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子宮頸癌診療原則

2019年10月24日 第二版

婦癌醫療團隊擬訂

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。

修訂指引

- 本共識依下列參考資料修改版本
  - NCCN Clinical Practical Guidelines in Oncology ™ Cervical Cancer (V.2019)[1]
  - 婦癌研究委員會(2011)，子宮頸癌篩檢臨床指引與子宮頸癌臨床指引：國家衛生研究院[2-3]
  - 其他相關子宮頸癌臨床指引[4-10]

會議討論

上次會議：2019/01/22

本共識與上一版的差異

上一版	新版
1. 原為 2014 FIGO分期(p. 4-5) 2. 流程圖一在FIGO IB1分期治療，與FIGO IB2分期治療流程不同，原無FIGO IB3分期 (p. 8) 3. 流程圖二在FIGO IB流程原只有FIGO IB2分期，無FIGO IB3分期(p. 9) 4. 化學治療部分，第IV期B，持續性疾病 /復發或轉移性疾病 之全身性化學治療的原則中陳列Gemcitabine+ Cisplatin or Carboplatin 化療處方(p. 13) 5. 線上未建置Paclitaxel 175mg/m2+ topotecan 0.75mg/m2 ± Bevacizumab 7.5~15mg/kg 化療處方(p. 14)	1. 更改為 2018 FIGO分期(p. 4-6) 2. 流程圖一將FIGO IB1分期治療流程增加FIGO IB2分期，並刪除腫瘤小於2公分字眼，而原FIGO IB2分期治療流程更改為FIGO IB3分期 (p. 8) 3. 流程圖二FIGO IB2分期，更改為FIGO IB3分期(p. 9) 4. 化學治療部分，刪除第IV期B，持續性疾病 /復發或轉移性疾病 之全身性化學治療的原則中之Gemcitabine+ Cisplatin or Carboplatin 化療處方(p. 13) 5. 新增Paclitaxel 175mg/m2+ topotecan 0.75mg/m2 ± Bevacizumab 7.5~15 mg/kg 化療處方(p. 14)

2018 FIGO staging

Stage	Description
I	The carcinoma is strictly confined to the cervix (extension to the uterine corpus should be disregarded)
IA	Invasive carcinoma that can be diagnosed only by microscopy, with maximum depth of invasion <5 mm[a]
IA1	Measured stromal invasion <3 mm in depth
IA2	Measured stromal invasion ≥3 mm and <5 mm in depth
IB	Invasive carcinoma with measured deepest invasion ≥5 mm (greater than Stage IA), lesion limited to the cervix uteri[b]
IB1	Invasive carcinoma ≥5 mm depth of stromal invasion, and <2 cm in greatest dimension
IB2	Invasive carcinoma ≥2 cm and <4 cm in greatest dimension
IB3	Invasive carcinoma ≥4 cm in greatest dimension
II	The carcinoma invades beyond the uterus, but has not extended onto the lower third of the vagina or to the pelvic wall
IIA	Involvement limited to the upper two-thirds of the vagina without parametrial involvement
IIA1	Invasive carcinoma <4 cm in greatest dimension
IIA2	Invasive carcinoma ≥4 cm in greatest dimension
IIB	With parametrial involvement but not up to the pelvic wall
III	The carcinoma involves the lower third of the vagina and/or extends to the pelvic wall and/or causes hydronephrosis or nonfunctioning kidney and/or involves pelvic and/or para-aortic lymph nodes[c]
IIIA	The carcinoma involves the lower third of the vagina, with no extension to the pelvic wall
IIIB	Extension to the pelvic wall and/or hydronephrosis or nonfunctioning kidney (unless known to be due to another cause)
IIIC	Involvement of pelvic and/or para-aortic lymph nodes, irrespective of tumor size and extent (with r and p notations)[c]
IIIC1	Pelvic lymph node metastasis only
IIIC2	Para-aortic lymph node metastasis
IV	The carcinoma has extended beyond the true pelvis or has involved (biopsy proven) the mucosa of the bladder or rectum. (A bullous edema, as such, does not permit a case to be allotted to Stage IV)
IVA	Spread to adjacent pelvic organs
IVB	Spread to distant organs

When in doubt, the lower staging should be assigned.

[a]Imaging and pathology can be used, where available, to supplement clinical findings with respect to tumor size and extent, in all stages.

[b]The involvement of vascular/lymphatic spaces does not change the staging. The lateral extent of the lesion is no longer considered.

[c]Adding notation of r (imaging) and p (pathology) to indicate the findings that are used to allocate the case to Stage IIIC. Example: If imaging indicates pelvic lymph node metastasis, the stage allocation would be Stage IIIC1r, and if confirmed by pathologic findings, it would be Stage IIIC1p. The type of imaging modality or pathology technique used should always be documented.

Source: Bhatla et al.[17]

Cervix Uteri AJCC 第八版

Primary Tumor		
T		**T Criteria**
TX		Primary tumor cannot be assessd
T0		No evidence of primary tumor
T1		The carcinoma is strictly confined to the cervix (extension to the uterine corpus should be disregarded)
T1a		Invasive carcinoma that can be diagnosed only by microscopy, with maximum depth of invasion
	T1a1	Measured stromal invasion <3 mm in depth or <7 mm in horizontal spread
	T1a2	Measured stromal invasion ≥3 mm and <5 mm in depth, with <7 mm in horizontal spread
T1b		Clinically visible lesion confined to the cervix or microscopic lesion greater than T1a/IA2. Includes all macroscopically visible lesions, even those with superficial invasion.
	T1b1	Clinically visible lesion <4 cm in greatest dimension
	T1b2	Clinically visible lesion ≥4 cm in greatest dimension
T2		The carcinoma invades beyond the uterus, but has not extended onto the lower third of the vagina or to the pelvic wall
T2a		Involvement limited to the upper two-thirds of the vagina without parametrial involvement
	T2a1	Invasive carcinoma <4 cm in greatest dimension
	T2a2	Invasive carcinoma ≥4 cm in greatest dimension
T2b		With parametrial involvement but not up to the pelvic wall
T3		The carcinoma involves the lower third of the vagina and/or extends to the pelvic wall and/or causes hydronephrosis or nonfunctioning kidney
T3a		The carcinoma involves the lower third of the vagina, with no extension to the pelvic wall
T3b		Extension to the pelvic wall and/or hydronephrosis or nonfunctioning kidney (unless known to be due to another cause)
T4		The carcinoma has extended beyond the true pelvis or has involved (biopsy proven) the mucosa of the bladder or rectum. (bullous edema, as such, does not permit a case to be allotted to T4)

* The pelvic sidewall is defined as the muscle, fascia, neurovascular structures and skeletal portions of the bony pelvis. On rectal exam, there is no cancer-free space between the tumor and pelvic sidewall.

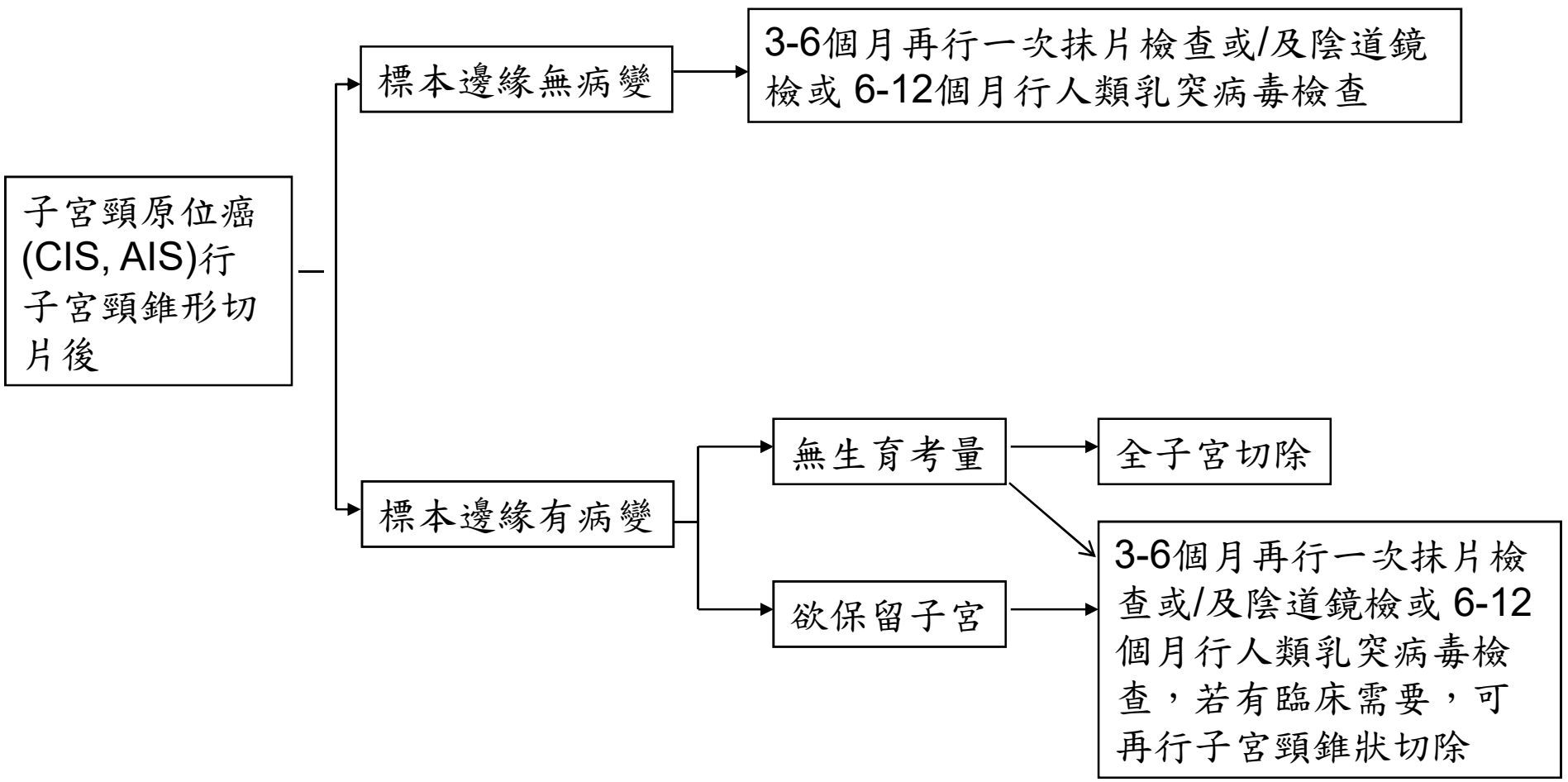
Cervix Uteri AJCC 第八版

Regional Lymph Node (N)	
N	**N Criteria**
NX	Regional lymph node cannot be assessed
N0	No regional lymph node metastasis
N0(i+)	Isolated tumor cells in regional lymph node(s) no greater than 0.2 mm
N1	Regional lymph node metastasis

Distant Metastasis (M)	
M	**M Criteria**
M0	No distant metastasis
M1	Distant metastasis (including peritoneal spread or involvement of the supraclavicular, mediastinal, or distant lymph nodes; lung; liver; or bone)

AJCC STAGE GROUPS			
T	**N**	**M**	**Stage**
T1	Any N	M0	I
T1a	Any N	M0	IA
T1a1	Any N	M0	IA1
T1a2	Any N	M0	IA2
T1b	Any N	M0	IB
T1b1	Any N	M0	IB1
T1b2	Any N	M0	IB2
T2	Any N	M0	II
T2a	Any N	M0	IIA
T2a1	Any N	M0	IIA1
T2a2	Any N	M0	IIA2
T2b	Any N	M0	IIB
T3	Any N	M0	III
T3a	Any N	M0	IIIA
T3b	Any N	M0	III
T4	Any N	M0	IVA
Any T	Any N	M1	IVB

高雄榮總婦癌團隊 子宮頸原位癌臨床治療指引

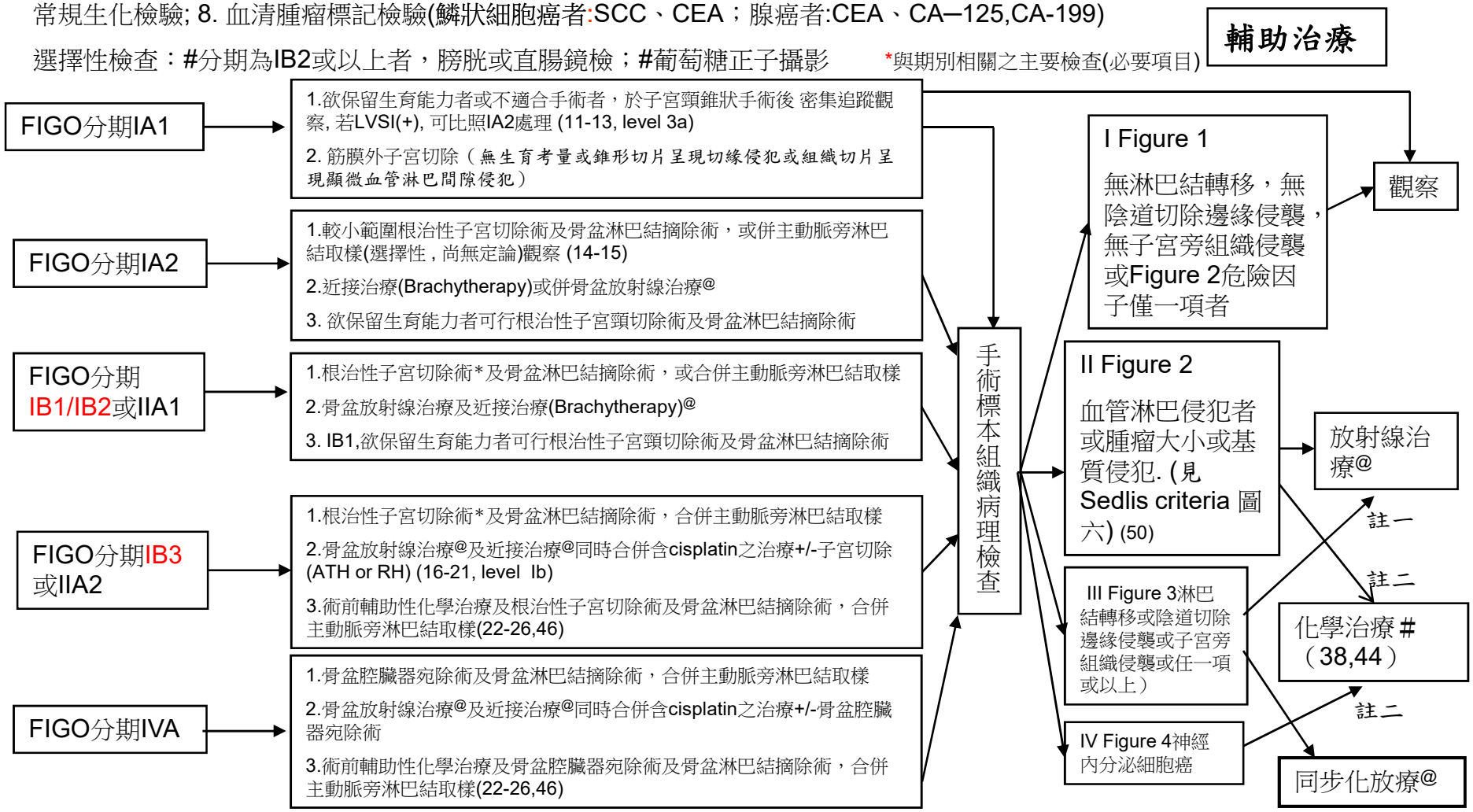


高雄榮總婦癌團隊　子宮頸癌臨床治療指引

子宮頸癌治療流程

治療前檢查：1.病史及理學檢查*；2.全血球計數；3.子宮頸切片之組織病理檢查；4.子宮頸錐狀手術+子宮頸管搔刮術(當子宮頸切片之組織病理檢查結果為微侵襲癌者)；5.胸部X光*；6.分期高於IA者，安排腹部或骨盆電腦斷層*或核磁共振 *(52)；7.常規生化檢驗; 8. 血清腫瘤標記檢驗(鱗狀細胞癌者:SCC、CEA；腺癌者:CEA、CA–125,CA-199)

選擇性檢查：#分期為IB2或以上者，膀胱或直腸鏡檢；#葡萄糖正子攝影　　*與期別相關之主要檢查(必要項目)



＊:含神經保留式根治性子宮切除術（nerve sparing radical hysterectomy）；#:請見表一；註一：病患年紀太大或合併多重內科疾病者；註二：年輕女性考慮避免性功能障礙者或接受過放射線治療者；@: 放射治療 、 近接治療或同步化放療請見放射腫瘤部治療指引

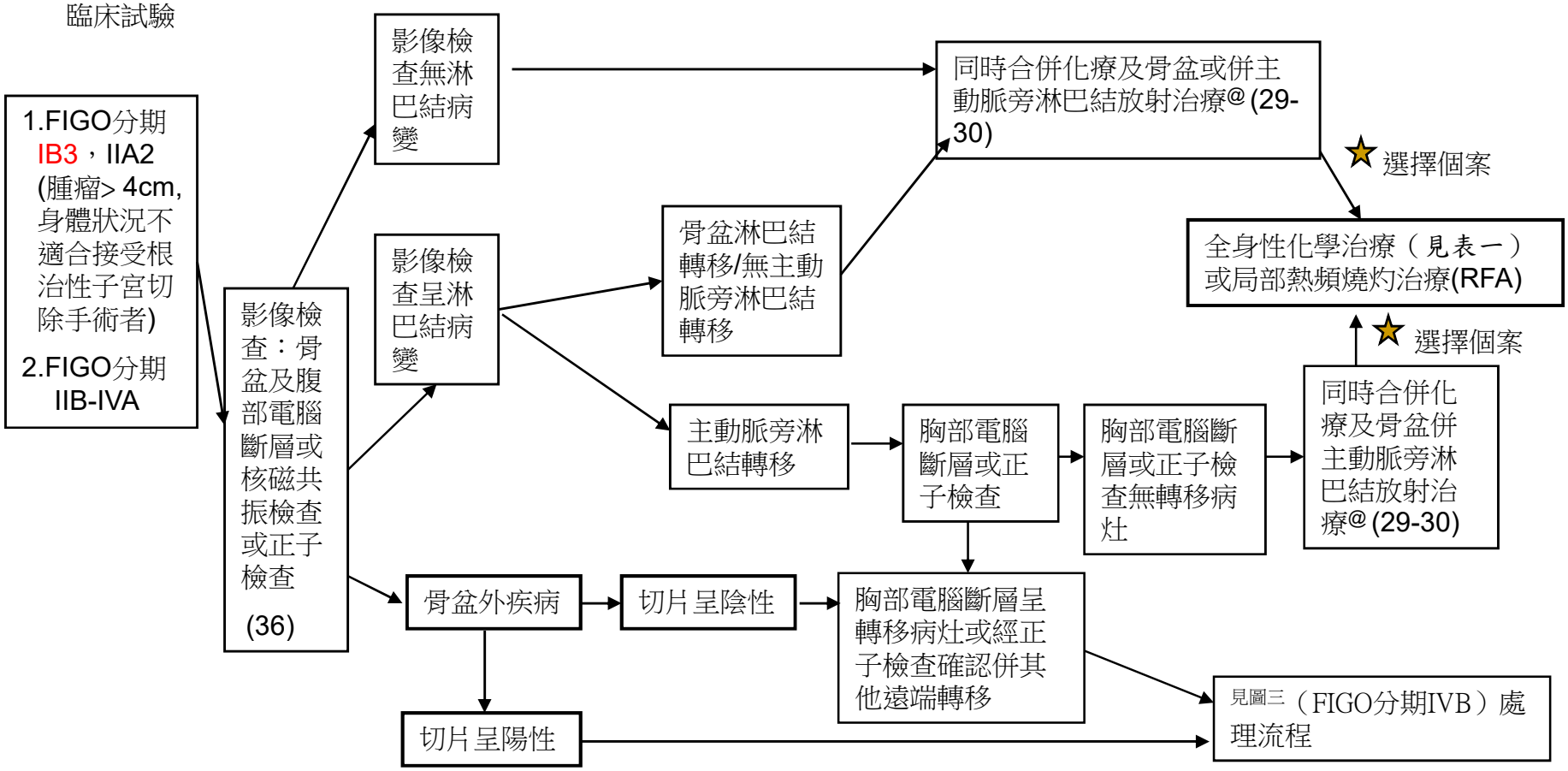
圖一

高雄榮總婦癌團隊　子宮頸癌臨床治療指引

FIGO分期IIB-IVA(局部晚期)子宮頸癌，或不適合施行根治性子宮切除手術之IB 、IIA治療流程

1.放射治療包括體外放射治療及近接治療@

2.同步化放療時使用含cisplatin 40 mg/m^2 /carboplatin 100 mg/m^2 or AUC2 weekly x 6 courses （或配合放療療程）之化療或臨床試驗



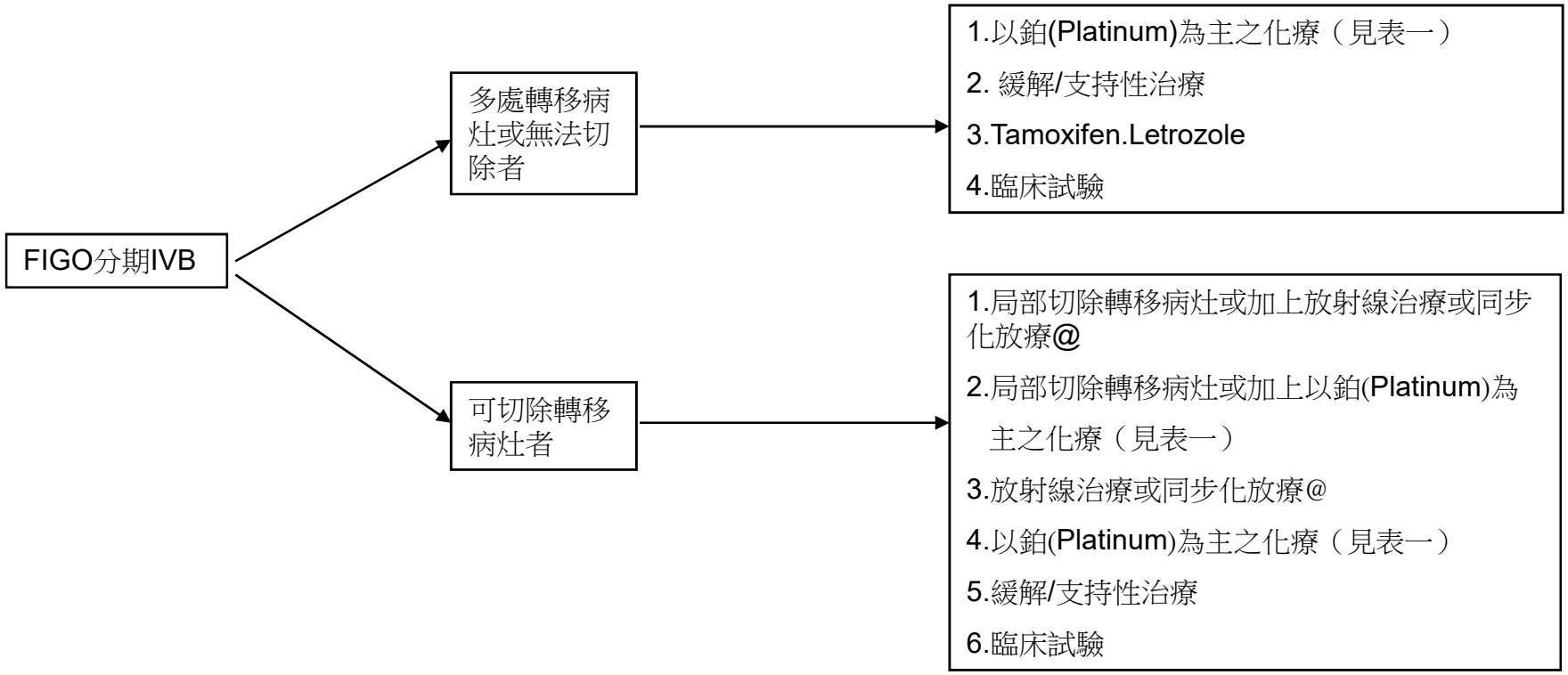
@：放射治療或同步化放療及併主動脈旁淋巴結放射治療請見放射腫瘤部治療指引

★: 仍有residual tumor

圖二

高雄榮總婦癌團隊　子宮頸癌臨床治療指引

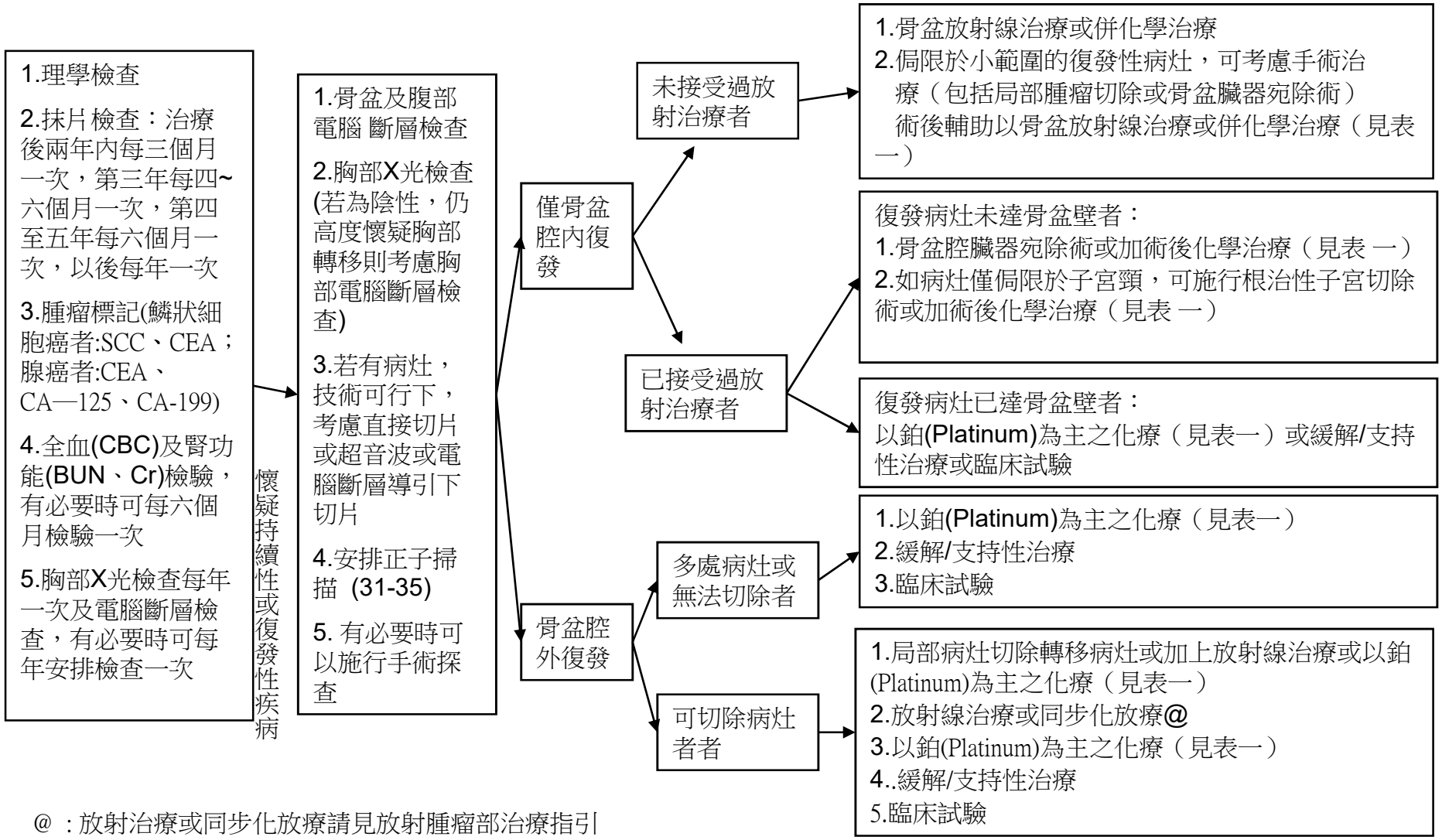
FIGO分期IVB(遠端轉移)子宮頸癌治療流程



圖三

高雄榮總婦癌團隊　子宮頸癌臨床治療指引

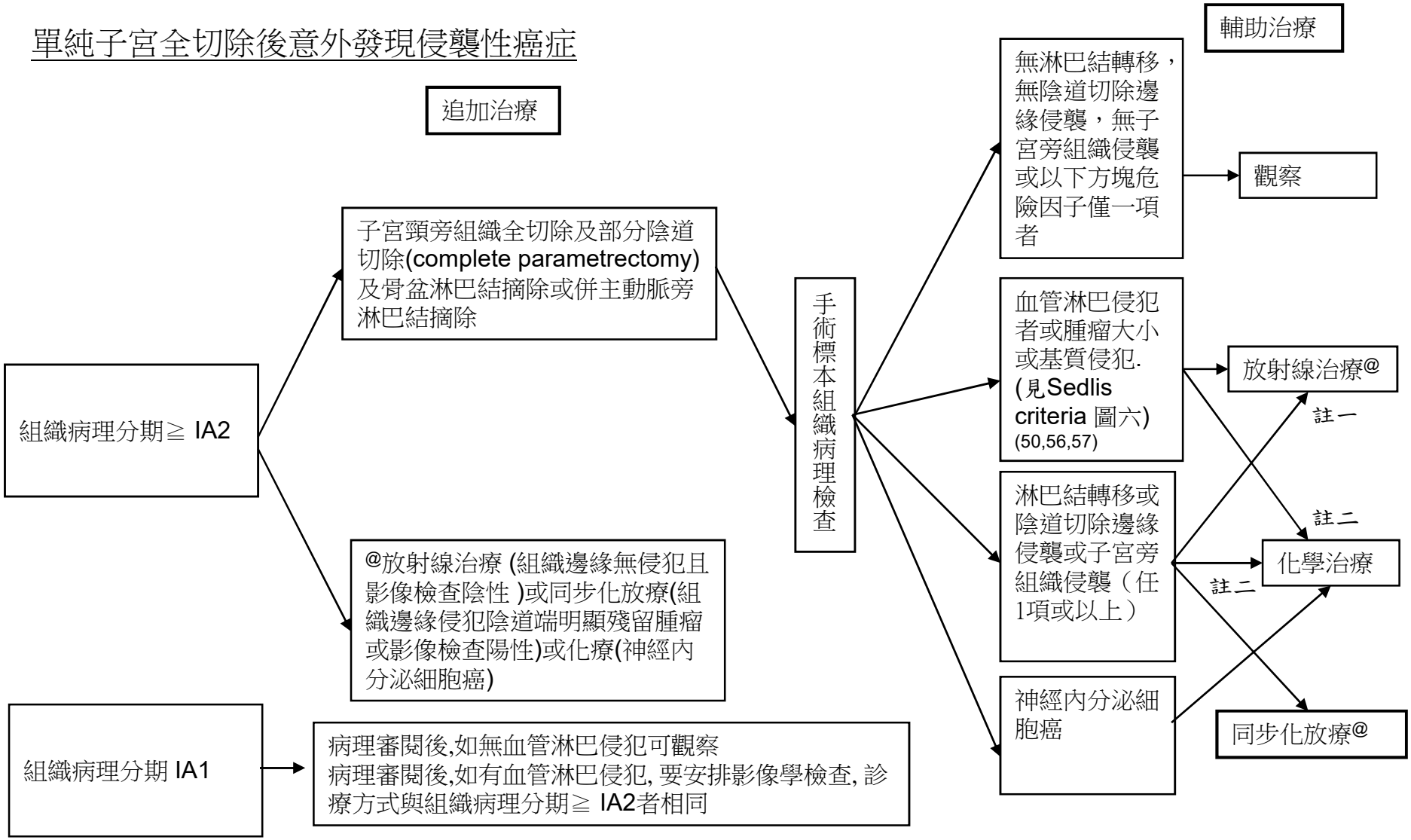
子宮頸癌治療後追蹤及復發的處置



@ : 放射治療或同步化放療請見放射腫瘤部治療指引

圖四

單純子宮全切除後意外發現侵襲性癌症



#:請見表一；註一：病患年紀太大或合併多重內科疾病者；註二：年輕女性考慮避免性功能障礙者或接受過放射線治療者；

@: 放射治療或同步化放療請見放射腫瘤部治療指引

圖五

SEDLIS CRITERIA FOR EXTERNAL PELVIC RADIATION AFTER RADICAL HYSTERECTOMY IN NODE-NEGATIVE, MARGIN-NEGATIVE, PARAMETRIA-NEGATIVE CASES[1,2,3,4]

LVSI	Stromal Invasion	Tumor Size (cm) (Determined by clinical palpation)
+	Deep 1/3	Any
+	Middle 1/3	≥2
+	Superficial 1/3	≥5
-	Middle or Deep 1/3	≥4

LVSI: Lymphovascular space invasion

圖六

高雄榮總婦癌團隊　子宮頸癌臨床治療指引-化學治療或同步化學與放射治療

術前新輔助化學治療：以 platinum-based 為原則，可使用以下的選擇

1.IP (ifosfamide 4 gm/m2+cisplatin 50mg/m2 or carboplatin AUC=5 every 21 days x 3~6 cycles)(48,49)
2.Irinotecan 60mg/m2+cisplatin 50mg/m2 or carboplatin AUC=5 every 28 days x 3~6 cycles (optional)(43,47)
3.(IB2-IIB) weekly Taxol + Carboplatin(AUC=2) (D1,D8,D15)x 9 cycles(58)
4.Clinical trials

手術後輔助化學治療：以 platinum-based 為原則，可使用以下的選擇

1.IP (ifosfamide 4 gm/m2+cisplatin 50mg/m2 or carboplatin AUC=5 every 21 days x 6 cycles) (38,45,49)
2.Clinical trials

神經內分泌癌手術後輔助化學治療或化放療以 platinum-based 為原則可使用以下的選擇

1.VP-16/cyclophosphamide/platinum (VP-16 100mg/m2+cyclophosphamide 500mg/m2+cisplatin 50mg/m2 or carboplatin AUC=5 every 21 days x 6 cycles) (53,54)

第IV期B，持續性疾病 (persistent disease)復發或轉移性疾病 (recurrent/metastatic disease) 之全身性化學治療或免疫療法為原則，可使用以下的選擇

1.Topotecan 0.75mg/m2 x 3 days+ cisplatin 50mg/m2 or carboplatin AUC=5 every 21 days x 6 cycles(GOG 179, level Ib) (42) ± Bevacizumab 7.5~15 mg/kg
2.IP (ifosfamide 4gm/m2+cisplatin 50mg/m2 or carboplatin AUC=5 every 21 days x 6 cycles)(GOG 110, level Ib)
3.Paclitaxel 175mg/m2+ cisplatin 50mg/m2 or carboplatin AUC=5 every 21 days x 6 cycles)(optional)(GOG 169, GOG 204, level Ib) (51) ± Bevacizumab 7.5~15 mg/kg (GOG 240) (55)
4.Irinotecan/platinum (Irinotecan 60mg/m2+cisplatin 50mg/m2 or carboplatin AUC=5 every 28 days x 6 cycles) (optional) (43,47)
5. Paclitaxel 175mg/m2(D1)+ topotecan 0.75mg/m2(D1-3) ±Bevacizumab 7.5~15 mg/kg(D1) every 21~28 days (63)
6. Tamoxifen 10mg QD (61,62)
7. Keytruda(Pembrolizumab) for PD-L1(+) or MSI-H/dMMR tumor ((59, 60 (KEYNOTE-028,158)) / **8.Clinical trials**

同步化放療時使用含cisplatin 40 mg/m^2 /carboplatin 100 mg/m^2 or AUC2 weekly x6 cycles 之化療或臨床試驗藥物(29)

高雄榮總婦癌團隊　子宮頸癌臨床治療指引-化學治療或同步化學與放射治療

1. **CCRT-CISPLATIN(40MG/M2)**
2. **CCRT-CARBOPLATIN(100MG/M2) OR AUC2**
3. **CCRT-WEEKLY CISPLATIN(40MG/M2) + GEMCITABINE(120MG/M2)**
4. **P(CARBOPLATIN(ACU=5))C(CYCLOPHASPHAMIDE (500MG/M2))+VP-16(100MG/M2)-CCR. <60ML/MIN**
5. **P(CISPLATIN(50MG/M2)) C+VP-16-CCR. >60ML/MIN**
6. **1ST LINE. I(IFOSFAMIDE+MESNA(4GM/M2)) P(CARBOPLATIN(AUC=5))-CCR.< 60ML/MIN**
7. **1ST LINE. IP(CISPLATIN(50MG/M2))-CCR.> 60ML/MIN**
8. **2ND LINE. TAXOL (PAYSELF) (175MG/M2)(D1) +TOPOTECAN(0.75MG/M2)(D1-3)**

高雄榮總婦癌團隊　子宮頸癌臨床治療指引-化學治療或同步化學與放射治療

9. 2ND LINE. IRINOTECAN(PAYSELF) (60MG/M2) +CARBOPLATIN(AUC=5) (D1)
10. 2ND LINE. IRINOTECAN(PAYSELF)(60MG/M2)+CISPLATIN (50MG/M2) (D1)
11. 2ND LINE. IRINOTECAN(PAYSELF)(60MG/M2)-D8 OR D15
12. 2ND LINE. TAXOL (PAYSELF)(175MG/M2)+ CARBOPLATIN (AUC=5)-CCR.< 60ML/MIN
13. 2ND LINE. TAXOL (PAYSELF) (175MG/M2) +CISPLATIN (50MG/M2)-CCR.> 60ML/MIN
14. 2ND LINE. TOPOTECAN(0.75MG/M2) +CARBOPLATIN (AUC=5)-CCR.< 60ML/MIN
15. 2ND LINE. TOPOTECAN (0.75MG/M2) +CISPLATIN (50MG/M2)-CCR.> 60ML/MIN
16. WEEKLY TAXOL(80MG/M2) +CISPLATIN(20MG/M2) (D1 OR D8 OR D15)

17. WEEKLY TAXOL(80MG/M2) +CARBOPLATIN(AUC=2)
(D1 OR D8 OR D15)
18.AVASTIN (PAYSELF)(7.5~15MG/KG)
19. TAMOXIFEN 10mg QD
20. PEMBROLIZUMAB(KEYTRUDA)

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