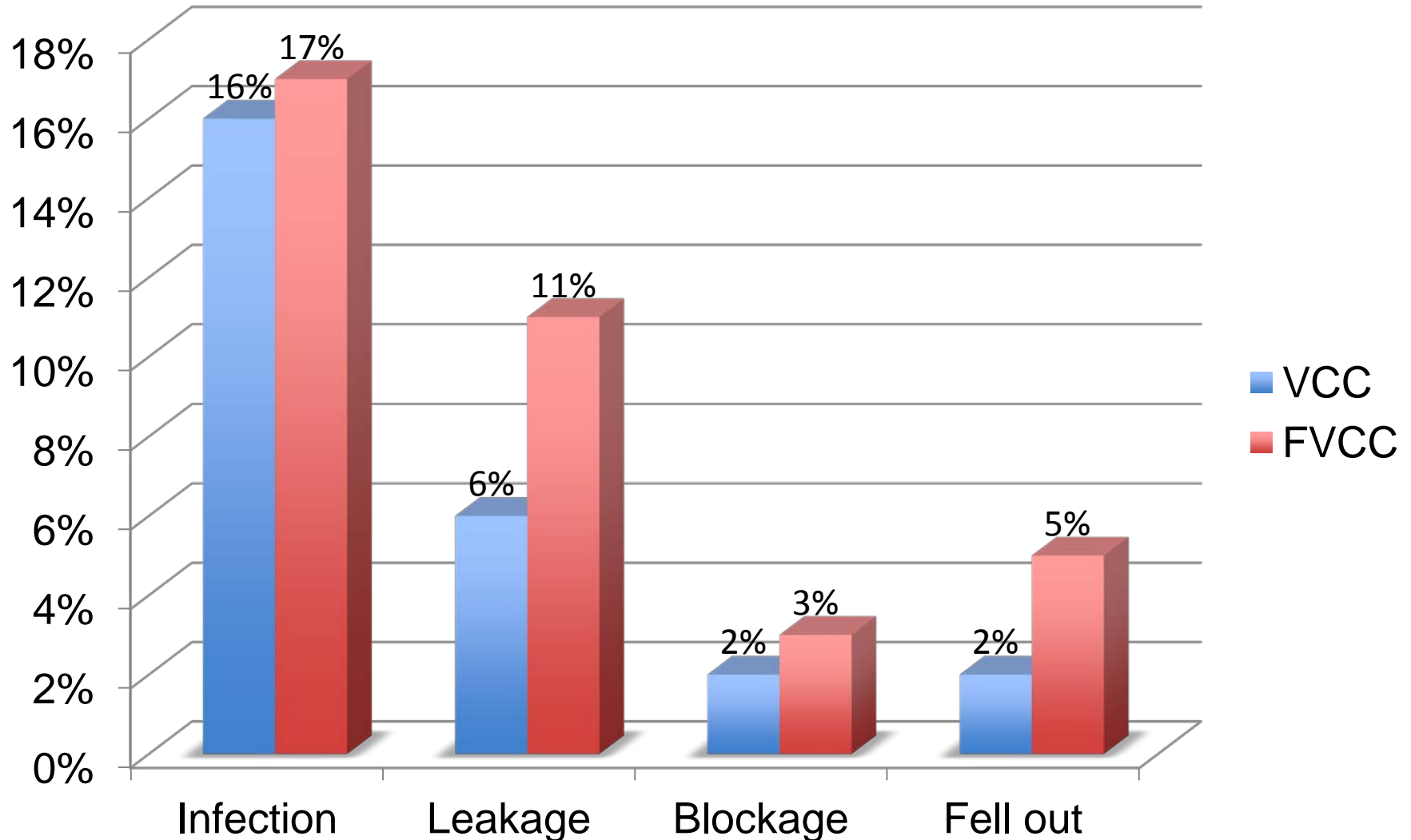


Major G-tube complications

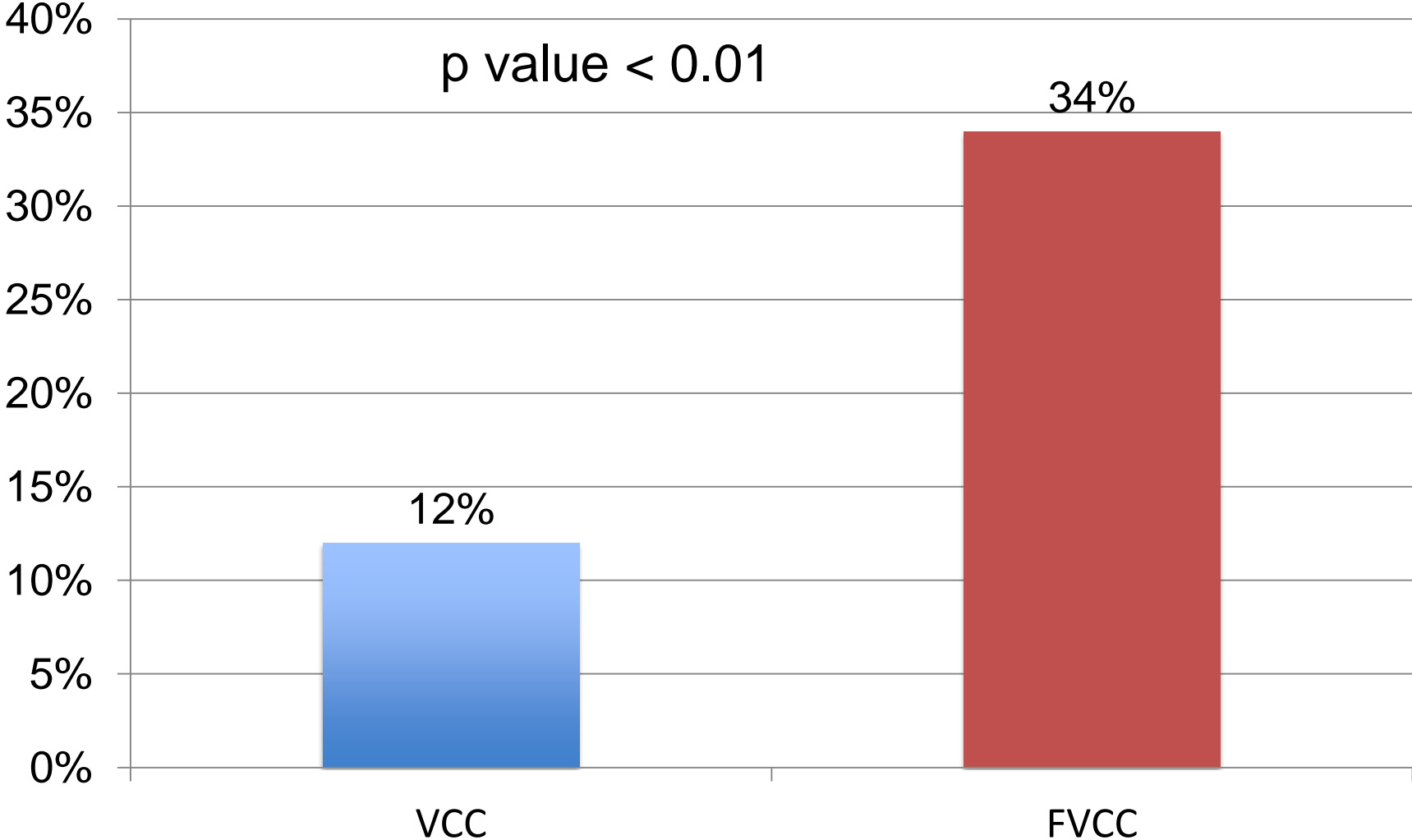


Major G-tube complications

Subset analysis of G-tubes only

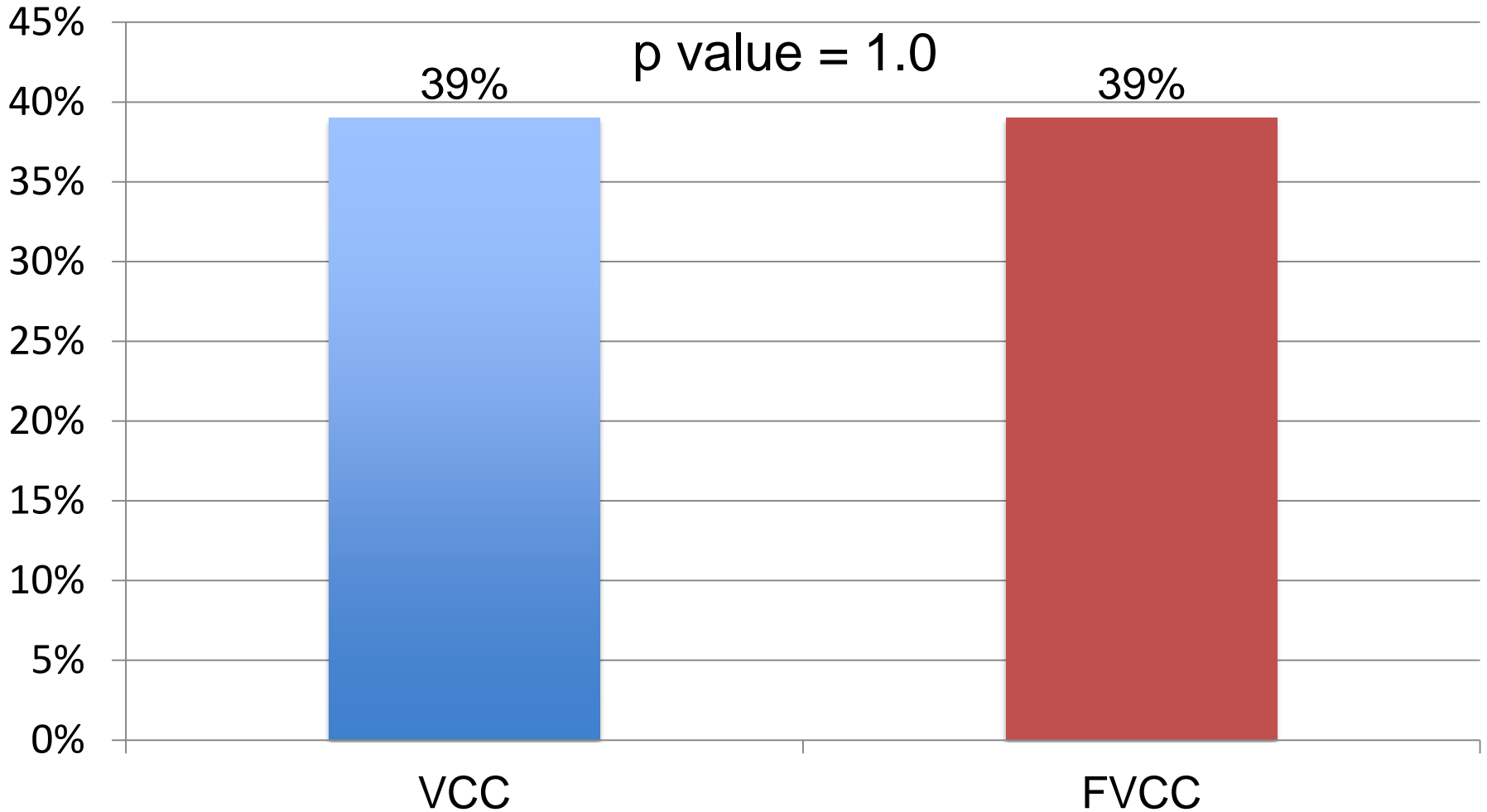


G-tube dependence (>90 days)

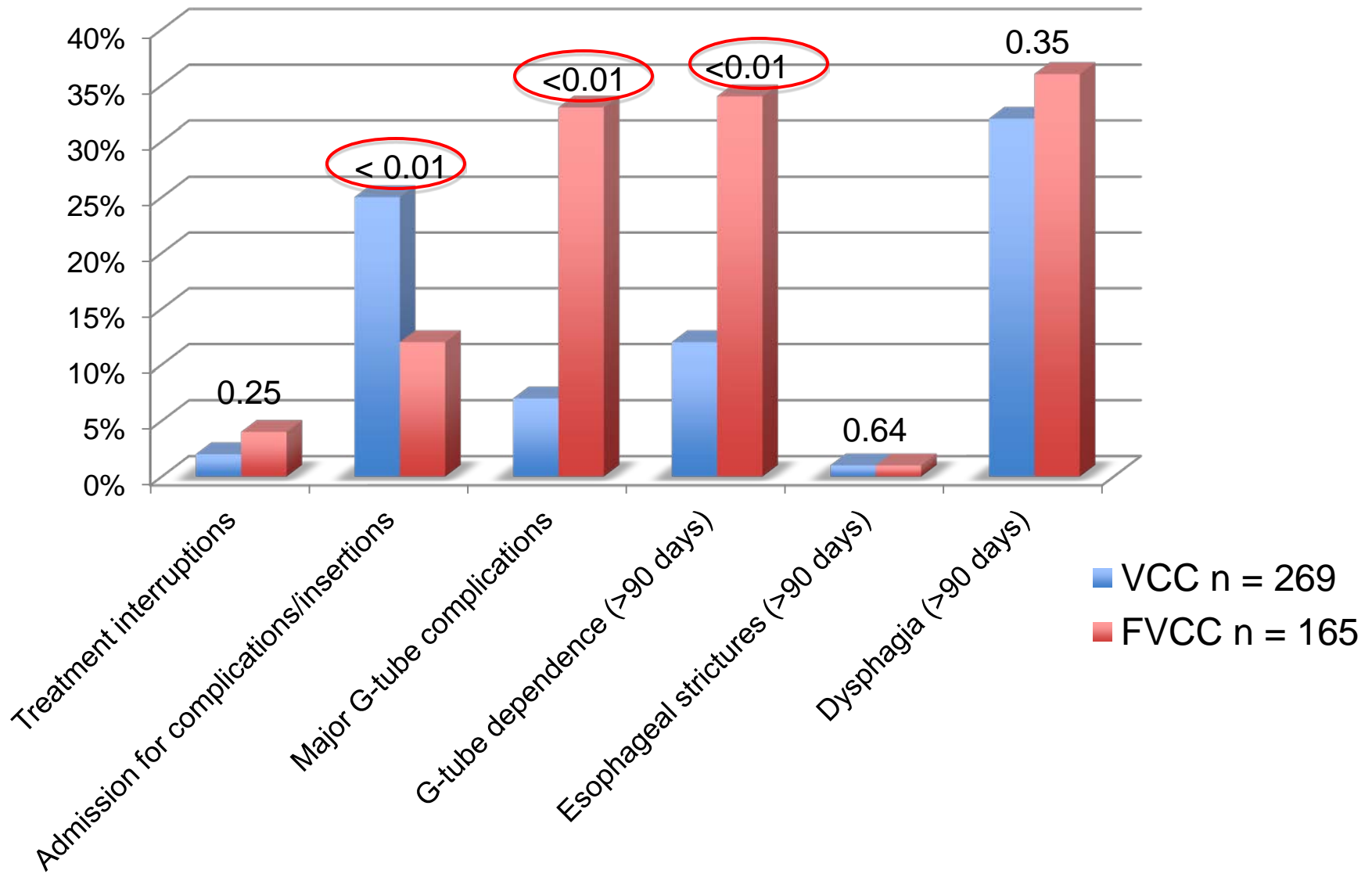


G-tube dependence (>90 days)

Subset analysis of G-tubes only



G-tube-related complications



Results:

Weight Differences

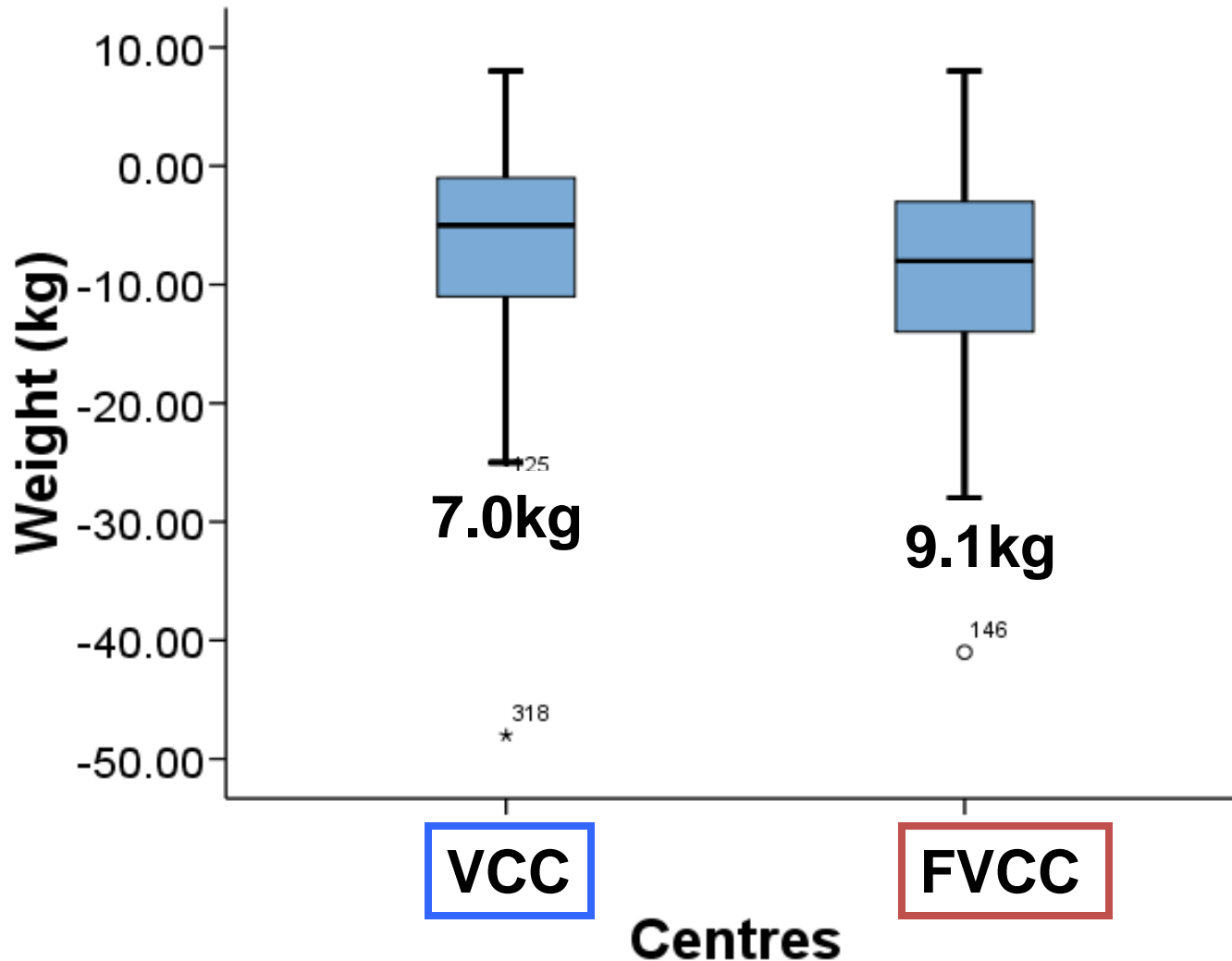


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Mean weight loss at 1 year



Weight differences

- After controlling for time since first weight:
 - Patients from VCC had 1.52 kg less weight loss than patients from FVCC (p = 0.08)
 - Weight difference was not statistically significant



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Results:

Overall Survival

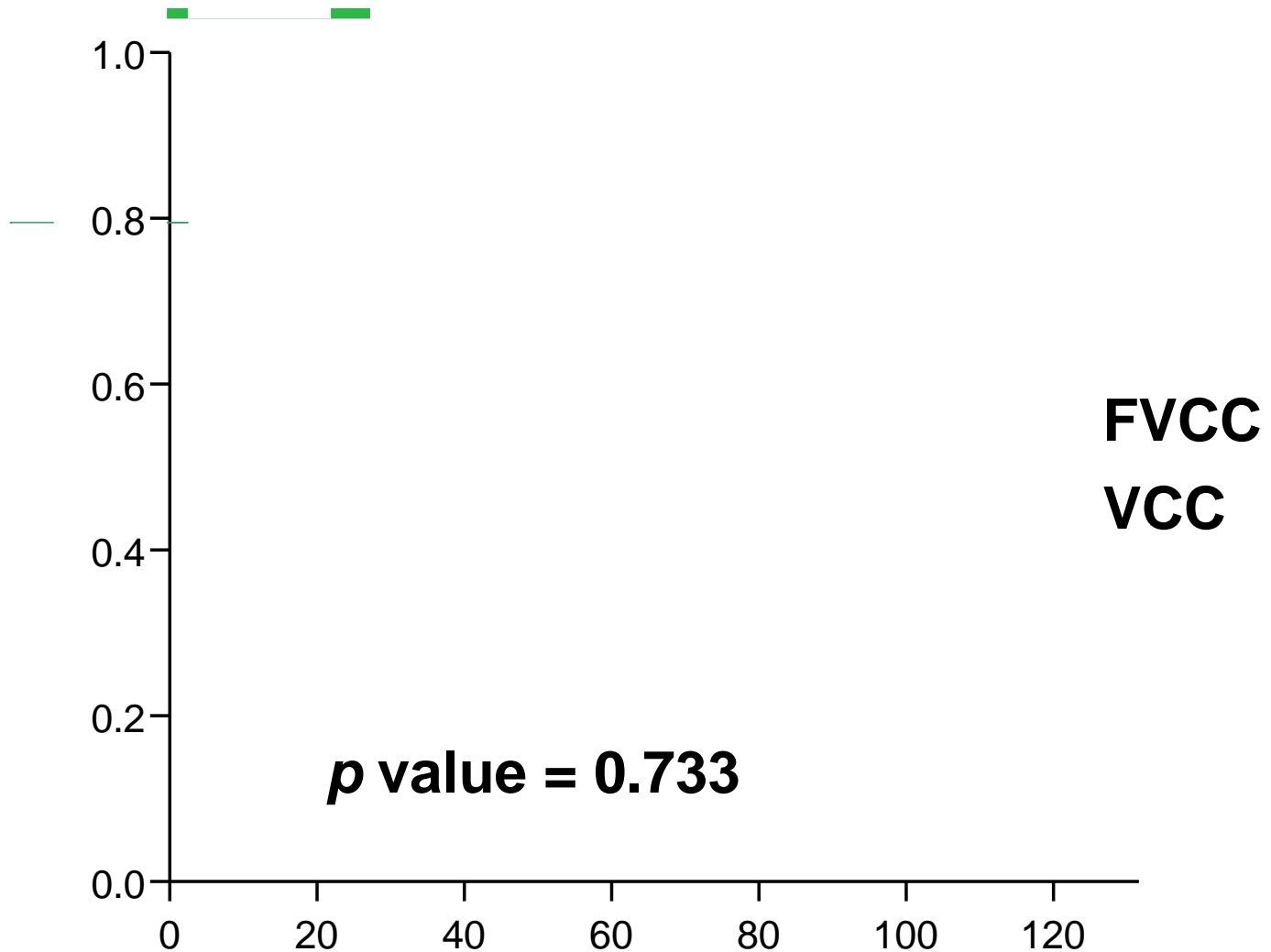


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Overall Survival comparison between centers



Conclusions



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Conclusions

- Centre with **therapeutic approach**, has to admit more patients for G-tube insertions/ complications
- Centre with **prophylactic approach**, has ~5x more G-tube complications
- Centre with **prophylactic approach**, has ~3x increased rate of G-tube dependence (>90 days)
- No significant difference in weight loss or survival between **prophylactic** and **therapeutic** approaches



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Conclusions

- Our results are highly suggestive that a **prophylactic approach** results in complications and G-tube dependence in patients who potentially would never have received a G-tube if a therapeutic approach was used.
- Since weight loss and survival are similar for both groups, **therapeutic approach** should be preferred.



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Thank you for
your attention

