

大腸直腸癌診療指引

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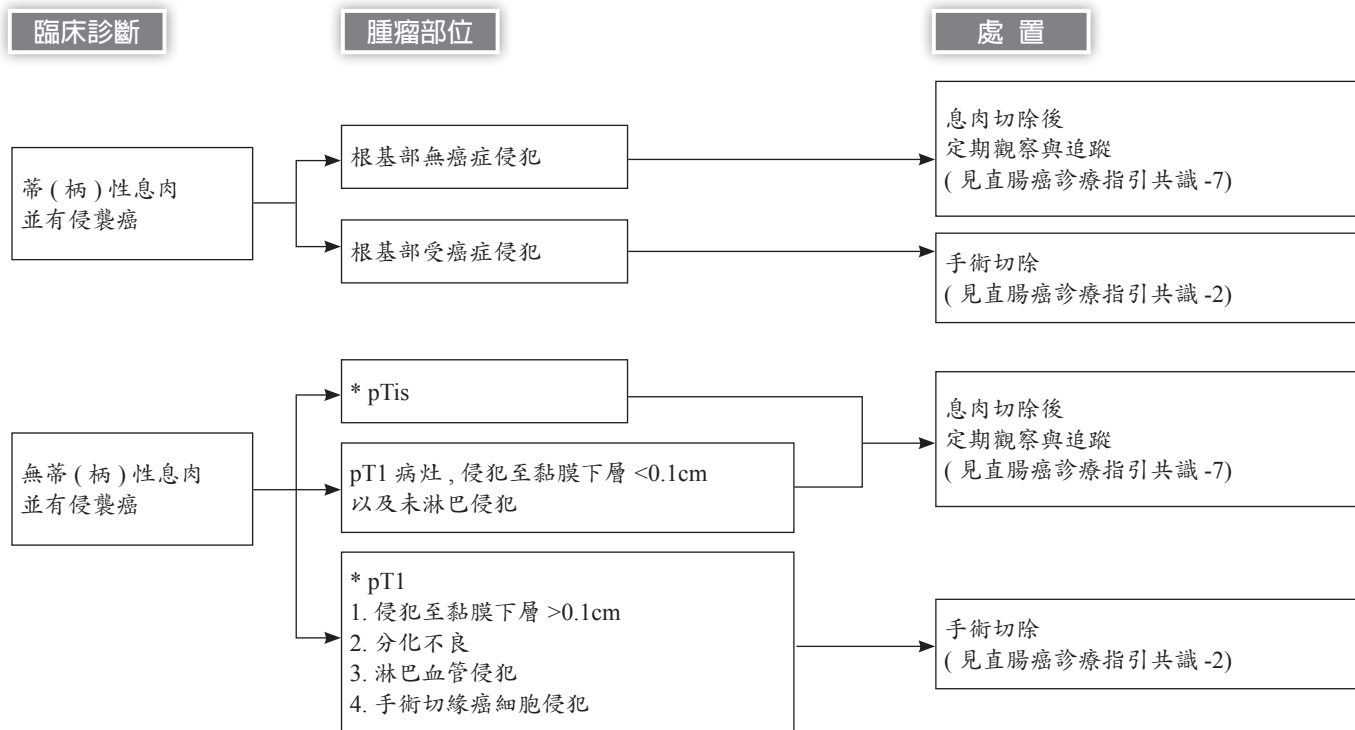
二、討論日期：106 年 10 月 11 日

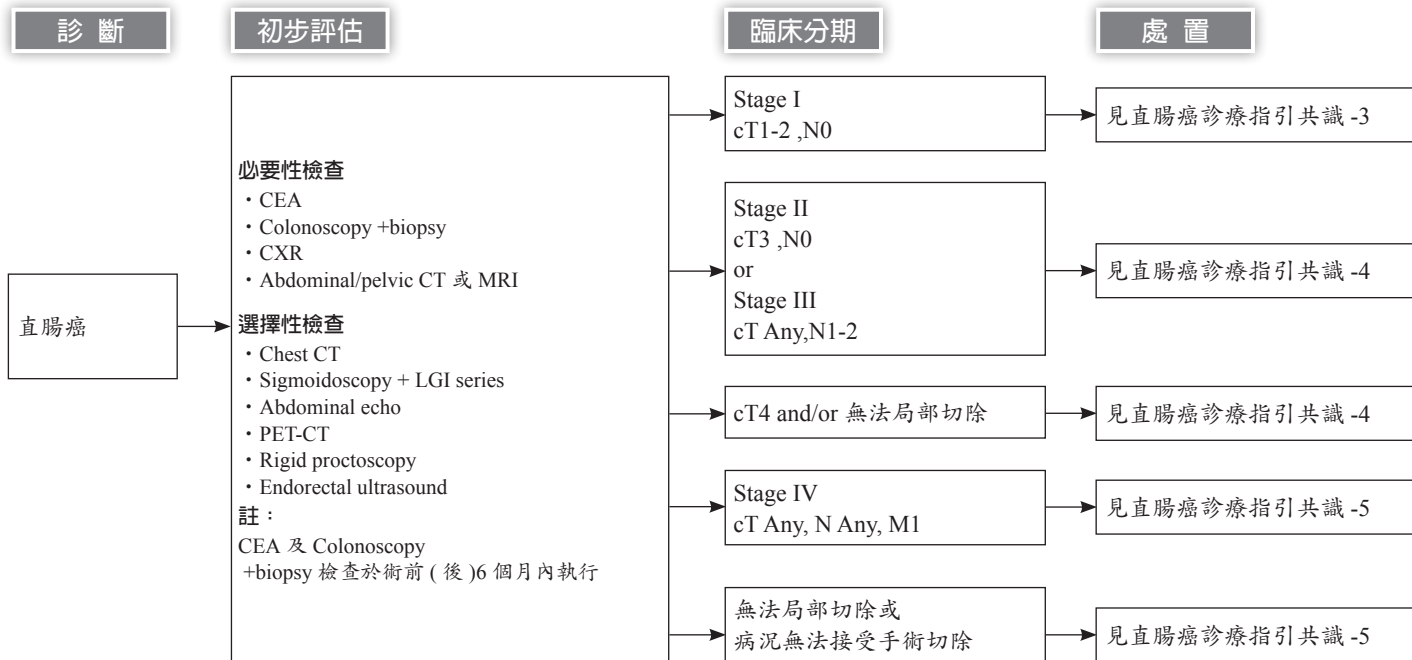
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106 年版與上一版差異：

105 年版	106 年修訂版
<p>直腸癌診療指引共識 - 2</p> <ol style="list-style-type: none"> 1. 直腸癌可手術切除 2. 選擇性檢查 3. 無法局部切除或病況無法接受手術 	<p>新增 直腸癌。</p> <p>新增 Endorectal ultrasound。</p> <p>修訂 格式，往上合併。</p>
<p>直腸癌診療指引共識 - 3</p> <ol style="list-style-type: none"> 1. pT1,NX 病灶 ,(且有危險因子)pT2,Nx 	<p>修訂 前導性化放療相關路徑。</p>
<p>直腸癌診療指引共識 - 4</p> <p>Stage II cT3,N0,M0 Stage III cT1-3,N1-2</p> <ol style="list-style-type: none"> 1. 前導性放射線治療及化學治療 2. 輔助性化學治療 	<p>修訂 前導性放射線治療 ± 化學治療。</p> <p>修訂 輔助性化學治療 ± 放射線治療。</p>
<p>直腸癌診療指引共識 - 2</p> <ol style="list-style-type: none"> 1. Clinical T4b 診療指引路徑 	<p>新增 Clinical T4b → 前導性化學治療 → 手術切除 → T3-4N0 或 pT Any,N1-2。 Clinical T4b → 接至上方手術路徑。</p>
<p>大腸癌診療指引共識 - 4</p> <ol style="list-style-type: none"> 1. 更正 HIPEC 適應條件 	<p>修訂 ECOG : 0-1，術式描述修正為腫瘤減量手術 ± 腹腔內熱化學治療。</p>

《直腸癌診療指引共識 -1》

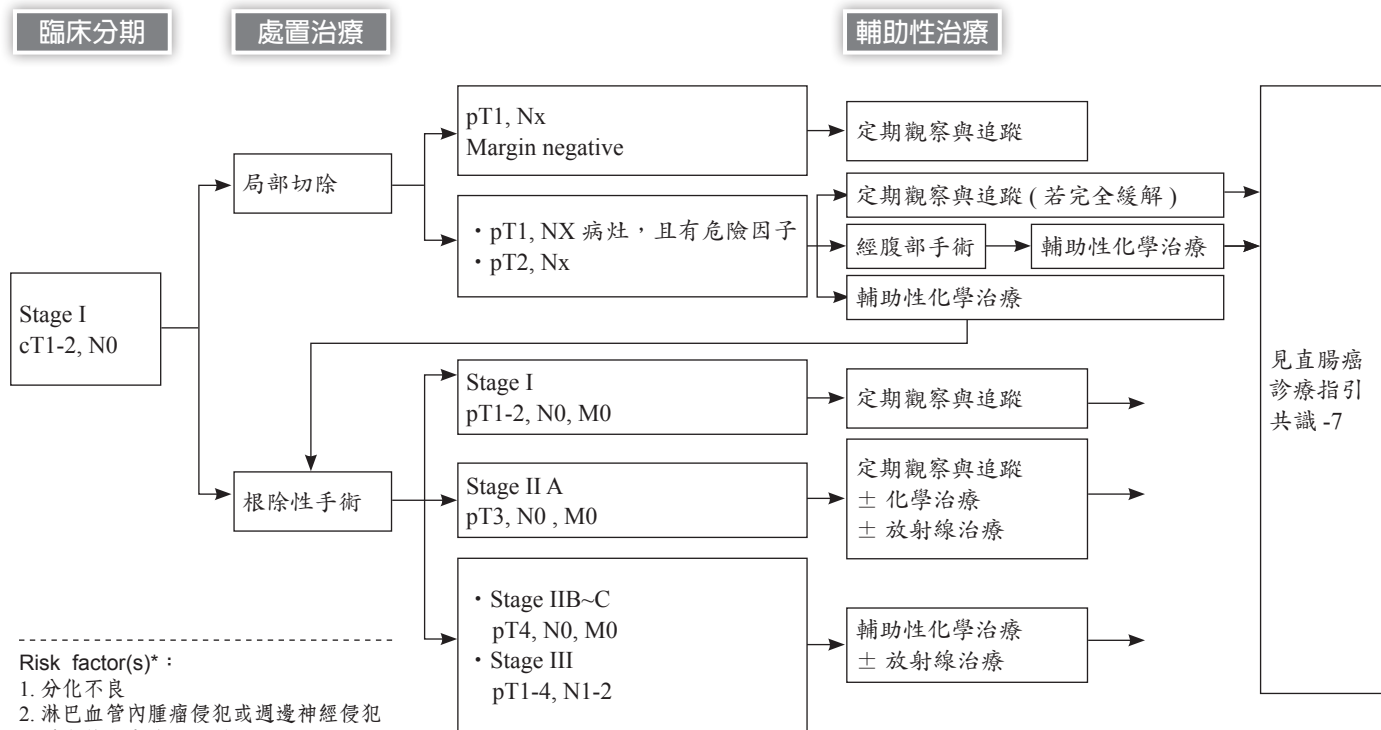




直腸癌定義：

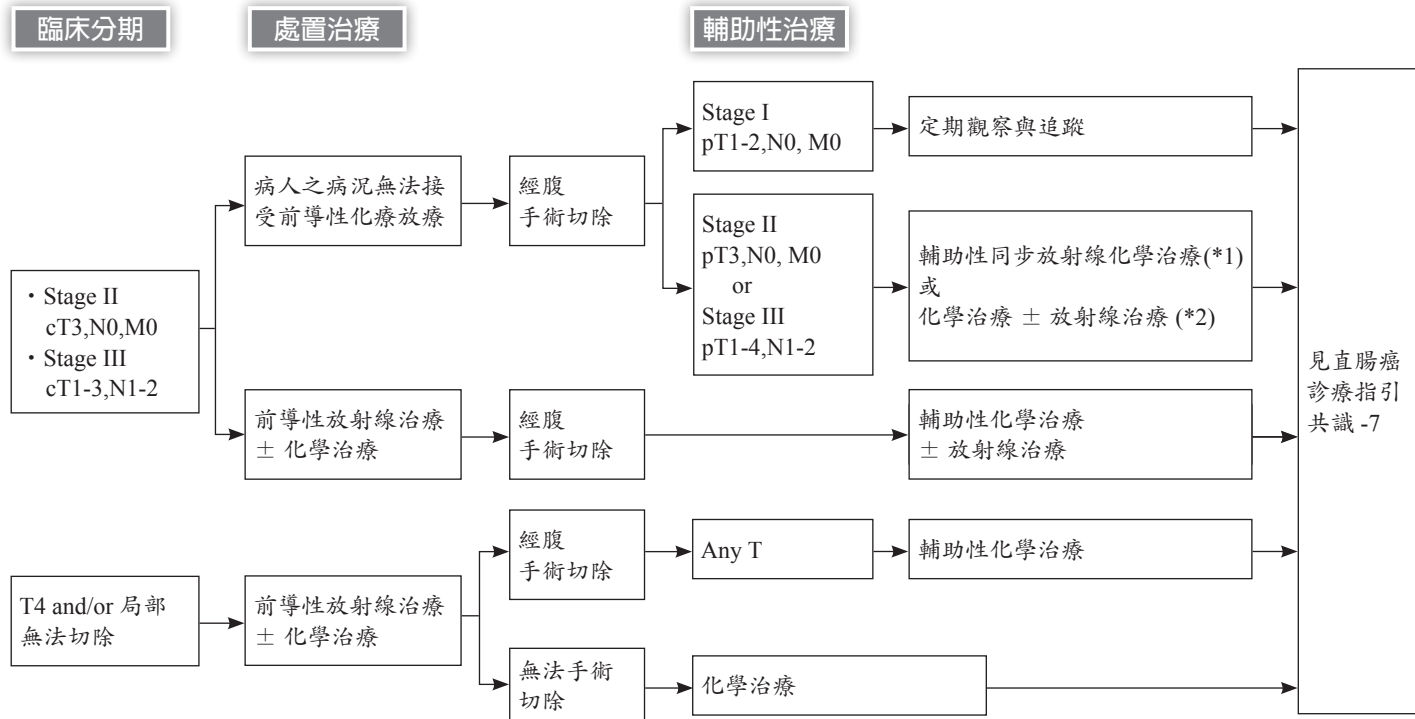
距離肛門口 15 公分以內之直腸，依病灶下緣距肛門口的距離分為上 (>11cm)、中 (>7cm & ≤ 11 cm)、下 (≤ 7 cm) 三段。對於中、下段局部廣泛性的癌症，且年齡介於 18 至 75 歲的病人，可接受手術前放射及化學治療，之後再實施根治性手術切除。對於上段直腸癌患者，則建議由臨床醫師視患者狀況而定，可直接進行手術，或採用手術前放射及化學治療，之後再實施根治性手術切除。

《直腸癌診療指引共識 -3》



Risk factor(s)* :

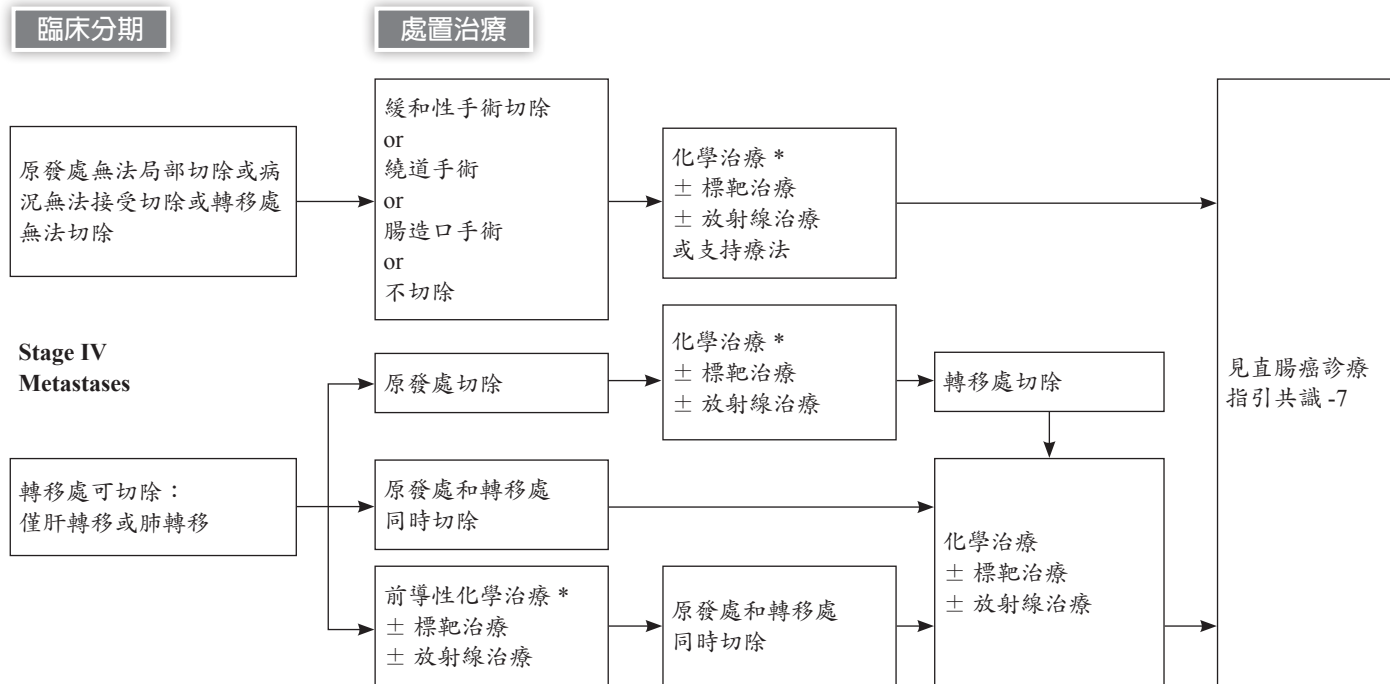
1. 分化不良
2. 淋巴血管內腫瘤侵犯或週邊神經侵犯
3. 手術的安全邊距不足
4. SM3(Submucosa layer 3) invasion
5. StageIIA,pT3N0M0 : (without risk factor) added inspection MSI or MMR (optional),if MSI low adjuvant chemotherapy



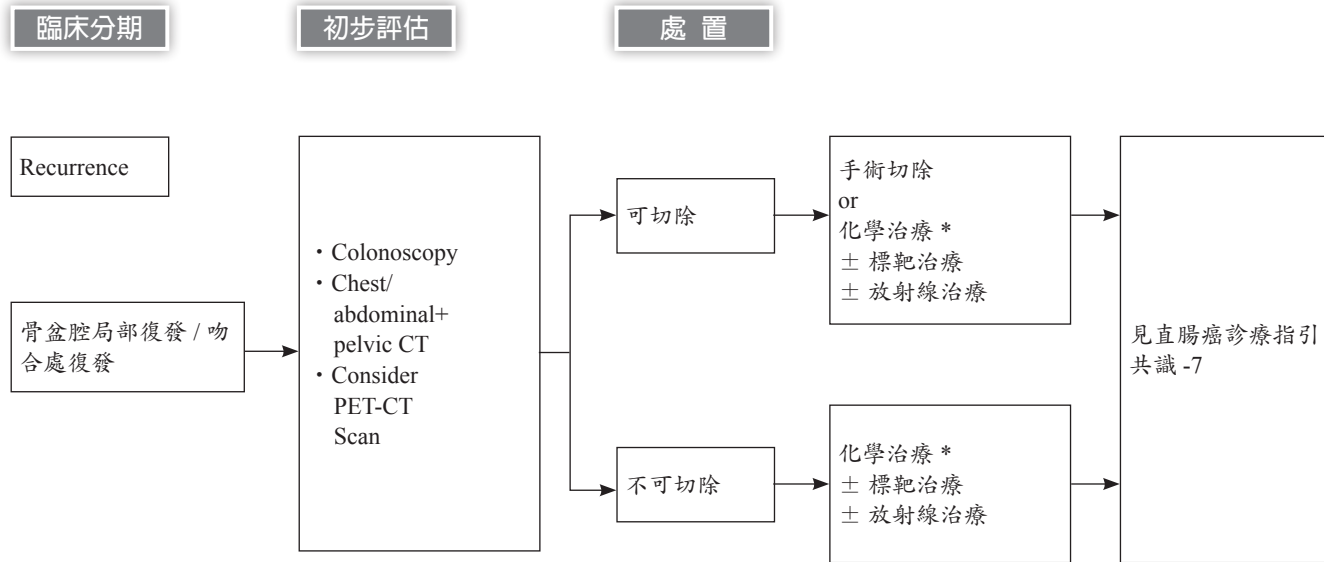
*1. 若所選擇的化療藥物非為 Fluoropyrimidines 類 (如: oxaliplatin), 則不建議同步接受放射線治療。

*2. 若病人的分期接近 T3,N0 且手術的安全邊距足夠, 以及預後特徵良好, RT 的治療成效較小, 建議單獨使用化學治療。

《直腸癌診療指引共識 -5》



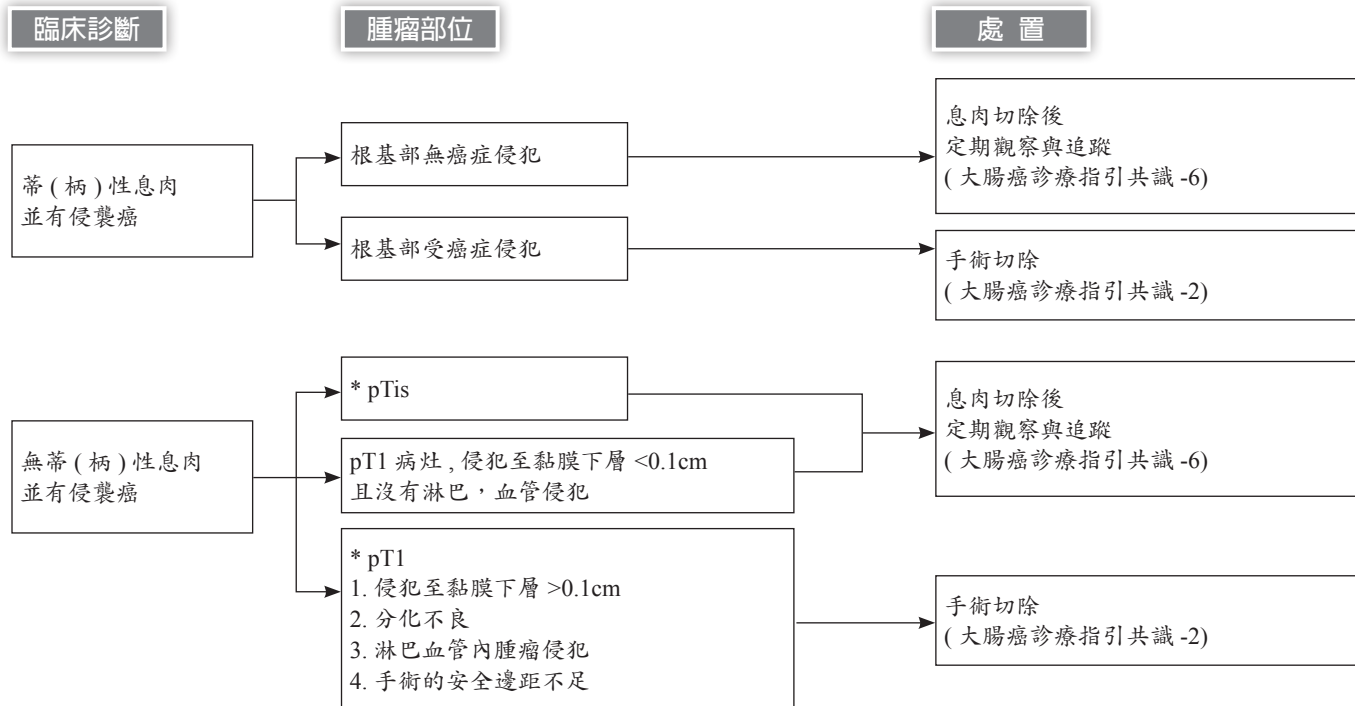
※ Stage IV 化學治療前加驗 RAS Mutation (其餘 Stage Optional, optional 項目包括: B-RAF, MSI, MMR)



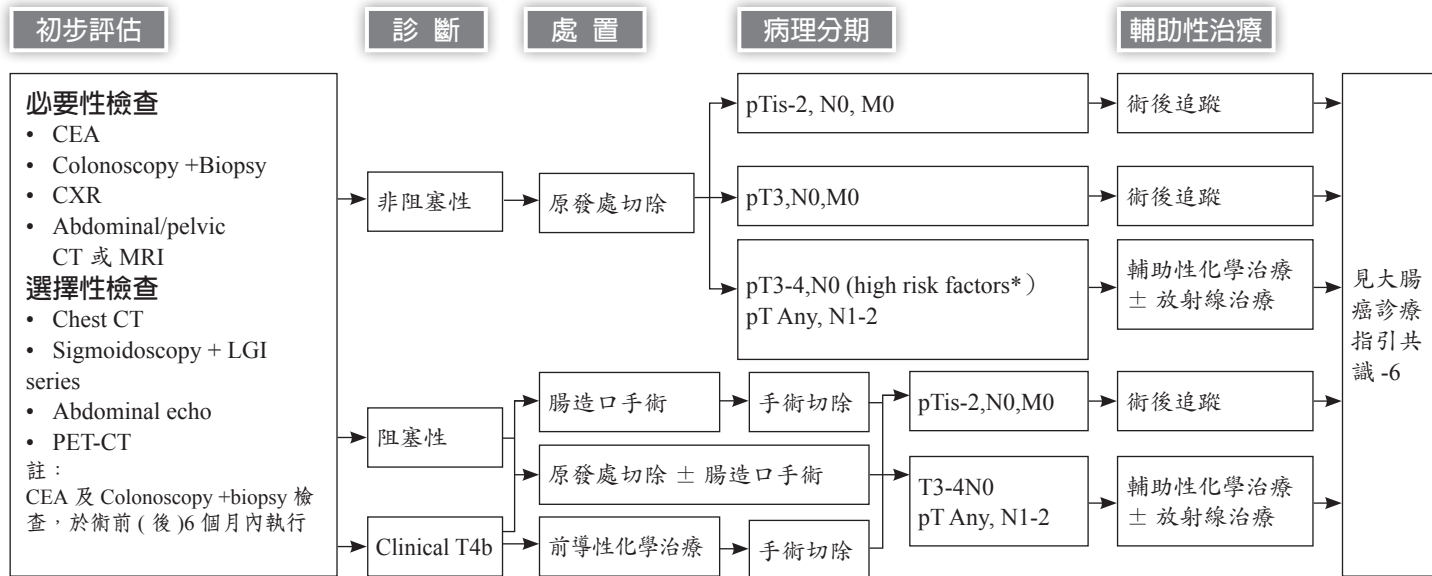
※ Stage IV 化學治療前加驗 RAS Mutation (其餘 Stage Optional, optional 項目包括 :B-RAF,MSI,MMR)

《直腸癌診療指引共識 -7》

Follow up Program for Rectal Cancer Patients (at least 5 years)	
CEA	術後第一個月，兩年內每 3-6 個月一次，以後每 6 個月一次。
Chest /Abdomen + pelvic CT	(1) High risk patients : 每 6 個月一次。 eg : Stage III or lymphatic or venous invasion by tumor ; poorly differentiated tumors)
	(2) Stage IV patients : 兩年內每 3-6 個月一次，以後每 6-12 個月一次
Colonoscopy or Barium enema + Sigmoidoscopy	第一年一次，之後每隔一年一次。 1. 術前為阻塞型病灶，未全程做完大腸鏡檢者，術後 3-6 個月內即應再施檢一次。 2. 若為 advanced adenoma，追蹤 1 年。 3. 若非為 advance adenoma，追蹤 3 年而後追蹤 5 年
Rigid proctoscopy (選擇性)	每 6 個月一次。
Abdomen sono (選擇性)	每 6 個月一次。
PET-CT scan (選擇性)	臨床評估需要時

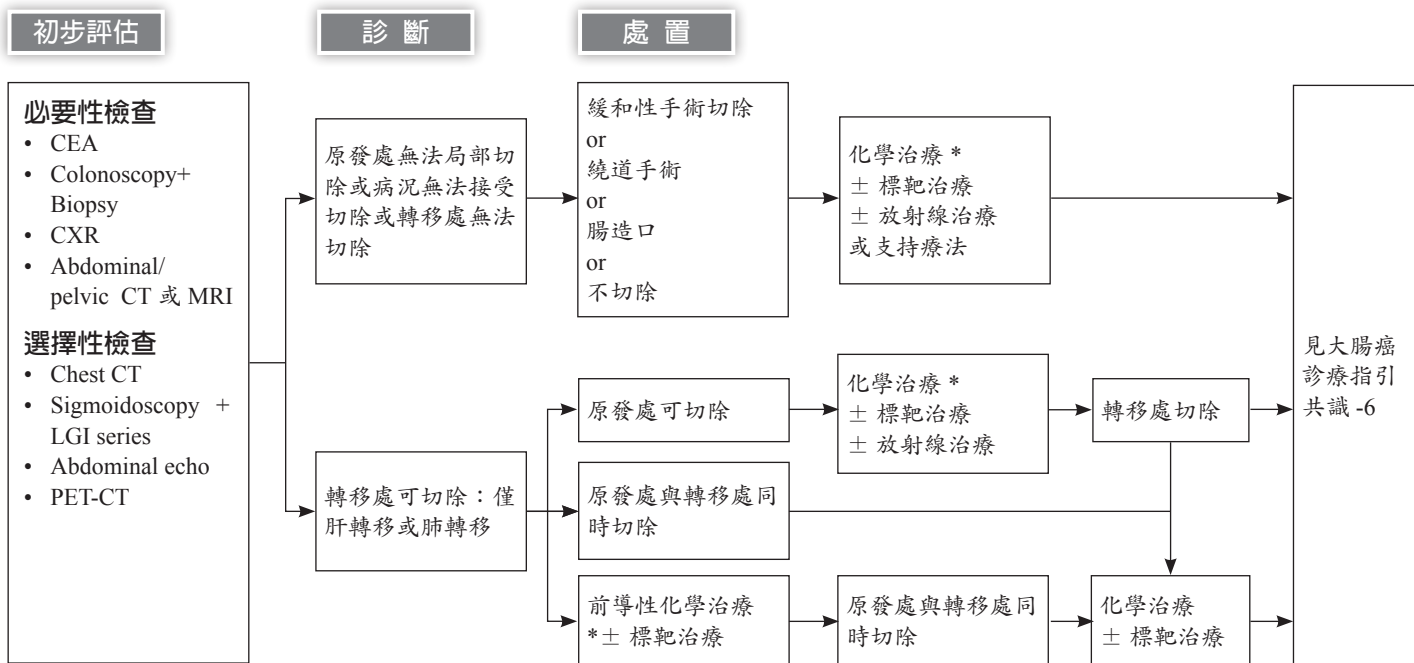


《大腸癌診療指引共識 -2》



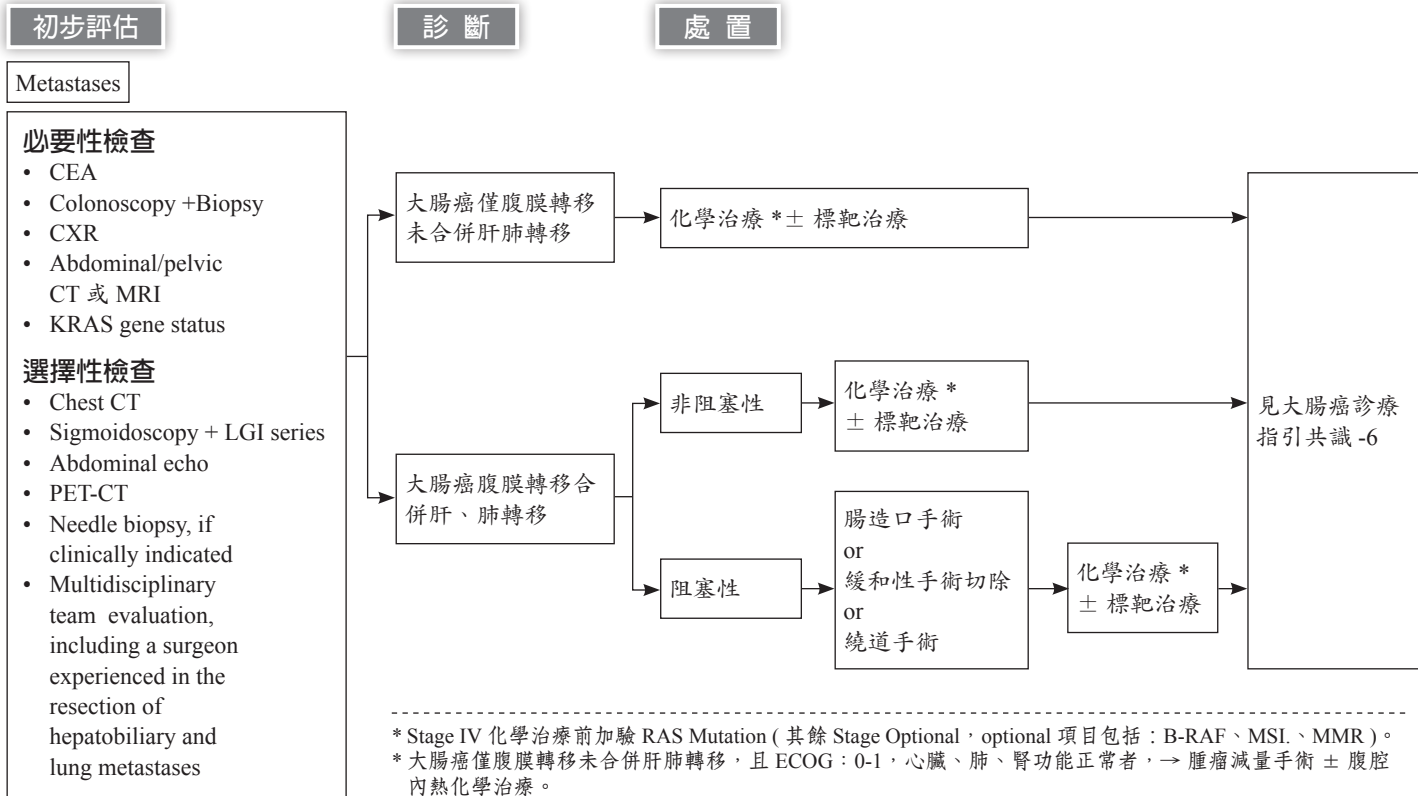
*High risk factors :

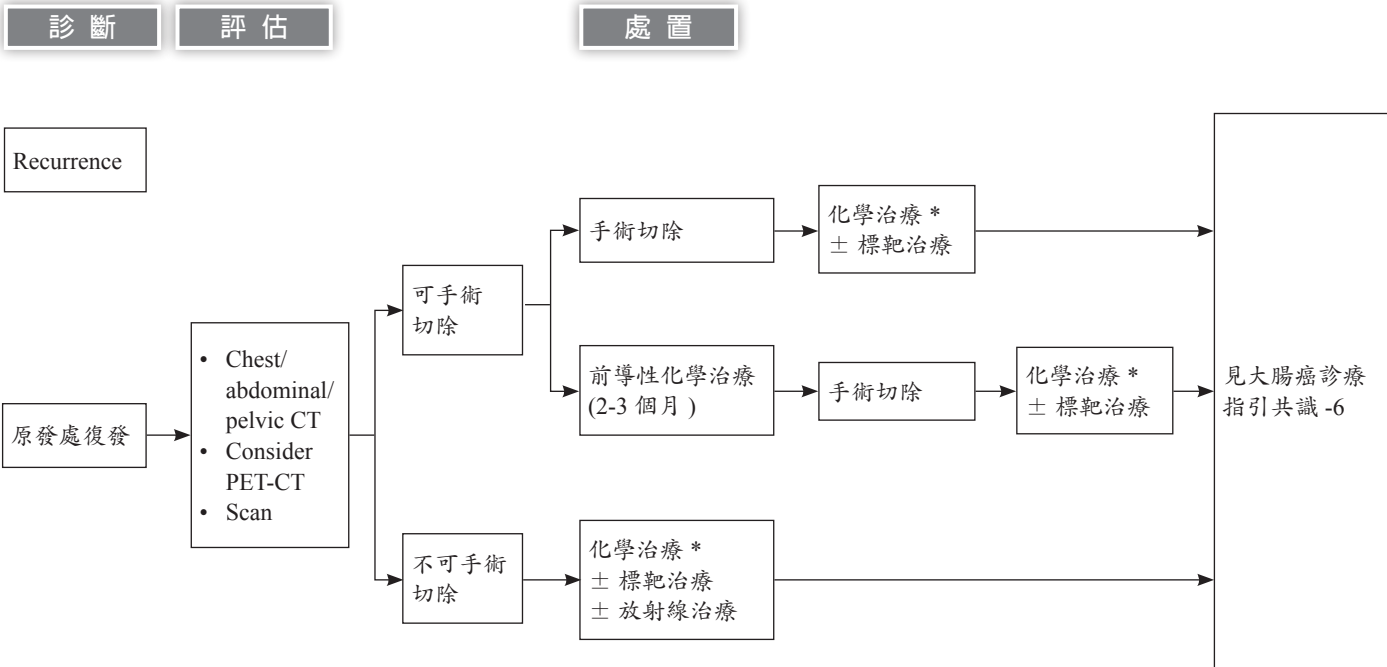
1. 分化不良 (poorly differentiated)
2. 淋巴血管內腫瘤侵犯 或 神經週圍浸潤 (lymphatic/vascular/perineural invasion)
3. 淋巴摘除 <12 顆 (<12 lymph nodes examined)
4. 局部穿孔 (localized perforation)
5. 完全腸道阻塞 (bowel obstruction)
6. 手術的安全邊距不足、無法界定或手術邊距有癌細胞侵犯 (close, indeterminate or positive margins)
7. StageIIA,pT3N0M0 : (without risk factor) 加驗 MSI or MMR (optional),if MSI low → adjuvant chemotherapy



※ Stage IV 化學治療前加驗 RAS Mutation (其餘 Stage Optional, optional 項目包括 :B-RAF、MSI、MMR)。

《大腸癌診療指引共識-4》





※ Stage IV 化學治療前加驗 RAS Mutation (其餘 Stage Optional, optional 項目包括 :B-RAF、MSI、MMR)。

《大腸癌診療指引共識 -6》

Follow up Program for Rectal Cancer Patients (at least 5 years)	
CEA	術後第一個月，兩年內每 3-6 個月一次，以後每 6 個月一次。
Chest /Abdomen + pelvic CT	(1) High risk patients : 每 6 個月一次。 eg : Stage III or lymphatic or venous invasion by tumor ; poorly differentiated tumors)
	(2) Stage IV patients : 兩年內每 3-6 個月一次，以後每 6-12 個月一次
Colonoscopy or Barium enema + Sigmoidoscopy	第一年一次，之後每隔一年一次。 1. 術前為阻塞型病灶，未全程做完大腸鏡檢者，術後 3-6 個月內即應再施檢一次。 2. 若為 advanced adenoma，追蹤 1 年。 3. 若非為 advance adenoma，追蹤 3 年而後追蹤 5 年。
Abdomen sono (選擇性)	每 6 個月一次。
PET-CT scan (選擇性)	臨床評估需要時。

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Adjuvant Therapy of Colon Cancer

mFOLFOX6

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Oxaliplatin	85	1	Q2W	12	1-3
Leucovorin	400	1	Q2W	12	1-3
5-FU	400	1	Q2W	12	1-3
5-FU	1200	1-2	Q2W	12	1-3

* Continuous infusion for 24 hours

FOLFOX4

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Oxaliplatin	85	1	Q2W	12	9
Leucovorin	200	1	Q2W	12	9
5-FU	400	1	Q2W	12	9
5-FU	600	1-2	Q2W	12	9

* Continuous infusion for 24 hours

FLOX

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Oxaliplatin	85	1, 15, 29	Q8W	3	4
Leucovorin	500	1, 8, 15, 22, 29, 36	Q8W	3	4
5-FU	500	1, 8, 15, 22, 29, 36	Q8W	3	4

Capecitabine

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Capecitabine	1250 PO BID	1-14	Q3W	8	5

CapeOx

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Oxaliplatin	130	1	Q3W	8	6
Capecitabine	1000 PO BID	1-14	Q3W	8	6

5-FU+LV

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Leucovorin	500	1, 8, 15, 22, 29, 36	Q8W	4	7
5-FU	500	1, 8, 15, 22, 29, 36	Q8W	4	7

sLV5FU2

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Leucovorin	400	1	Q2W	12	8
5-FU	400	1	Q2W	12	8
5-FU	1200	1-2	Q2W	12	8

* Continuous infusion for 24 hours

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
UFUR	300-350/day PO	1-28	Q4W	6	10

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
TS-1	50-75 PO	1-28	Q42D	4	11

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Chemotherapy

mFOLFOX6

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Oxaliplatin	85	1	Q2W	12	1-3
Leucovorin	400	1	Q2W	12	
5-FU	400	1	Q2W	12	
5-FU	1200	1-2	Q2W	12	

* Continuous infusion for 24 hours

sLV5FU2

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Leucovorin	400	1	Q2W	12	4, 13
5-FU	400	1	Q2W	12	
5-FU	1200	1-2	Q2W	12	

* Continuous infusion for 24 hours

Capecitabine

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Capecitabine	1250 PO BID	1-14	Q3W	8	5

CapeOx

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Oxaliplatin	130	1	Q3W	8	6, 7
Capecitabine	1000 PO BID	1-14	Q3W	8	

5-FU+LV

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Leucovorin	500	1, 8, 15, 22, 29, 36	Q8W	4	8
5-FU	500	1, 8, 15, 22, 29, 36	Q8W	4	

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
UFUR	300-350/day PO	1-28	Q4W	6	14

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
TS-1	40-60mg PO BID	1-28	Q42D	4	15

Chemotherapy + RT

XRT + continuous infusion 5-FU

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
5-FU	225	1-5 or 1-7	Q4W	During XRT	9

XRT + 5-FU/LV

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
5-FU	400	1-4	Q4W	During week 1, 5 of XRT	10
Leucovorin	20	1-4	Q4W		

XRT + Capecitabine

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Capecitabine	825 PO BID	1-5	QW	5	11, 12

XRT + mFOLFOX6

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Oxaliplatin	85	1			
Leucovorin	400	1			
5-FU	400	1			
5-FU	1200	1-2			

* Continuous infusion for 24 hours

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3. Maindrault-Goebel F, deGramont A, Louvet C, et al. Evaluation of oxaliplatin dose intensity in bimonthly leucovorin and 48-hour 5-fluorouracil continuous infusion regimens (FOLFOX) in pretreated metastatic colorectal cancer. *Annals of Oncology* 2000;11:1477-1483.
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6. Schmoll HJ, Cartwright T, Taernero J, et al. Phase III trial of capecitabine plus oxaliplatin as adjuvant therapy for stage III colon cancer: a planned safety analysis in 1,864 patients. *J Clin Oncol* 2007;25:102-109.
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First-line therapy

mFOLFOX6 or mFOLFOX7

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Oxaliplatin	85	1	Q2W	8-12	1, 2, 3, 28
Leucovorin	400	1	Q2W	8-12	
5-FU (optional)	400	1	Q2W	8-12	
5-FU	1200	1-2	Q2W	8-12	

* Continuous infusion for 24 hours

FOLFOX + Bevacizumab

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Bevacizumab	5 mg/kg	1	Q2W		4
Oxaliplatin	85	1	Q2W		
Leucovorin	400	1	Q2W		
5-FU (optional)	400	1	Q2W		
5-FU	1200	1-2	Q2W		

* Continuous infusion for 24 hours

FOLFOX + Panitumumab (KRAS/NRAS WT gene only)

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Panitumumab	6 mg/kg	1	Q2W		5
Oxaliplatin	85	1	Q2W		
Leucovorin	400	1	Q2W		
5-FU (optional)	400	1	Q2W		
5-FU	1200	1-2	Q2W		

* Continuous infusion for 24 hours

FOLFOX + Cetuximab (KRAS/NRAS WT gene only)

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Cetuximab	500 (400 → 250)	1	Q2W (QW)		6
Oxaliplatin	85	1	Q2W		
Leucovorin	400	1	Q2W		
5-FU (optional)	400	1	Q2W		
5-FU	1200	1-2	Q2W		

* Continuous infusion for 24 hours

CapeOx

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Oxaliplatin	130	1	Q3W	Max 16	7
Capecitabine	850-1000 PO BID	1-14	Q3W	Max 16	

CapeOx + Bevacizumab

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Bevacizumab	7.5 mg/kg	1	Q3W	Max 16	7
Oxaliplatin	130	1	Q3W	Max 16	
Capecitabine	850-1000 PO BID	1-14	Q3W	Max 16	

FOLFIRI

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Irinotecan	180	1	Q2W		8, 9
Leucovorin	400	1	Q2W		
5-FU (optional)	400	1	Q2W		
5-FU	1200	1-2	Q2W		

* Continuous infusion for 24 hours

FOLFIRI + Bevacizumab

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Bevacizumab	5 mg/kg	1	Q2W		10
Irinotecan	180	1	Q2W		
Leucovorin	400	1	Q2W		
5-FU (optional)	400	1	Q2W		
5-FU	1200	1-2	Q2W		

* Continuous infusion for 24 hours

FOLFIRI + Cetuximab (KRAS/NRAS WT gene only)

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Cetuximab	500 (400 → 250)	1	Q2W (QW)		11, 12
Irinotecan	180	1	Q2W		
Leucovorin	400	1	Q2W		
5-FU (optional)	400	1	Q2W		
5-FU	1200	1-2	Q2W		

* Continuous infusion for 24 hours

FOLFIRI + Panitumumab (KRAS/NRAS WT gene only)

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Panitumumab	6 mg/kg	1	Q2W		13
Irinotecan	180	1	Q2W		
Leucovorin	400	1	Q2W		
5-FU (optional)	400	1	Q2W		
5-FU	1200	1-2	Q2W		

* Continuous infusion for 24 hours

Capecitabine

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Capecitabine	825-1250 PO BID	1-14	Q3W		5

Capecitabine + Bevacizumab

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Bevacizumab	7.5 mg/kg	1	Q3W		16
Capecitabine	825-1250 PO BID	1-14	Q3W		

FOLFOXIRI ± Bevacizumab

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
± Bevacizumab	5 mg/kg	1	Q2W		21, 22
Oxaliplatin	85	1	Q2W		
Irinotecan	180	1	Q2W		
Leucovorin	400	1	Q2W		
5-FU	1600	1-2	Q2W		

* Continuous infusion for 24 hours

Cetuximab (KRAS/NRAS WT gene only)

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Cetuximab	500 (400 → 250)	1	Q2W (QW)		12, 25

Panitumumab (KRAS/NRAS WT gene only)

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Panitumumab	6 mg/kg	1	Q2W		26

Pembrolizumab (MSI-H)

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Pembrolizumab	2 mg/kg	1	Q3W		30

Nivolumab (MSI-H)

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Nivolumab	3 mg/kg	1	Q2W		31

Nivolumab (MSI-H)

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Nivolumab	240 mg	1	Q2W		31

Bolus or Infusional 5FU/Leucovorin

Roswell Park

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Leucovorin	500	1, 8, 15, 22, 29, 36	Q8W		17
5-FU	500	1, 8, 15, 22, 29, 36	Q8W		

Simplified biweekly infusional 5-FU/LV (sLV5FU2)

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Leucovorin	400	1	Q2W		8
5-FU	400	1	Q2W		
5-FU	1200	1-2	Q2W		

Weekly

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Leucovorin	20	1	QW		18
5-FU	500	1	QW		

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Leucovorin	500	1	QW		19
5-FU	2600	1	QW		

Second-line and other therapy

FOLFIRI + Ziv-aflibercept

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Ziv-aflibercept	4 mg/kg	1	Q2W		14
Irinotecan	180	1	Q2W		
Leucovorin	400	1	Q2W		
5-FU (optional)	400	1	Q2W		
5-FU	1200	1-2	Q2W		

* Continuous infusion for 24 hours

FOLFIRI + Ramucirumab

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Ramucirumab	8 mg/kg	1	Q2W		15
Irinotecan	180	1	Q2W		
Leucovorin	400	1	Q2W		
5-FU (optional)	400	1	Q2W		
5-FU	1200	1-2	Q2W		

* Continuous infusion for 24 hours

IROX

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Oxaliplatin	85	1	Q3W		20
Irinotecan	200	1	Q3W		

Irinotecan

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Irinotecan	125 (180) (300-350)	1, 8 (1)	Q3W (Q2W)(Q3W)		23, 24

Cetuximab (KRAS/NRAS WT gene only) + Irinotecan

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Cetuximab	500 (400 → 250)	1	Q2W (QW)		12, 25
Irinotecan	125 (180) (300-350)	1, 8 (1)	Q3W (Q2W)(Q3W)		

Regorafenib

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
Regorafenib	160 mg PO	1-21	Q4W		27

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
UFUR	200mg PO BID/TID	1-28	Q4W		32

藥品名	劑量 mg/m ²	給藥日	頻率	週期	參考文獻
TS-1	50-75mg PO BID	1-28	Q42D		33

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《直腸癌放射治療共識》

一、治療範圍

1. 直腸腫瘤 / 低位乙狀結腸腫瘤或腫瘤原發部位
2. 骨盆腔內淋巴轉移病灶
3. 骨盆腔高風險淋巴轉移範圍

二、治療劑量 / 次數

1. 總劑量：45~60 Gy
2. 分次劑量：1.8~2.0 Gy

三、治療方式：

使用強度調控放射治療技術，包含弧形及螺旋放射規畫，可考慮搭配影像導引治療，治療選擇可使用同步照射高與低危險部位的方式或先給予整個照射部位部份劑量照射後，再針對高危險部位加強劑量。

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