

屏東榮民總醫院

喉癌診療原則

2024年01月09日 2024第一版

喉癌醫療團隊擬訂

注意事項：這個診療原則主要作為醫師和其他保健專家診療癌症病人參考之用。假如你是一個癌症病人，直接引用這個診療原則並不恰當，只有你的醫師才能決定給你最恰當的治療。

Carcinoma of the Glottis Larynx

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WORK-UP

- History(pack yr smoked) & PE; fiberoptic exam
 - Biopsy of primary site or FNA of the neck
 - Contrast and thin angled cuts CT of larynx * and/or MRI with contrast of primary and neck *
 - Bone scan* (若有PET, 可不作此項檢查)
 - Abd. Sono*
 - 臨床需求時安排以下檢查
 - ✓Chest CT (with or without contrast)
 - ✓Consider FDG PET/CT
 - ✓Preanesthesia studies
 - ✓Pulmonary function evaluation for conservation surgery candidates
 - ✓Consider videostroboscopy for select patients
 - ✓EUA with endoscopy
 - ✓Neck Sono
 - ✓Panendoscopy
 - ✓Dental evaluation
 - Panorex ± teeth extraction
 - ✓Nutrition, Speech and Swallowing evaluation/therapy
 - ✓Audiogram
 - ✓Smoking cessation counseling
 - ✓Fertility/reproductive counseling
- (* 期別之相關之主要檢查)

STAGING & TREATMENT

- **[Tis, N0]**
詳見 Page 2
- **[T1-2, N0; select T3, N0]**
詳見 Page 3
- **[T3 requiring total laryngectomy, N0-1]**
詳見 Page 4
- **[T3 requiring total laryngectomy, N2-3]**
詳見 Page 6
- **[T4a]**
詳見 Page 7
- **[T4b, N0-3; Unresectable N; Unfit for surgery]**
詳見 Page 8
- **[M1]**
詳見 Page 9

FOLLOW-UP

(base on risk of relapse, second primaries. Treatment sequelae, and toxicities)

- **[Post-Tx within 1 year]**
 - Every 1-3 months: complete head and neck exam + fiberoptic examination
 - Baseline CT or MRI
 - ± Neck Sono
- **[1-2 years after Tx]**
 - Every 2-6 months: complete head and neck exam + fiberoptic examination
 - Clinical indicated every 1 year: Larynx CT or MRI, CxR, Bone scan & Abd. Sono ± Neck Sono ± TSH, free T4*
- **[3-5 years after Tx]**
 - Every 4-8 months: complete head and neck exam + fiberoptic examination
- **[5 years later after Tx]**
 - Every 12 months: complete head and neck exam + fiberoptic examination
 - (*if RT, every 6-12 months)

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Carcinoma in situ

Primary treatment

Pathological features

Adjuvant Treatment

**Endoscopic resection
(Preferred)**

Follow-up

RT^{\$}, 註1

Follow-up

Carcinoma of the Glottis Larynx

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**Amenable to larynx preserving
(conservation) surgery**

(T1-2, N0 or select T3, N0) @

Primary treatment

RT\$, 註1

**Partial laryngectomy
/endoscopic or open
resection as indicated
and ND as indicated**

Pathological features

Adjuvant Treatment

Adverse features* (-)

Adverse features* (+)

Positive margin

ENE(Extranodal extension)

Other adverse features(+)

pN1 without other risk features

Follow-up

Follow-up

Re-resection, if feasible or RT註1

CRT註1-2

RT註1

Consider RT註1

@Nodal disease in such glottis tumors is rare

*Adverse features: extranodal extension, positive or close margins, pT4 primary, pN2 or pN3 nodal disease, perineural invasion, vascular invasion, lymphatic invasion, **subglottic extension**

\$RT: Either IMRT or 3D conformal RT is recommended

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T3 requiring(amenable to) total laryngectomy, N0-1, M0

Primary treatment

Pathological features

Adjuvant treatment

Concurrent CRT or RT if patient not candidate for CRT^{註1-2}

Follow-up, clinical assessment after 4-8 week as appropriate

pN0 without other risk features

Follow-up

pN1 without other risk features

Consider RT^{註1}

Surgery, including ipsilateral or bilateral neck dissection; consider thyroidectomy to clear central compartment nodes

Adverse features* (+)

Extranodal extension and/or positive margin

CRT^{註1-2}

Other adverse features(+)

RT or consider CRT^{註1-2}

Induction Chemotherapy^{註3}

CT or MRI (with contrast) of primary and neck (option)

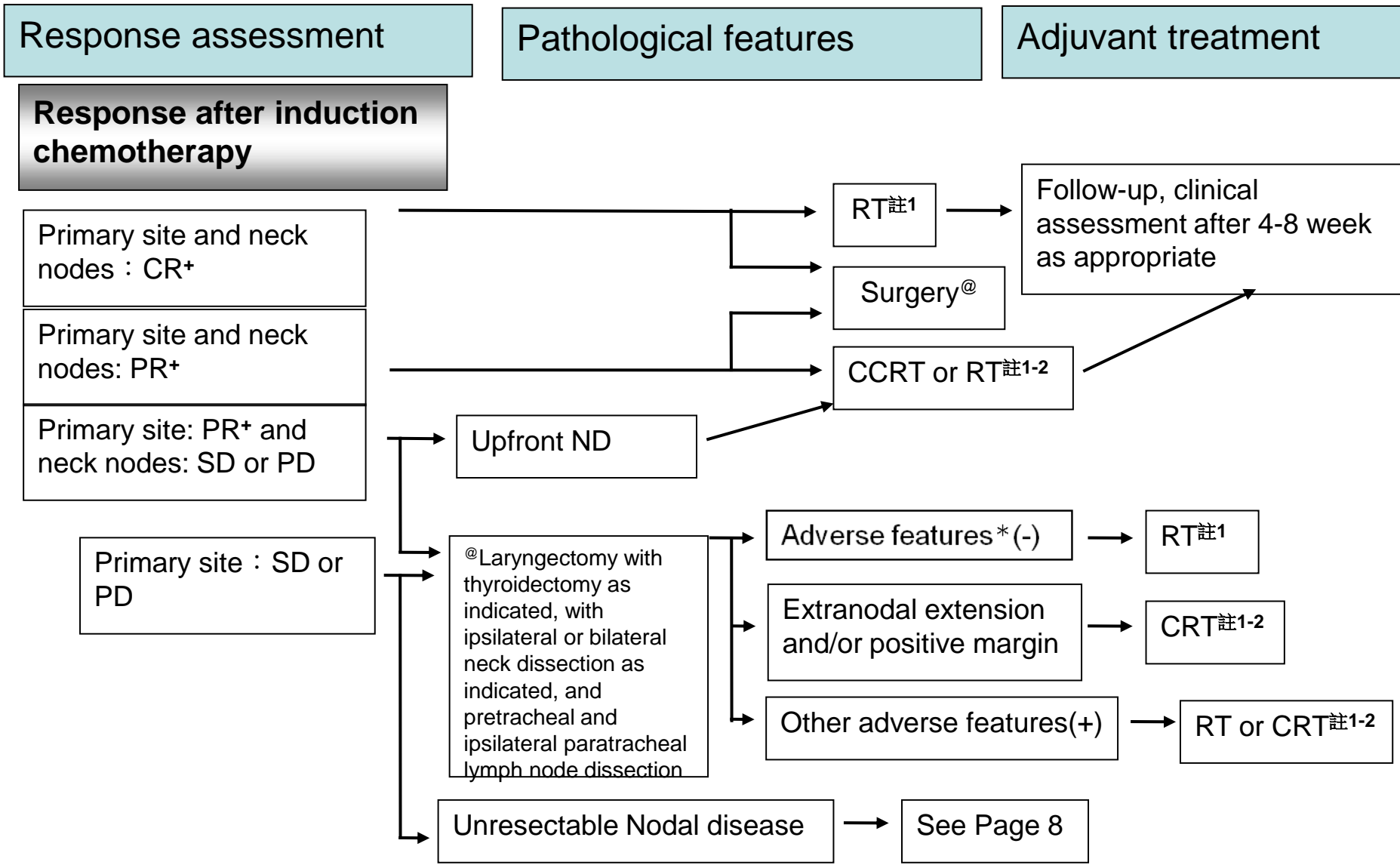
See Response Assessment (Page 5)

Clinical trials

* Adverse features : extranodal extension, positive margins, close margins, pT4 primary, pN2 or pN3 nodal disease, perineural invasion, vascular invasion, lymphatic invasion, **subglottic extension**

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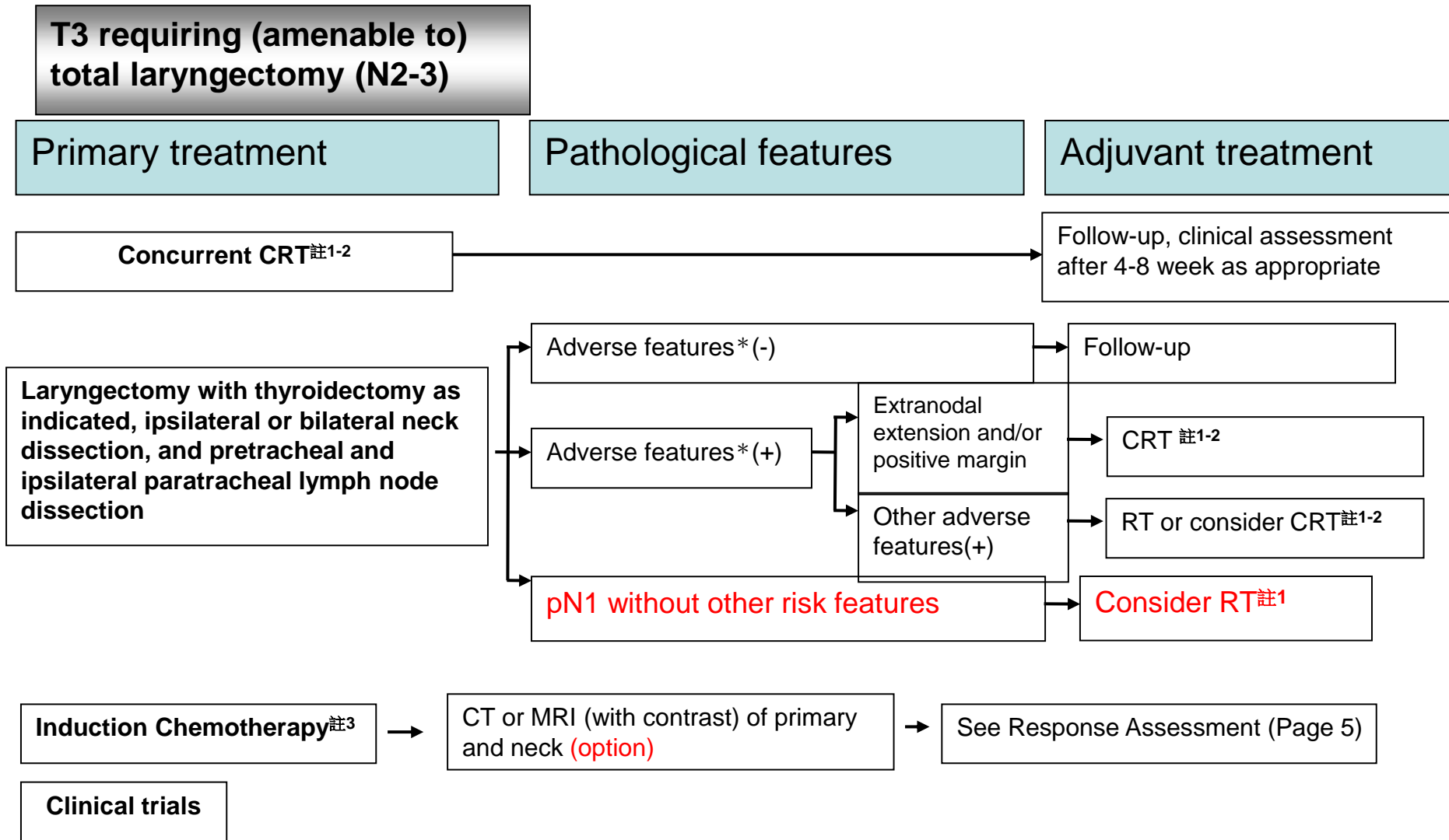


+ Primary site evaluated by CT or MRI(with contrast) of primary head and neck

* Adverse features : extranodal extension, positive margins, close margins, pT4 primary, pN2 or pN3 nodal disease, perineural invasion, vascular invasion, lymphatic invasion, **subglottic extension**

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* Adverse features : extranodal extension, positive margins, close margins, pT4 primary, pN2 or pN3 nodal disease, perineural invasion, vascular invasion, lymphatic invasion, **subglottic extension**

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Primary treatment

Pathological features

Adjuvant treatment

T4a, N0-3

Surgery, including ipsilateral or bilateral neck dissection; thyroidectomy to clear central Compartment nodes, especially when there is thyroid cartilage with gross invasion of the thyroid gland and significant subglottic extension

Adverse features* (-)

Follow-up

Adverse features* (+)

Extranodal extension and/or positive margin

CRT 註1-2

Other adverse features(+)

RT or consider CRT註1-2

pN1 without other risk features

Consider RT註1

Select T4a patients (high PS, multiple comorbidity or decline surgery)

Consider CRT註1-2

Follow-up, clinical assessment after 4-8 week as appropriate

Clinical trial for function-preserving surgical or RT management

Induction Chemotherapy註3

CT or MRI (with contrast) of primary and neck (option)

See Response Assessment (Page 5)

* Adverse features : extranodal extension, positive margins, close margins, pT4 primary, pN2 or pN3 nodal disease, perineural invasion, vascular invasion, lymphatic invasion, subglottic extension

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Newly diagnosed (M0)T4b, N0-3;
Unresectable nodal disease;
Unfit for surgery

Treatment

Clinical trial preferred

PS 0-1 #

Concurrent CRT^{註1-2}

Induction C/T^{註3} as indicated followed by RT or CRT^{註1,3}

PS 2*

RT^{註1}

Concurrent CRT^{註1-2}

PS 3\$

Palliative RT^{註1}

Single-agent systemic therapy^{註4}

Best supportive care

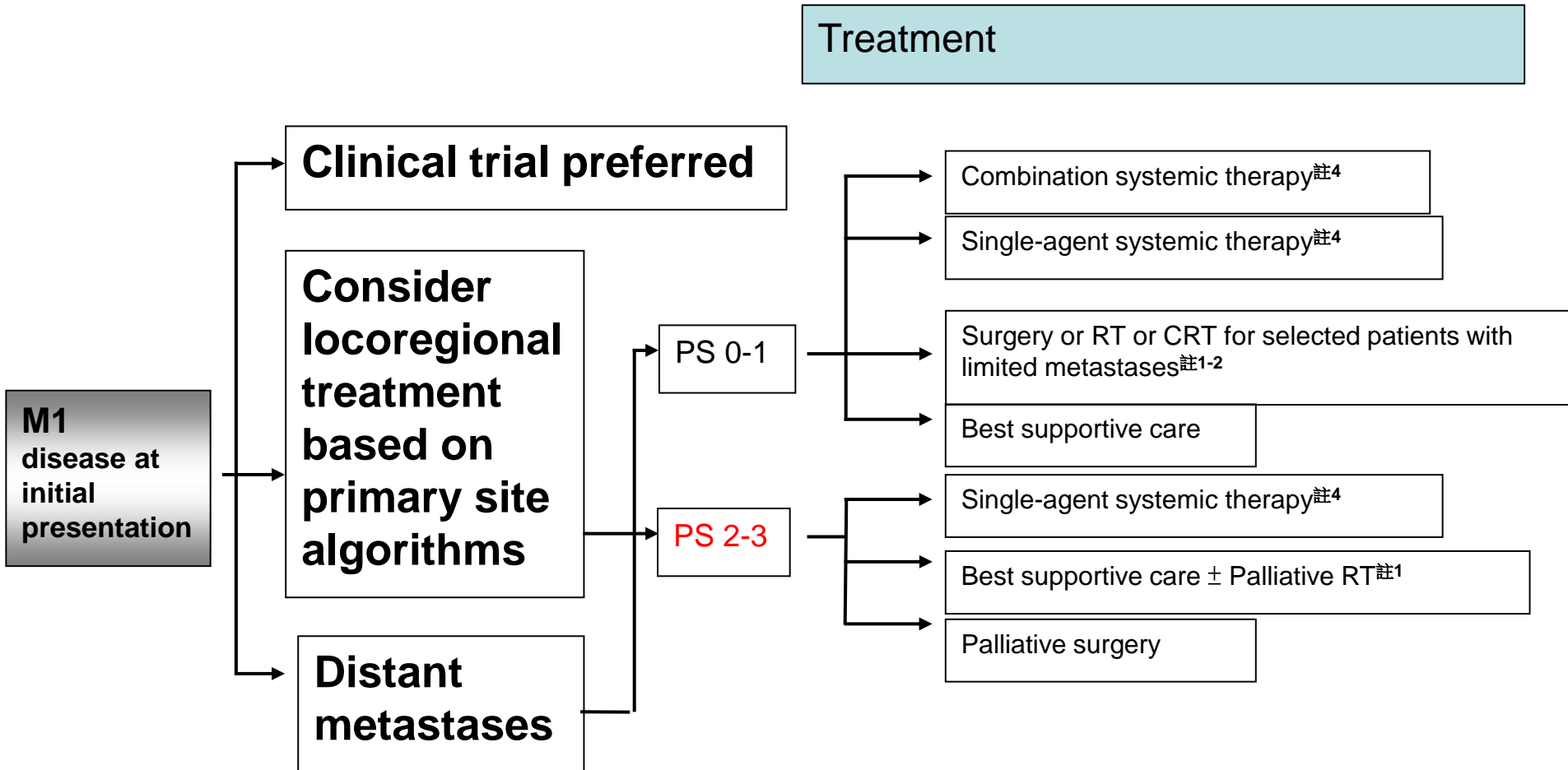
ECOG Performance Status 0-1^{註6}

* ECOG Performance Status 2

\$ ECOG Performance Status 3

Carcinoma of the Glottis Larynx

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1. PS 0-1若治療無效，除 best supportive care 外可再考慮systemic therapy, clinical trial or palliative RT

2. PS 2-3 single agent systemic therapy 若治療無效，除 best supportive care 外可再考慮 alternate single agent systemic therapy or palliative RT

Carcinoma of the Glottis Larynx

註1

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Principles of Radiotherapy

Definitive (RT alone)

- Tis, N0 : 60.75 - 66 Gy (2.0-2.25 Gy/fraction)
- T1, N0 : 63 - 66 Gy (2.0-2.25 Gy/fraction) or 50 - 52 Gy (3.28-3.12 Gy/fraction)
- T2, N0 : 65.25 - 70 Gy (2.0-2.25 Gy/fraction)
- \geq T2, N1 :
 - ✓ High risk : Primary tumor and involved lymph nodes
 - 66 - 70 Gy (2.0-2.2 Gy/fraction) ; daily Monday-Friday in 6-7 weeks
 - Concomitant boost accelerated RT
 - ◆ 72 Gy /6 weeks (1.8 Gy/fraction, large field ; 1.5Gy boost as second daily fraction during last 12 treatment days)
 - ◆ 66–70 Gy (2.0 Gy/fraction; 6 fractions/wk accelerated)
 - Hyperfractionation : 79.2 – 81.6 Gy /7 weeks (1.2 Gy/fraction, twice daily)
 - ✓ Low to intermittent risk : Sites of suspected subclinical spread

Postoperative (RT or Concurrent CRT)

- Preferred interval between resection and postoperative RT is \leq 6 weeks
- High risk: Adverse features such as positive margins
 - ✓ 60–66 Gy (1.8–2.0 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)

Concurrent CRT

- High-risk: typically 70–70.2 Gy (1.8–2.0 Gy/fraction); daily Monday–Friday in 7 weeks
- Low to intermediate risk: 44–50 Gy (2.0 Gy/fraction) to 54–63 Gy (1.6–1.8 Gy/fraction)

Carcinoma of the Glottis Larynx

註2 屏東榮民總醫院 臨床診療指引 Ver.1 修訂於 2024.01.09 Page 11 (Ref. 22-27)

Principles of Chemotherapy

Concurrent with RT

Regimen 1 : q3w CDDP ± Cetuximab^{註5} + RT

- Cisplatin (80-100mg/ m²) q3w during R/T
- Cetuximab(400mg/ m²) loading dose first week, then Cetuximab(250mg/ m²) maintain dose D1 + Cisplatin (80-100mg/ m²) q3w D2 during R/T

Regimen 2: Weekly CDDP ± Cetuximab^{註5} + RT

- Cisplatin (30-40mg/ m²) weekly during R/T
- Cetuximab(400mg/ m²) loading dose first week, and then Cisplatin (30-40mg/ m²) weekly D1 + Cetuximab(250mg/ m²) maintain dose D2 during R/T
- Carboplatin (AUC x 2mg) qw during R/T

Regimen 3: q3w Carboplatin^{註5} ± Cetuximab^{註5} + RT

- Carboplatin (AUC x 5mg) q3w during R/T
- Cetuximab(400mg/ m²) loading dose first week, then Cetuximab(250mg/ m²) maintain dose D1 + Carboplatin (AUC x 5mg) q3w D2 during R/T

Regimen 4: Weekly Cetuximab^{註5} + RT

- Cetuximab(400mg/ m²) loading dose first week, then Cetuximab(250mg/ m²) maintain dose during RT

Regimen5 : Carboplatin + 5-FU + Hydroxyurea (CCr < 60) + RT

- Carboplatin (AUC x 1.25mg) D1-D4
- Fluorouracil (5-FU) (850mg/m²) D1-D4
- Hydroxyurea 1CAP BID D1-D5

Regimen6 : Cisplatin + 5-FU + Hydroxyurea + RT

- Cisplatin(20mg/ m²) D1-D4
- Fluorouracil (5-FU) (850mg/m²) D1-D4
- Hydroxyurea 1CAP BID D1-D5

Carcinoma of the Glottis Larynx

註3

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Regimens of Chemotherapy

Induction, adjuvant, 建議1-4cycles

Regimen 1 : q3-4 weeks T^{註5} + P ± F ± weekly Cetuximab^{註5}

- Taxotere(60 mg/ m²) D1
- Cisplatin(60-75 mg/ m²) D1
- Fluorouracil (5-FU) (600-750mg/m²) D2-D5
- Cetuximab (400mg/ m²) loading dose first week, then Cetuximab (250mg/ m²) maintain dose

Regimen 2: q3-4 weeks Platinum ± F ± weekly Cetuximab^{註5}

- Cisplatin(80-100mg/ m²) D1 or Cisplatin (20mg/ m²) D1-D5 or Carboplatin (AUC x 5mg) D1
- Fluorouracil (5-FU) (600-1000mg/m²) D2-D5
- Cetuximab(400mg/m²) loading dose first week, then weekly Cetuximab (250mg/ m²)

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註3

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Regimens of Chemotherapy

Induction, adjuvant, 建議1-4cycles

Regimen 3: weekly Cetuximab^{註5}

- Cetuximab (400mg/ m²) loading dose first week, then Cetuximab (250mg/ m²) maintain dose

Regimen 4: oral Fluorouracil

- Ufur cap (tegafur 100mg+uracil 224mg) 2# BID-TID
(Salvage or palliative CT中作為取代iv-formed 5-FU之替代藥物)

Regimen 5: weekly Methotrexate

- Methotrexate (40-60mg/ m²)

Carcinoma of the Glottis Larynx

註4

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Regimens of Chemotherapy

Recurrent, unresectable, metastatic *

Regimen 1 (First line): q3 weeks Pembrolizumab^{註5} ± Platinum ± F

- Pembrolizumab(200mg) D1 (if CPS \geq 1)
- Cisplatin(80-100mg/m²) D1 or Cisplatin (20mg/ m²) D1-D5 or Carboplatin (AUC x 5mg) D1
- Fluorouracil (5-FU) (600-1000 mg/m²) D2-D5

Regimen 2 (First line): q3 weeks Pembrolizumab^{註5}

- Pembrolizumab(200mg) D1 (if CPS \geq 1)

Regimen 3 (Subsequent line): q2 weeks Nivolumab^{註5}

- Nivolumab(3mg/kg) D1

Regimen 4 (Subsequent line): q3 weeks Pembrolizumab^{註5}

- Pembrolizumab(200mg) D1 (if disease progression on or after platinum therapy)

Regimen 5: q3-4 weeks Platinum ± F ± weekly Cetuximab^{註5}

- Cisplatin(80-100mg/ m²) D1 or Cisplatin (20mg/ m²) D1-D5 or Carboplatin (AUC x 5mg) D1
- Fluorouracil (5-FU) (600-1000 mg/m²) D2-D5
- Cetuximab(400mg/ m²) loading dose first week, then weekly Cetuximab (250mg/ m²)

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註4 屏東榮民總醫院 臨床診療指引 Ver.1 修訂於 2024.01.09 Page 15 (Ref. 22-27)

Regimens of Chemotherapy

Recurrent, unresectable, metastatic *

Regimen 6: q3-4 weeks T ± Platinum ± weekly Cetuximab^{註5}

- Taxotere(60 mg/ m²) D1
- Cisplatin(60-75 mg/ m²) D1 or Carboplatin (AUC x 5mg) D1
- Cetuximab(400mg/ m²) loading dose first week, then weekly Cetuximab (250mg/ m²)

Regimen 7: cisplatin+ epirubicin+ 5-FU+ Leucovorin

- Cisplatin (60 mg/ m²) D1
- Epirubicin (50 mg/ m²) D1
- Fluorouracil (5-FU) (2000 mg/m²) D1

Regimen 8: q2 weeks Bevacizumab

- Bevacizumab (200 mg/ m²) D1

Regimen 9: weekly Gemcitabine

- Gemcitabine (1000 mg/m²) D1

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註5

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特殊用藥健保給付規定

Taxotere

- 頭頸部癌，限局部晚期且無遠端轉移之頭頸部鱗狀細胞癌且無法手術切除者。
- 與Cisplatin 及5-FU 併用，作為放射治療前的引導治療，限使用四個療程。

Cetuximab

- 限與放射線療法合併使用於局部晚期之口咽癌、下咽癌及喉癌患者，使用總療程以接受8 次輸注為上限。需經事前審查核准後使用。

符合下列條件之一：

- 1.年齡 ≥ 70 歲
 - 2.Ccr < 50 ml/min
 - 3.聽力障礙者 (聽力障礙定義為500Hz、1000Hz、2000Hz 平均聽力損失大於25 分貝)
 - 4.無法耐受platinum-based 化學治療。
- 限無法接受局部治療之復發及/或轉移性頭頸部鱗狀細胞癌，且未曾申報 cetuximab 之病患使用。需經事前審查核准後使用，使用總療程以18週為限，每9週申請一次，需無疾病惡化情形方得繼續使用。(106/4/1)

Carboplatin

- 限腎功能不佳 (CCr < 60) 或曾作單側或以上腎切除之惡性腫瘤患者使用。

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註5

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特殊用藥健保給付規定

Pembrolizumab、Nivolumab

- I. 先前未曾接受全身性治療且無法手術切除之復發性或轉移性(第三期或第四期)頭頸部鱗狀細胞癌成人患者。(第一線使用僅限Pembrolizumab，112/12/1)
- II. 先前已使用過platinum類化學治療失敗後，又有疾病惡化的復發性或轉移性(第三期或第四期)頭頸部鱗狀細胞癌成人患者。(108/4/1、109/11/1、112/12/1)
- III. 本類藥品與cetuximab僅能擇一使用，且治療失敗時不可互換。

• 符合下列條件：

1. 病人身體狀況良好(ECOG \leq 1)
2. NYHA (the New York Heart Association) Functional Class I 或 II
3. GOT $<$ 60U/L及GPT $<$ 60U/L，且T-bilirubin $<$ 1.5mg/dL；Creatinine $<$ 1.5mg/dL，且 eGFR $>$ 60mL/min/1.73m²
4. PD-L1 表現量 TPS \geq 50%，TC \geq 10%，CPS \geq 20

• 初次申請以12 週為限，用藥後每 12 週評估一次，以 i-RECIST 或 mRECIST 標準評定反應，依下列原則給付：

- I. 有療效反應者(PR 及 CR)得繼續使用；
- II. 出現疾病惡化(PD)或出現中、重度或危及生命之藥物不良反應時，應停止使用；
- III. 疾病呈穩定狀態者(SD)，可持續再用藥 4 週，並於 4 週後再次評估，經再次評估若為 PR、CR 者，得再繼續使用 12 週。若仍為 SD 或已 PD 者，應停止使用。

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註6

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Eastern Cooperative Oncology Group (ECOG) Performance Status

Grade	Description	Suggestion
0	Normal activity fully ambulatory (無症狀)	按照標準化療評估及療程。
1	Symptoms, but nearly fully ambulatory (有症狀，完全步行，但對生活無影響)	按照標準化療評估及療程。
2	Some bed time, but needs to be in bed less than 50% of normal daytime (躺在床上的時間<50%)	按照標準化療評估及療程。
3	Needs to be in bed more than 50% of normal daytime (躺在床上的時間>50%)	可視情況考慮停止化學治療。
4	Unable to get out of bed (長期完全臥床)	建議停止化學治療。
5	Dead	

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