MANAGEMENT OF CA HYPOPHARYNX

GENERAL TREATMENT RECOMMENDATIONS BASED ON HYPOPHARYNX TUMOR STAGE

Stage I	Radiation alone or voice preservation surgery if feasible
Stage II	Radiation alone
Stage III and IV with functional laryngopharynx	Concurrent chemoradiation followed by selective neck dissection
Stage III and IV with dysfunctional laryngopharynx[a]	Laryngopharyngectomy with adjuvant RT or CRT

RT, radiation therapy; CRT, chemoradiation therapy.

[a]Patients with bulky, destructive tumors that severely compromise the airway or destroy cartilage, bone, and deep soft tissue are often best served with immediate laryngopharyngectomy and postoperative radiation or chemoradiation.

- For patients presenting with early-stage definitive radiotherapy alone or voice-preserving surgery are viable and acceptable treatment options.

- The vast majority of patients, however, present with stage III or IV disease and warrant multimodality treatment.

Primary Surgery
T1 and T2 Tumors

- Indications for primary surgical management of patients with early cancers of the hypopharynx
  - ✓ History of previous H&N radiation
  - ✓ Organ conservation approaches possible
  - ✓ Those who refuse radiation

Role of surgeon in Ca hypo pharynx patients who undergo non operative treatment approaches

Performing

- ✓ Endoscopic biopsy
- ✓ Detailed assessment of tumor extent
- ✓ Methods to secure the airway (tracheotomy or laser debulking)
- ✓ Methods to ensure adequate nutrition (gastrostomy)
- ✓ Multidisciplinary oncologic follow-up after nonoperative treatment

Selected T1 and T2 hypopharynx cancers may lend themselves to surgical excision.

Favorable subsites include

- Upper pyriform sinus
- Posterior pharyngeal wall.

- The standard supraglottic laryngectomy encompasses the aryepiglottic fold and may be extended to include part of the arytenoids, the base of the tongue, and the upper pyriform sinus.

Relative contraindications to organ conservation surgery for hypopharynx cancers

- Cartilage invasion
- Vocal fold fixation
- Postcricoid invasion
- Deep pyriform sinus invasion
- Extension beyond the larynx

- In recent years, advancements in organ preservation surgery have included the use of
- Transoral laser microsurgery
- Transoral robotic surgery.
- For selected cases, these approaches can achieve oncologic tumor removal, while limiting normal tissue disruption, thereby potentially avoiding tracheostomy and the use of feeding tubes

- Recent results have demonstrated that appropriately selected T1 or T2 lesions can achieve negative margins by transoral laser microsurgery or transoral robotic surgery.
- Oncologic outcomes appear similar to open surgical approaches using this technique and are likely accompanied by lower rates of permanent gastrostomy tube or tracheostomy placement

FIVE-YEAR ONCOLOGIC OUTCOMES FOR TRANSORAL MICROLASER SURGERY FOR T1 OR T2 HYPOPHARYNGEAL TUMORS

Study (Reference)	T Stage	N	Node (+)	LC	DSS	OS	Permanent Gastrostomies	Permanent Tracheostomies
Martin et al. (36)	pT1	20	62%	84%	NR	68% (stage I–II)	3.5%[a]	3.5%[a]
	pT2	48		70%	NR			
Karatzanis et al. (35)	pT1	45	56%	90%	78%	NR	0	0
	pT2	74	64%	83%	70%	NR	4%	2.5%

LC, local control; DSS, disease-specific survival; NR, not reported; OS, 5-year overall survival.

[a]Entire cohort, including T3 and T4 patients.

T3 or T4 Resectable Tumors

- Most T3 and T4 hypopharynx cancers that are treated surgically will require total laryngectomy with efforts to preserve a posterior strip of the hypopharynx spanning the oropharynx to the esophagus.

- For more bulky tumors of the hypopharynx, total laryngopharyngectomy, removal of the larynx and the entire hypopharynx, is required.
- This procedure creates a gap between the oropharynx and esophagus that must be reconstructed with a tubed fasciocutaneous flap such as the radial forearm free flap or anterolateral thigh flap, a free jejunum, or a tubed pedicled myocutaneous flap

Types of surgeries in T3 T4 Ca hypopharynx

Partial laryngo pharyngectomy

- For small medial and anterior PF sinus lesions
- Removes false cords ,epiglottis ,areyepiglottic folds , PF sinus but True vocal cords are preserved

Total laryngo pharyngectomy

- For more advanced hypopharyngeal lesions
- Total laryngectomy with removal of variable amount of pharyngeal wall.

Postoperative Radiation Therapy

- Most advanced hypopharynx cancers that are treated with initial surgical resection

- Postoperative radiation therapy can be added in an effort to enhance locoregional control rates

Indications for postoperative radiation

- T4 primary tumors
- Close or positive microscopic margins
- Cartilage or bony invasion
- More than one metastatic lymph node
- Extracapsular extension (ECE)
- ✓ Conventional therapy involves the use of a shrinking-field technique to deliver 54 to 63 Gy to all areas at risk and a boost to 60 to 66 Gy to regions of ECE or positive margins. The entire cervical nodal chain from the skull base to the clavicle bilaterally should be included

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PRINCIPLES OF RADIATION THERAPY[1,2]

POSTOPERATIVE:

RT

- Preferred interval between resection and postoperative RT is ≤6 weeks.
- PTV
  - High risk: Adverse features such as positive margins (See footnote h on HYPO-3).
    - 60-66 Gy (2.0 Gy/fraction; daily Monday-Friday) in 6-6.5 weeks
  - Low to intermediate risk: sites of suspected subclinical spread
    - 44-50 Gy (2.0 Gy/fraction) to 54-63 Gy (1.6-1.8 Gy/fraction)[4]

POSTOPERATIVE CHEMORADIATION

- Concurrent single-agent cisplatin at 100 mg/m^2 every 3 weeks is recommended.[7-10]

Either intensity-modulated RT (IMRT) or 3-D conformal RT is recommended.

RESULTS OF RTOG 9501 POSTOP CHEMORADIATION TRIAL

	Arm 1[a] (%)	Arm 2[b] (%)	P
2-yr LRC	72	82	.003
2-yr DM	23	20	NS

RTOG, Radiation Therapy Oncology Group; LRC, locoregional control; DM, distant metastasis; NS, not significant.

[a]Arm 1: 60 Gy in 6 weeks.

[b]Arm 2: 60 Gy in 6 weeks with concurrent cisplatin (100 mg/m^2) days 1, 22, and 43.

Adapted from Cooper JS, Pajak TF, Forastiere AA, et al. Postoperative concurrent radiotherapy and chemotherapy for high-risk squamous-cell carcinoma of the head and neck. *N Engl J Med* 2004;350:1937–1944.

RESULTS OF EORTC POSTOPERATIVE CHEMORADIATION TRIAL

	Arm 1[a]		Arm 2[b]		
	Median	5 Year	Median	5 Year	p
PFS	23 months	36%	55 months	47%	0.04
OS	32 months	40%	72 months	53%	0.02

EORTIC, European Organisation for Research and Treatment of Cancer; PFS, progression-free survival; OS, overall survival.

[a]Arm 1: RT alone 66 Gy in 6 ½ weeks.

[b]Arm 2: 66Gy in 6½ weeks with concurrent cisplatin (100 mg/m^2) days 1, 22, and 43.

Adapted from Bernier J, Domenge C, Ozsahin M, et al. Postoperative irradiation with or without concomitant chemotherapy for locally advanced head and neck cancer. *N Engl J Med* 2004;350:1945–1952.

Definitive Radiation Therapy
T1 and T2 Tumors

- Curative radiation therapy (RT) is generally the preferred treatment option for patients with T1 or T2 hypopharynx tumors.
- Affords good potential for organ preservation without compromise in clinical outcome
- A classical course of radiation therapy for hypopharynx cancer lasts 6 to 7 weeks, with treatment delivered 5 days per week

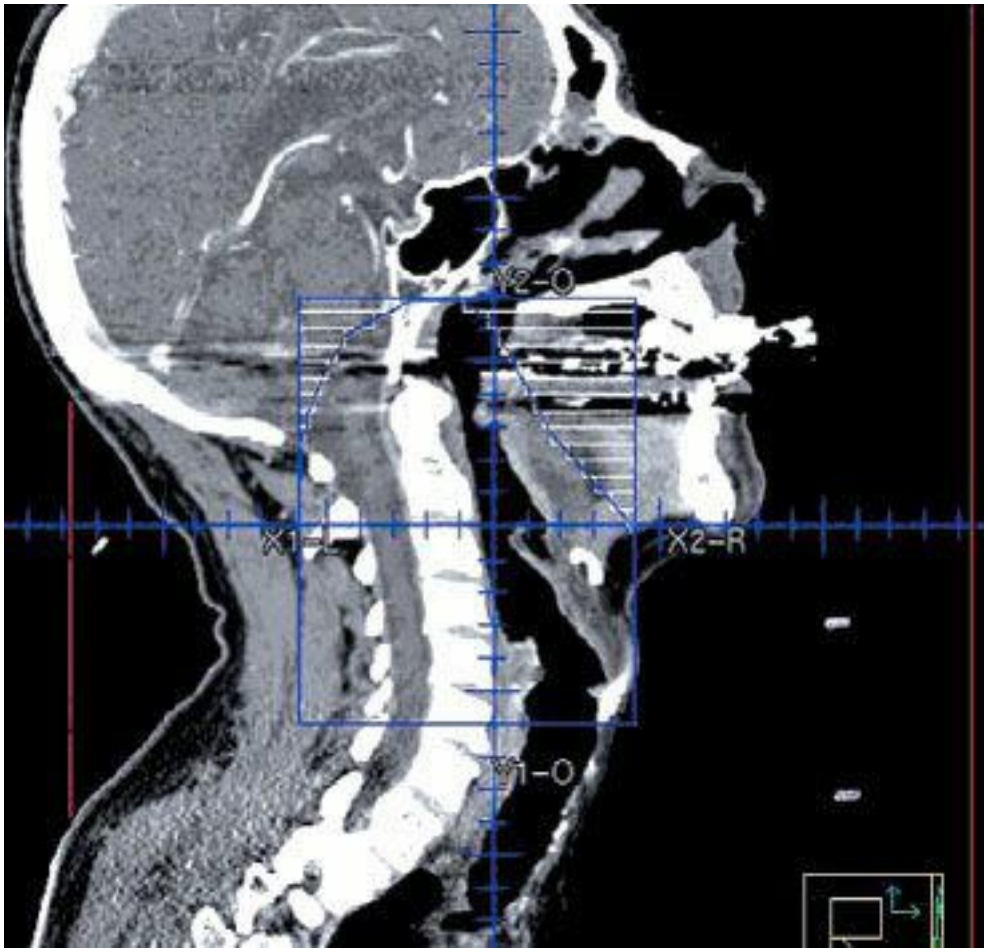
- Conventional treatment involves a shrinking-field technique that initiates with opposed lateral fields encompassing the primary tumor and upper neck lymphatics with a matched anterior field to complete treatment of the lower neck
- One of the most common worldwide fractionation regimens involves the delivery of 2 Gy daily fractions to 70 Gy over 7 weeks

GENERAL ANATOMIC LANDMARKS FOR FIELD DESIGN USING CONVENTIONAL HEAD AND NECK RADIOTHERAPY FOR HYPOPHARYNX CANCER

Border	*Description*
Superior	Include base of skull
Posterior	Behind vertebral spinous processes (or further if required to cover metastatic cervical lymph nodes)
Inferior	Lower aspect of cricoid cartilage unless extensive caudal tumor extension
Anterior	Flash skin at level of thyroid cartilage

For T1 lesions, classical dose is 66–70 Gy in 2 Gy daily fractions. For T2–T4 lesions, consider altered fractionation regimens or concurrent cisplatin-based chemotherapy, particularly for patients over 70 years of age. Gross disease should generally receive 70 Gy with concurrent chemotherapy.

Digitally reconstructed radiograph depicting a classical lateral field designed to encompass the T2 pyriform sinus cancer . plus bilateral cervical lymphatics from skull base to cricoid, with a matching anterior low-neck field to extend the lymphatic coverage to the level of the clavicle



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PRINCIPLES OF RADIATION THERAPY[1,2]

DEFINITIVE:

RT Alone

- PTV
  - High risk: Primary tumor and involved lymph nodes (this includes possible local subclinical infiltration at the primary site and at the high-risk level lymph node(s))
    - Fractionation:
      - 66 Gy (2.2 Gy/fraction) to 70 Gy (2.0 Gy/fraction); daily Monday-Friday in 6-7 weeks[3]
      - 66-70 Gy (2.0 Gy/fraction; 6 fractions/week accelerated)
      - Concomitant boost accelerated RT: 72 Gy/6 weeks (1.8 Gy/fraction, large field; 1.5 Gy boost as second daily fraction during last 12 treatment days)
      - Hyperfractionation: 81.6 Gy/7 weeks (1.2 Gy/fraction, twice daily)
  - Low to intermediate risk: Sites of suspected subclinical spread
    - 44-50 Gy (2.0 Gy/fraction) to 54-63 Gy (1.6-1.8 Gy/fraction)[4]

CONCURRENT CHEMORADIATION[5,6]

- PTV
  - High risk: typically 70 Gy (2.0 Gy/fraction)
  - Low to intermediate risk: 44-50 Gy (2.0 Gy/fraction) to 54-63 Gy (1.6-1.8 Gy/fraction)[4]

Either intensity-modulated RT (IMRT) or 3-D conformal RT is recommended.

- Due to the high likelihood of subclinical nodal metastases even in the clinically N0 neck, patients traditionally receive comprehensive radiation to encompass nodal regions from the skull base to the clavicle .
- Due to the varying thicknesses of the head and neck, custom compensators or wedges should be used for the lateral fields to improve dose homogeneity .

- Shrinking field techniques to spare direct spinal cord dose after approximately 45 Gy, as well as final mucosal reductions after 54 to 60 Gy, are often appropriate with posterior neck boosting, with electrons to supplement posterior chain nodal dosing without excessive dose to the spinal cord

Altered fractionation techniques

- Hyperfractionation (e.g., 1.1–1.4 Gy twice daily)
- Accelerated fractionation (e.g., 6 fraction per week or concomitant boost regimens).
- Improved locoregional control rates for H&N cancer patients

- A recent meta-analysis examined 15 trials that compared conventional fractionation to altered fractionation, either
- Hyperfractionation or accelerated fractionation
- Small but statistically significant survival benefit of 3.4% at 5 years with altered fractionation.
- The benefit was higher with hyperfractionation compared to accelerated fractionation and was more pronounced for patients younger than age 50.

- Early T-stage hypopharynx patients with N0 or N1 neck disease can be considered for treatment with radiation alone or concurrent radiation plus chemotherapy.
- In this setting, gross disease should receive 70 Gy and the contralateral neck (N0) should receive 50 to 54 Gy

- T1N0 lesions, patients may achieve 5-year disease-specific survival (DSS) on the order of 90%.
- T2N0 lesions may achieve DSS above 70%.

LOCAL CONTROL FOR CARCINOMA OF THE POSTERIOR PHARYNGEAL WALL TREATED WITH RADIATION ALONE

	Local Control After RT		Ultimate Local Control After Salvage	
Stage	2 Year (%)	5 Year (%)	2 Year (%)	5 Year (%)
T1	100	100	100	100
T2	79	74	86	81
T3	59	49	66	66
T4	36	36	36	36

RT, radiation therapy.

Adapted from Amdur RJ, Mendenhall WM, Stringer SP, et al. Organ preservation with radiotherapy for T1-T2 carcinoma of the pyriform sinus. *Head Neck* 2001;23:353–362.

CAUSE-SPECIFIC AND OVERALL SURVIVAL FOR CARCINOMA OF THE PYRIFORM SINUS TREATED WITH RADIATION ALONE

Stage	5-Year Cause Specific Survival (%)	5-Year Overall Survival (%)
I	96	57
II		61
III	62	41
IVa	49	29
IVb	33	25

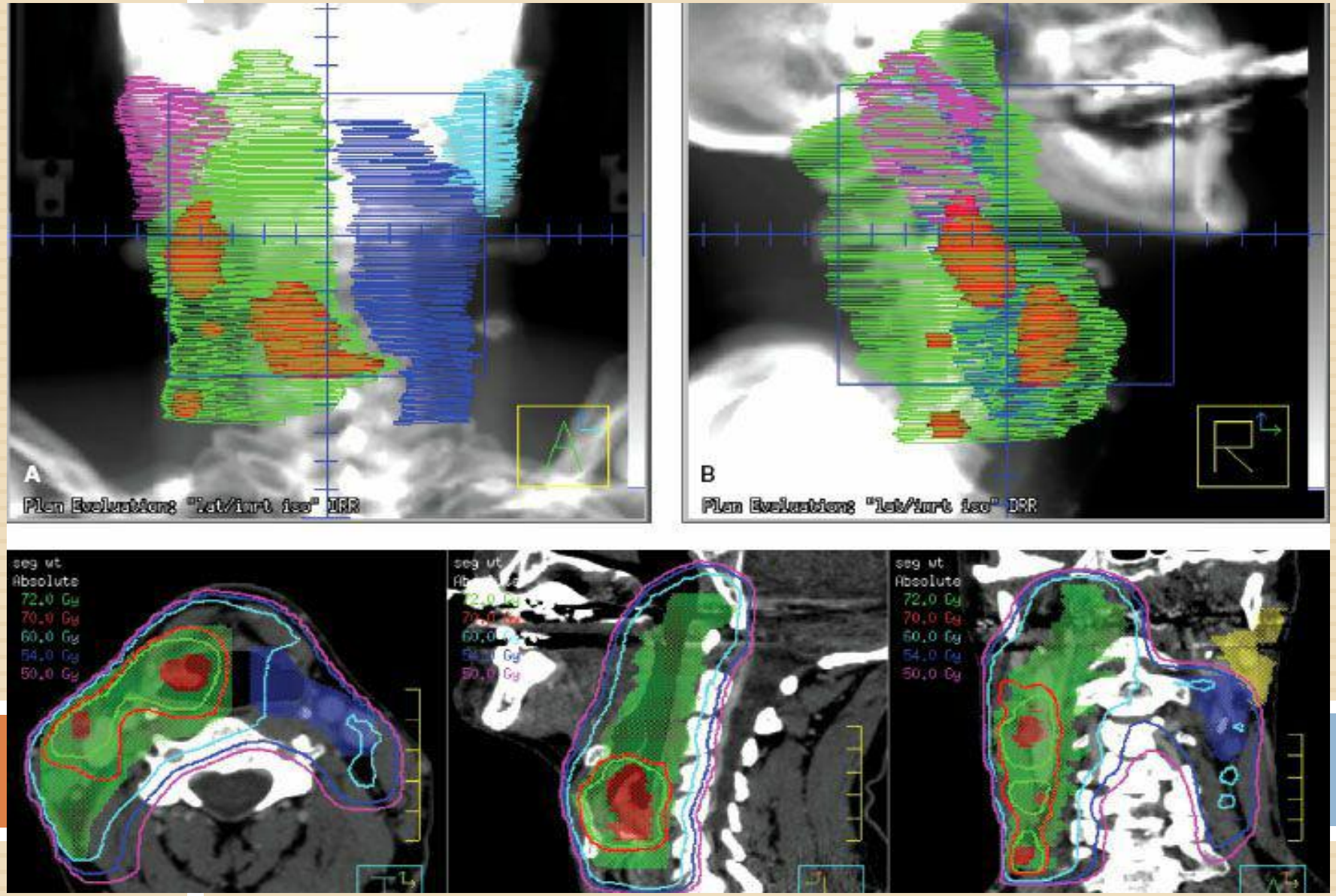
Adapted from Amdur RJ, Mendenhall WM, Stringer SP, et al. Organ preservation with radiotherapy for T1-T2 carcinoma of the pyriform sinus. *Head Neck* 2001;23:353–362.

IMRT

- IMRT in H&N cancer as a means of diminishing normal tissue toxicities
- Particularly xerostomia resulting from irradiation of major salivary glands.
- Excellent candidates for IMRT include patients with unilateral T1 to T3 primary lesions with N2b or less neck disease.

- A recent randomized trial of conventional radiotherapy versus IMRT in patients with T1-4N0-3 oropharyngeal and hypopharyngeal tumors at high risk for xerostomia highlighted the benefits of IMRT for parotid sparing

- Patients were treated either postoperatively or definitively
- Contralateral parotid was constrained to <24 Gy to the whole gland.
- Grade 2 or worse xerostomia was significantly reduced at both 12 months (74% conventional vs 38% IMRT)
- At 24 months (83% conventional vs 29% IMRT).[5]
- These benefits translated to significantly better quality-of-life scores in the IMRT group and strongly support a role for IMRT in H&N SCC radiotherapy.



Beam's eye projections of intensity-modulated radiation therapy target contours for patient with T2N2bM0 tumor of the right pyriform sinus

T3 and T4 Tumors

- Hypopharynx cancer patients who are technically resectable may not undergo primary surgery.
- These include age (e.g., patients over 70 to 80 years old),
- Presence of significant medical comorbidities, or patient unwillingness to accept total laryngectomy.
- Curative-intent radiation or chemoradiation is often pursued in these setting

- Conventional radiation therapy commonly involves a shrinking three-field technique to deliver approximately 70 Gy in 2-Gy daily fractions to areas of gross disease and 50 to 60 Gy to areas of microscopic disease.
- If patients are scheduled to undergo postradiotherapy neck dissection, then gross nodal disease can be limited to 60 to 63 Gy
- If patients are not candidates for postradiotherapy neck dissection, then gross nodal disease should be carried to 70 Gy

- In patients with adequate performance status, concurrent chemoradiation strategies using platinum-based chemotherapy should be considered.
- Once-daily radiation regimens without concurrent chemotherapy may be quite reasonable for hypopharynx patients over 70 years of age or for those patients with modest performance status

Molecular-targeted therapies in the treatment of H&N cancer patients

- Another alternative to concomitant chemotherapy or accelerated fractionation is the more recent introduction of molecular-targeted therapies in the treatment of H&N cancer patients
- The most mature clinical dataset in H&N cancer involves the use of EGFR inhibitors such as cetuximab (monoclonal antibody against the EGFR)

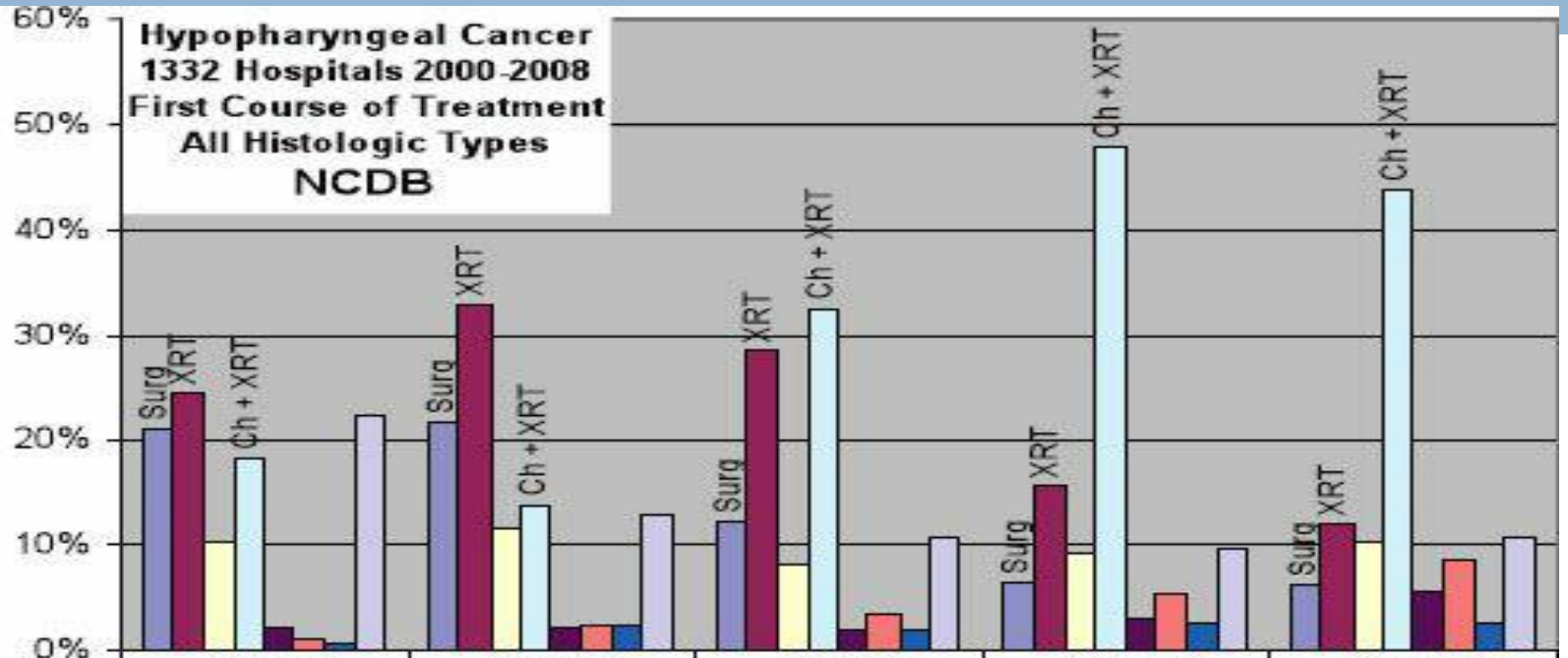
International phase III trial

- High-dose radiation alone versus radiation plus cetuximab in advanced H&N cancer patients confirmed a locoregional control improvement (10% at 5 years) .
- Overall survival advantage (10% at 5 years) with the addition of cetuximab.
- A relatively small subset of patients with hypopharynx cancer was enrolled in this study of 424 patients, and this subset did not demonstrate a clear advantage with use of the EGFR inhibitor treatment.

- Data from the NCDB Benchmark Reports addressing 16,136 cases diagnosed in 2000 to 2008 reveal the combination of radiation and chemotherapy to be the most common initial treatment overall for stage II (32.6%), stage III (47.8%), and stage IV (43.8%) disease.
- Over 50% of stage III and stage IV cases received initial treatment with chemotherapy in some form—either alone or in combination with radiation or surgery.

- It has been reported that approximately 35% to 45% of patients with advanced hypopharyngeal tumors treated with concurrent chemoradiotherapy utilizing IMRT can be expected to live 5 years, with laryngeal preservation in approximately two-thirds of survivors .

The stage-specific first course of treatment for hypopharyngeal cancer in the United States from 2000 to 2008 is presented with unknown stage excluded. S, surgery; XRT, radiotherapy; Ch, chemotherapy. (From National Cancer Data Base. Commission on Cancer. American College of Surgeons. Benchmark Reports



	Stage 0 (N=176)	Stage I (N=1020	Stage II (N=1849)	Stage III (N=3288)	Stage IV (N=9803)
Surg	21%	21.60%	12.30%	6.50%	6.20%
XRT	24.40%	33%	28.40%	15.60%	12%
S + XRT	10.20%	11.60%	8.30%	9.30%	10.20%
Ch + XRT	18.20%	13.80%	32.60%	47.80%	43.80%
Ch	2.30%	2.30%	2.10%	3%	5.70%
S + Ch + XRT	1.10%	2.50%	3.40%	5.40%	8.60%
Other	0.60%	2.40%	2.10%	2.70%	2.70%
None	22.20%	12.80%	10.90%	9.60%	10.90%

ONCOLOGIC OUTCOMES FOR PATIENTS UNDERGOING CONCURRENT CHEMORADIOTHERAPY AND INTENSITY-MODULATED RADIATION THERAPY FOR ADVANCED HYPOPHARYNGEAL CANCERS

Study (Reference)	Total Patients in Study (n)	Stage	# of Patients per Stage (%)	Larynx Preservation Rate (%)	5-Year OS (%)
Huang et al. (58)	33	II III IV	2 (6%) 5 (15%) 26 (79%)	67	44
Liu et al. (59)	27	II III IV	5 (19%) 4 (15%) 18 (66%)	63	35

OS, overall survival.

Induction Chemotherapy and Sequential (Chemo)radiation

- For patients with locoregionally advanced H&N cancer.

- EORTC conducted a randomized trial for patients with tumors that would require total laryngectomy as the surgical approach.

EORTC trial

Induction chemotherapy with cisplatin and 5- florouracil (5-FU) ⇒ definitive radiation

- With a median follow-up of 10 years, this trial demonstrated no significant difference in 5- or 10-year overall survival or progression-free survival
- Larynx was preserved in 2/3 of patients in this arm

Primary surgical resection and postoperative radiation.

- With a median follow-up of 10 years, this trial demonstrated no significant difference in 5- or 10-year overall survival or progression-free survival
- Laryngectomy was done

TAX-324, which utilized similar induction chemotherapy arms (TPF vs. PF), followed by concurrent chemoradiotherapy with carboplatin.

Five-year survival in the TPF arm was 52% versus 42% receiving PF, while no increased rates of gastric feeding tubes or tracheostomies were noted between groups

. The EORTC study (TAX-323) randomized patients with locoregionally advanced, unresectable disease

induction 5-FU and cisplatin followed by definative RxT

- induction cisplatin and fluorouracil (PF)
- No survival benefit

indutction 5-FU, cisplatin, plus a taxane followed by defenative RxT

- induction docetaxel, cisplatin, and fluorouracil (TPF)
- TPF improved the median overall survival from 14.5 months to 18.8 months, with a 27% reduction in the risk of death

Post radiotherapy Neck Dissection

N0 or N1 patients treated with primary radiation or chemoradiation

↓

Adjuvant neck dissection not necessary

N2 or N3 neck disease

↓

Adjuvant neck dissection necessary

Detailed imaging of the neck 12 weeks postradiation with FDG-PET can serve as a valuable guide to help select those patients warranting adjuvant neck dissection.

Palliative Radiotherapy

- Patients with poor performance status who are not considered candidates for aggressive radiation or chemoradiation approaches should be managed with palliative intent.
- This may include short course radiation regimens such as 4 to 5 Gy × 5 fractions over 1 to 2 weeks with repeat of the same 3 weeks hence if favorable initial tolerance and response is achieved .

- A recent study suggests using a 3.7 Gy fraction twice daily × 2 consecutive days for 3 cycles every 2 to 3 weeks
- Described in RTOG-85-02,
- Similar palliative efficacy with less toxicity as compared to other palliative regimens.
- Other approaches described include 50 Gy in 16 fractions and 30 Gy in 5 fractions, 2 fractions per week.

Palliative Chemotherapy

- Patients with adequate or good performance status should be considered for palliative chemotherapy.
- Median overall survival for patients with metastatic disease is 6 to 10 months. Single-agent cisplatin is usually the first regimen, as it has been shown to improve overall survival.
- In combination with cisplatin as first-line treatment, cetuximab improved overall survival from 7.4 months to 10.1 months over cisplatin alone.

MANAGEMENT OF RECURRENCE

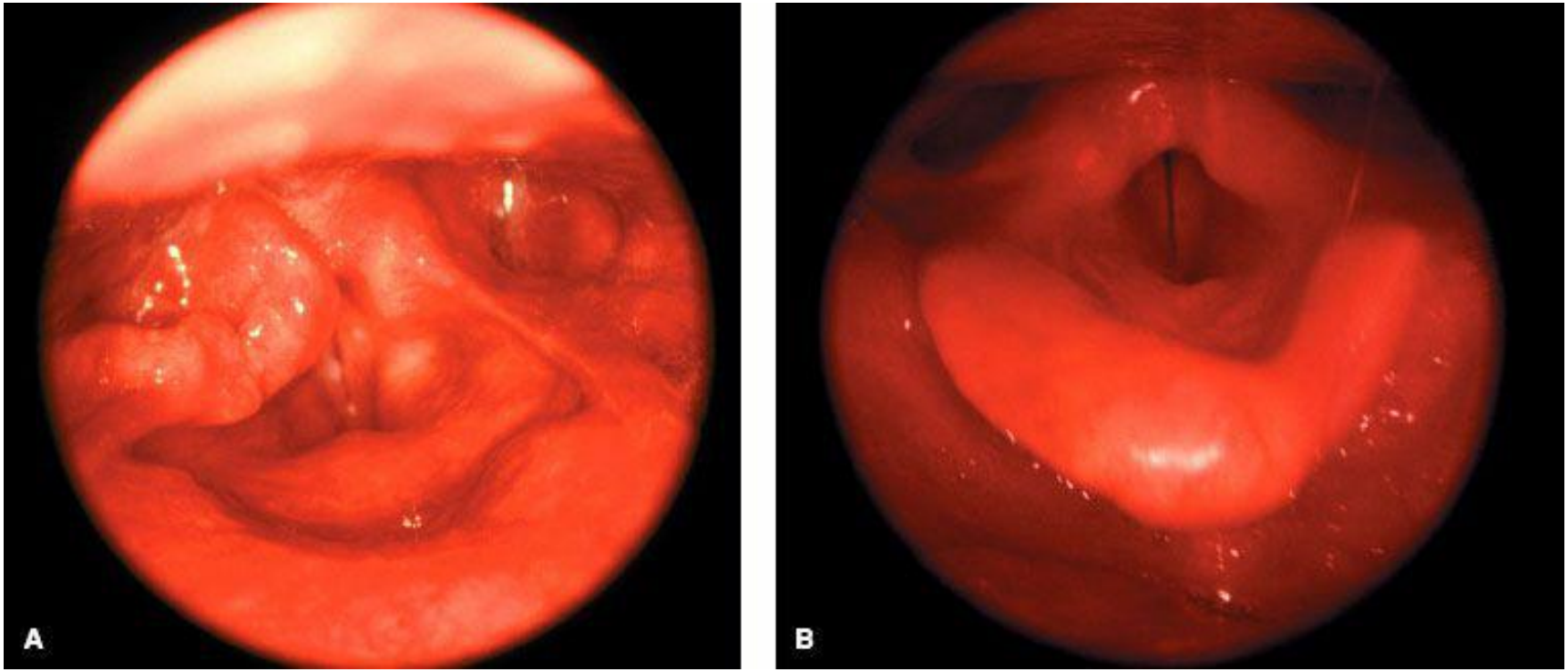
- After completion of treatment, patients should be followed closely for signs of recurrent or persistent disease. If recurrence is suspected, this should be confirmed by biopsy.
- If biopsy is confirmatory
- Patient should undergo complete restaging to assess the extent of disease.

- Recurrent patients who initially received comprehensive H&N radiation have traditionally not been considered good candidates for repeat high-dose radiation in light of normal tissue tolerances.
- However, two recent prospective RTOG studies have demonstrated that reirradiation to the H&N is feasible.
- With the advent of highly conformal radiation delivery techniques, selected patients may benefit from reirradiation approaches in conjunction with systemic chemotherapy.

- Many patients with recurrent disease, however, are not good candidates for aggressive surgery or salvage radiation therapy and are best served with systemic chemotherapy or best supportive care approaches .

COMPLICATIONS CHEMORADIATION Therapy

- Mucositis
- Fatigue
- Loss of taste acuity
- Radiation dermatitis
- Xerostomia
- Nausea
- Low counts
- Majority of patients who receive high-dose radiation across major segments of the larynx and hypopharynx will manifest some degree of edema, mucosal congestion, and eventual fibrosis .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Long term followup

- During the first 6 months after treatment, patients should be followed every 4 to 6 weeks with clinical examination, including fiberoptic nasopharyngoscopy.
- Recommended guidelines include a follow-up visit every 1 to 3 months during the first year, every 2 to 4 months for the second year, every 4 to 6 months for years 3 through 5, and every 6 to 12 months thereafter .

- If the patient received comprehensive H&N radiation, the serum thyroid-stimulating hormone level should be measured every 6 to 12 months.
- Imaging evaluation of the neck, most commonly with CT or MRI scan, are obtained at 3- to 6-month intervals during the first 2 years or as indicated based on clinical findings
- Functional imaging with FDG-PET can sometimes prove valuable to help differentiate post treatment fibrosis from persistent or recurrent disease.

Conclusion

- Despite an aggressive approach in the overall management of hypopharynx cancer patients, ultimate cure rates remain quite poor.
- There are relatively few early-stage patients; and for many advanced-stage patients, it is difficult to achieve long-term control.
- Even for those patients with excellent response to therapy, there exists a continuous risk for the development of second malignancies, particularly of the upper aerodigestive track with long-term follow-up.

- Post treatment patients often require aggressive speech and swallow therapy to maximize their functional outcome.
- There is significant interest in the incorporation of molecular targeted therapies in combination with traditional cytotoxic therapy and radiation in an effort to improve outcomes.

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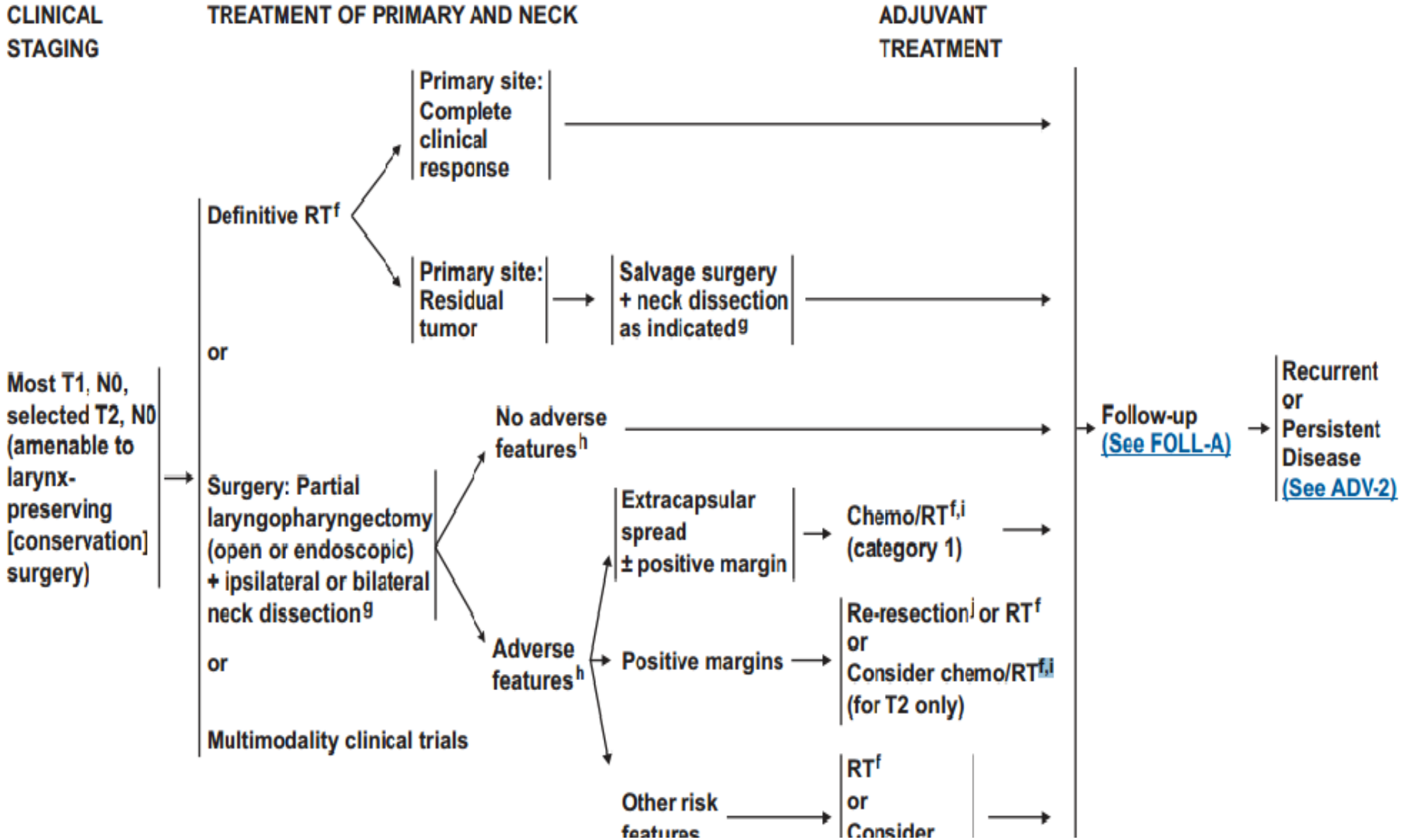

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CLINICAL STAGING

T2-3, any N if requiring [amenable to] pharyngectomy with total laryngectomy); T1, N+

TREATMENT OF PRIMARY AND NECK

- Induction chemotherapy[i,k] → See Response After Induction Chemotherapy (HYPO-4)
- or
- Laryngopharyngectomy + neck dissection,[g] including level VI
  - No adverse features[h] →
  - Adverse features[h]
    - Extracapsular spread and/or positive margin → Chemo/RT[f,i] (category 1) →
    - Other risk features → RT[f] or Consider chemo/RT[f,i] →
- or
- Concurrent systemic therapy/RT[f,h,l]
  - Primary site: complete clinical response
    - Residual tumor in neck → Neck dissection[g] →
    - Complete clinical response of neck → Post-treatment evaluation[m]
      - Negative → Observe →
      - Positive → Neck dissection[g] →
- or
- Primary site: residual tumor → Salvage surgery + neck dissection as indicated[g]
- Multimodality clinical trials

ADJUVANT TREATMENT

→ Follow-up (See FOLL-A)

→ Recurrent or Persistent Disease (See ADV-2)

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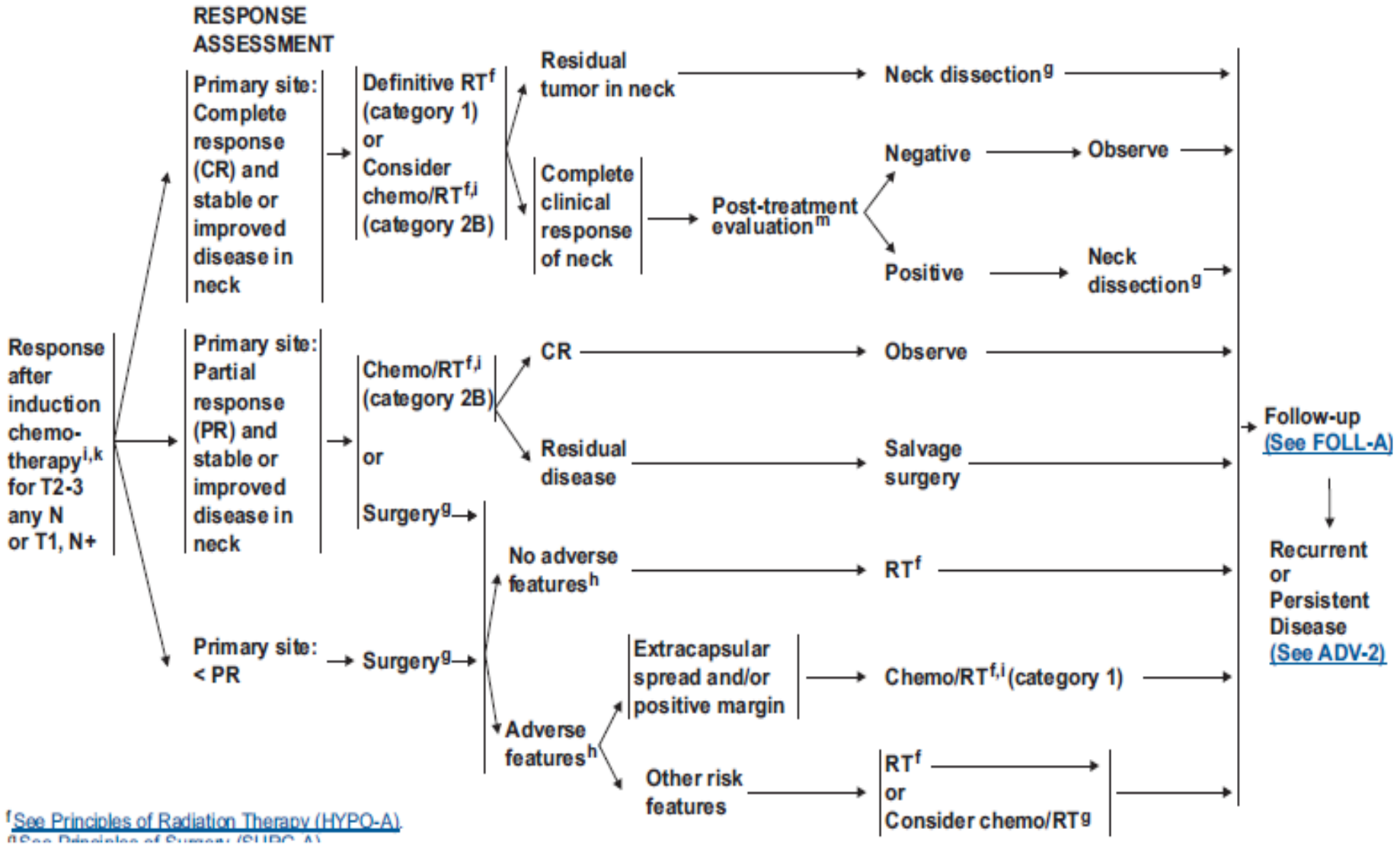

[f] See Principles of Radiation Therapy (HYPO-A).
[g] See Principles of Surgery (SURG-A).

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