B. セカンドルック手術

標準的には行わない（III, B）.

コメント

進行期にかかわらずSLOの有用性は認められない[12) 14)].

再発例や難治進行例に対する二次的腫瘍縮小術の意義については議論がある[14) 15)].

Ⅳ 化学療法

A. 初回化学療法

1. BEP療法(ブレオマイシン+エトポシド+シスプラチン)が標準的治療である(II, B).
2. プラチナ製剤はシスプラチンを用いる(II, B).
3. 投与コース数に関しての確立されたコンセンサスはない.

一般的に，完全摘出例には腫瘍マーカーが陰性化していれば3コースで終了し，不完全摘出例にはマーカー陰性化後さらに1～2コースを追加することがある(IV, E).

BEP療法
- ブレオマイシン：30mg/body　静注，day2, 9, 16
- エトポシド：100mg/m²　静注，day1～5
- シスプラチン：20mg/m²，　静注(1時間投与)，day1～5

3週間隔で3コースまたはそれ以上

コメント

1. 未分化胚細胞腫Ia期と未熟奇形腫(grade1) I期では省略できる.
2. ブレオマイシンによる肺障害を考慮し，その投与量やコース数を適宜変更する必要がある.
3. 放射線療法は化学療法が施行できない未分化胚細胞腫症例に限る.

付　記：化学療法の変遷(表17)

胚細胞腫瘍に対する術後化学療法として，1970年初期にVAC療法(ビンクリスチン＋アクチノマイシンD＋シクロホスファミド)の有効性が示され[15)～20)]，その後精巣腫瘍に用いられているPVB療法(シスプラチン＋ビンブラスチン＋ブレオマイシン)が標準的治療法とされた[21)～24)]．さらに，無病生存率や末梢神経障害の比較よりビンブラスチンをエトポシドに置き換えたBEP療法が最も標準的なレジメンとなった[25)～28)]．本腫瘍における化学療法の進歩は，胚細胞腫瘍の発生が卵巣の約10倍と高頻度である精巣での治療成績によるところが大きい．精巣胚細胞腫瘍ではランダム化比較試験結果にてPVBよりBEPが[25)]，EPよりBEPの方が良好である[29)]．また，シスプラチン併用とカルボプラチン併用との比較試験では両群間の奏効率に差がないものの，シスプラチン併用群の無病生存率が優れていたことにより，胚細胞腫瘍での標準的プラチナ製剤は上皮性卵巣腫瘍の場合と異なりシスプラチンである[30)]．

表17　胚細胞腫瘍の化学療法の変遷

報告者	報告年	対象	症例数	レジメン	成績
Slayton[16]	1978	非未分化胚細胞腫瘍（進行期・再発）	16	VAC	奏効率50%
Gershenson[17]	1983	内胚葉洞腫瘍	22	VAC	奏効率73%
Slayton[18]	1985	胚細胞腫瘍（残存腫瘍あり）	22	VAC	再発率68%
Gershenson[19]	1985	非未分化胚細胞腫瘍	80	VAC	奏効率70% I期86%, II期57%, III期50%, IV期0%
Gershenson[20]	1986	未熟奇形腫	21	VAC	奏効率86%
Einhorn[21]	1977	播種性精巣癌	50	PVB	奏効率100%
Taylor[22]	1985	胚細胞腫瘍（混合型含む）	14	PVB	奏効率100%
Williams[23]	1989	非未分化胚細胞腫瘍（残存腫瘍あり）	35	PVB（+ VAC/EP）	奏効率74%
Kumar[24]	1993	胚細胞腫瘍（進行期・再発）	17	PVB	奏効率70.5%
Williams[25]	1987	播種性精巣胚細胞腫瘍	261	PVB vs. BEP	BEPで毒性少なく，無病生存率良好(61% vs. 77%)
Gershenson[26]	1990	胚細胞腫瘍	26	BEP	無病生存率96%
Williams[27]	1991	未分化胚細胞腫	20	PVB/BEP（+ VAC）	奏効率91%
Williams[28]	1994	胚細胞腫瘍	93	BEP	無病生存率98%
Wit[29]	1997	非精上皮性精巣胚細胞腫瘍	395	EP vs. BEP	奏効率87% vs. 95%

B. 再発例に対する化学療法

シスプラチンにイホスファミド，エトポシド，パクリタキセル，ビンブラスチンなどを併用した3剤併用療法，骨髄移植や末梢血幹細胞移植下での大量化学療法 high-dose chemotherapy などより選択することが望ましい（III，C）．

コメント

精巣原発が大多数を占める胚細胞腫瘍再発例での治療成績を参考にするとシスプラチンを含む初回治療後に再発した症例に対し，VeIP 療法または VIP 療法と腫瘍減量手術との組み合わせで，20～30%の長期無病生存率が得られている[31)32)]．さらに，骨髄移植や末梢血幹細胞移植下でのカルボプラチン，エトポシド，シクロホスファミドまたはイホスファミドを用いた大量化学療法 high-dose chemotherapy も施行されており，20～50%の長期無病生存率が得られている[33)～35)]．

初回化学療法終了後6週以降の再発例（感受性腫瘍）に対してはさらなる cisplatin-based chemotherapy として VeIP 療法が推奨される[8)]．化学療法開始6週以内の無効例または再発例（抵抗性腫瘍）に対しては high-dose chemotherapy が治療の選択肢の一つとされるものの，その奏効率は低い[8)]．近年，パクリタキセルを用いた first-line salvage または second-line salvage chemotherapy が施行され，TIP 療法の有効性が報告されている[36)]．また TIP + high-dose chemotherapy（カルボプラチン，エトポシド）も試みられている[37)]．

以上，化学療法の実際の投与法については，表18にまとめた．

表18　胚細胞腫瘍（再発例を含む）の化学療法

レジメン・薬剤	投与量	投与スケジュール
BEP療法		
ブレオマイシン	30mg/body	静注, day 2, 9, 16
エトポシド	100mg/m^2	静注, day 1～5
シスプラチン	20mg/m^2/生食500m*l*	点滴静注, day 1～5
		3週間隔
VAC療法		
14歳以上		
ビンクリスチン	1.5mg/m^2（最高2.0mg）	静注, weekly, 8～12weeks
アクチノマイシンD	300 μg/m^2	静注, day 1～5
シクロホスファミド	150mg/m^2	静注, day 1～5
		4週間隔
13歳以下		
ビンクリスチン	2.0mg/m^2	静注, weekly, 8～12weeks
アクチノマイシンD	400 μg/m^2	静注, day 1～5
		4週間隔
PVB療法		
シスプラチン	20mg/m^2/生食500m*l*	点滴静注, day 1～5
ビンブラスチン	0.15mg/kg	静注, day 1～2
ブレオマイシン	20mg/m^2	静注, day 2, 9, 16
		3週間隔
VIP療法		
エトポシド	75mg/m^2	点滴静注, day 1～5
イホスファミド	1.2g/m^2	静注, day 1～5
シスプラチン	20mg/m^2/生食500m*l*	点滴静注, day 1～5
		3週間隔
VeIP療法		
ビンブラスチン	0.11mg/kg	静注, day 1～2
イホスファミド	1.2g/m^2	静注, day 1～5
シスプラチン	20mg/m^2/生食500m*l*	点滴静注, day 1～5
		3週間隔
TIP療法		
パクリタキセル	175～250 mg/m^2	点滴静注, day 1
イホスファミド	1.2g/m^2	静注, day 2～6
シスプラチン	20mg/m^2/生食500m*l*	点滴静注, day 2～5
		3週間隔

注）欧米での投与量であることを留意して施行する.

C. 化学療法による後障害

1. 卵巣機能と妊孕性

3～4コースの初回治療による卵巣機能障害は少ない（III，B）.

コメント

多くの抗がん剤により卵巣皮質の線維化と卵胞数の減少および卵胞成熟障害をきたすことが組織学的に証明されている[38]．臨床的にもシクロホスファミドは卵巣毒性が強いことで知られているが，一般に治療開始時の患者の年齢，使用薬剤，蓄積投与量，投与期間が卵巣機能に影響を及ぼす因子として重要である．ただし，VAC療法やシスプラチンを含んだPVB療法，BEP療法での初回治療による卵巣機能障害は少ないと報告され，実際に治療後に妊娠し健常児を得た報告も少なくない[39)～45)]．

2. 二次発癌

エトポシド投与により急性白血病と骨髄異形成の発生率が増大する（III，B）.

コメント

卵巣胚細胞腫瘍での多数例を対象とした報告はないが，精巣胚細胞腫瘍では初回治療として3～4コースのBEP療法（エトポシド2,000mg/m^2）を受けた348例中2例がエトポシドに関連した白血病に罹患し，一方3コース（エトポシド1,500mg/m^2）の投与を受けた67例では発症はなかったと報告されている[46]．さらにBEP療法を受けた精巣胚細胞腫瘍212例中4例が急性白血病に，1例が骨髄異形成に罹患したとの報告もある[47]．PVB療法を受けた127例ではこれらの合併症はみられておらず，エトポシド2,000 mg/m^{2}未満の投与例130例では発症がないことから，エトポシド2,000 mg/m^{2}が二次発癌発症の閾値と考えられている[47]．

付 記

(1) 上皮性卵巣腫瘍においても同様に化学療法後の二次発癌の危険性が報告されている[48]．

(2) 生殖補助技術の進歩により今後，悪性腫瘍を治療する前に患者の配偶子（精子・卵子）を凍結保存し，治療後に妊娠を試みる事例も増加することが考えられる．参考までに卵子・卵巣機能に悪影響を与える抗がん剤のリスク別分類を掲載した（表19）．

表19　卵子・卵巣機能に悪影響を与える抗がん剤

リスク発生頻度	抗がん剤
common	シクロホスファミド
possible	シスプラチン
	カルボプラチン
	ビンブラスチン
	エトポシド
	アクチノマイシン D
rare	ドキソルビシン
	ビンクリスチン
	メソトレキセート
	5-フルオロウラシル
	ブレオマイシン
no data	パクリタキセル
	ドセタキセル
	イホスファミド
	ジェムシタビン

The Chemotherapy Source Book 第3版（Michael C. Perry 編
Lippincott Williams & Wilkins 社 平成13年発行）より引用，一部改変

第4章■資料集

Ⅰ 抗がん剤の副作用一覧

（医薬品インタビューフォームより抜粋）

商品名 （一般名）	症例数	副作用 発現率 (%)	血液			消化器			
			白血球 減少	Hb 減少	血小板 減少	悪心・ 嘔吐	食欲 不振	下痢	腹痛
ランダ ブリプラチン （シスプラチン）	市販後調査 7,448例	83.9%	35.6%	27.2%	16.3%	72.7%	59.9%	5.7%	0.5%
パラプラチン （カルボプラチン）	市販後調査 5,598例	85.7%	57.2%	40.4%	41.9%	50.6%	46.0%	3.3%	2.3%
タキソール （パクリタキセル）	第2相臨床試験 477例	-	91.8%	76.1%	11.1%	36.9%	5.2%	14.0%	-
タキソテール （ドセタキセル）	第2相臨床試験 865例	-	97.2%	53.4%	12.4%	47.9%	58.7%	22.5%	3.4%
トポテシン カンプト （塩酸イリノテカン）	市販後調査 15,385例	-	73.1%	57.3%	28.0%	52.5%	48.1%	43.0%	12.2%
エンドキサン （シクロホスファミド）	103論文より集計 5,021例	-	37.9%	2.3%	6.1%	20.7%	3.8%	0.5%	0.1%
アドリアシン （塩酸ドキソルビシン）	市販後調査 768例	91.8%	49.7%	17.6%	16.8%	58.2%	54.7%	6.4%	0.7%
ピノルビン テラルビシン （塩酸ピラルビシン）	承認時，市販後調査 3,591例	71.2%	50.4%	-	14.5%	31.9%	36.4%	2.5%	-
ファルモルビシン （塩酸エピルビシン）	承認時，市販後調査 4,818例	56.7%	33.6%	20.3%	13.3%	36.7%	24.5%	1.9%	0.5%
ベプシド ラステット （エトポシド）	市販後調査 4,025例	88.1%	68.1%	50.4%	47.7%	40.1%	49.6%	5.7%	2.5%
ブレオ （塩酸ブレオマイシン）	承認時，市販後調査 1,613例	-	0.2%	0.2%	0%	14.6%	28.7%	1.2%	-

肝臓	腎臓	呼吸器	神経系	皮膚付属器	その他の副作用および注意事項
GOT/GPT上昇 肝機能障害	BUN/Cr上昇 Ccr低下	間質性肺炎	末梢神経障害	脱毛	
9.5%/10.3% -	13.0%/6.1% 9.8%	0.1%	1.5%	26.0%	聴覚障害(1.4%)，視覚障害(うっ血乳頭，球後視神経炎，皮質盲；0.1%未満)
9.1%/10.2% -	5.2%/2.6% 3.7%	0.1%未満	0.46%	20.2%	アナフィラキシー
35.6%/40.7% -	9.9%/5.3% -	1.3%	65.1%	83.6%	発熱(42.3%)，関節痛(40.3%)，筋肉痛(36.3%)，過敏症・発赤(13.8%)，心電図異常(2.2%)
20.3%/19.9% -	4.6%/1.6% -	0.1%	9.4%	76.8%	発熱(45.9%)，浮腫(8.0%)，アレルギー(6.8%)，心タンポナーデ，体液貯留，イレウス，急性膵炎(頻度不明)
- 1.2%	- -	0.9%	-	-	腸管麻痺(1.6%)，イレウス(0.4%) 高度な骨髄機能抑制の持続による重症感染症および高度な下痢の持続による脱水，電解質異常，循環不全に注意
- 1.0%	- -	-	-	24.3%	出血性膀胱炎(1.2%)，排尿障害(2.3%)，血尿(2.0%) 卵巣毒性，抗利尿ホルモン不適合分泌症候群(SIADH)
- 7.3%	- 0.5%	-	-	73.2%	心筋障害，心電図異常(9.8%) 総投与量500mg/m^{2}以上で重篤な心筋障害に注意
- 5.8%	- 2.0%	0.1%未満	-	21.5%	心筋障害(0.1～5%未満)，心電図異常(4.3%) 総投与量950mg/m^{2}以上でうっ血性心不全に注意
- 6.8%	- 1.2%	-	0.02%	24.2%	心筋障害(0.12%)，心電図異常(0.48%) 総投与量950mg/m^{2}以上でうっ血性心不全に注意
10.5%/12.2% -	5.6%/2.8% 0.22%	0.02%	0.89%	44.4%	二次発癌(急性白血病，骨髄異形成)
- 0.2%	- -	10.2%	-	29.5%	皮膚の硬化，色素沈着(40.6%)，発熱(39.8%)，口内炎(13.3%) 60歳以上の高齢者では間質性肺炎・肺線維症に特に注意

(－は記載なし)

Ⅱ 略語一覧

AGO	Arbeitsgemeinschaft Gynaekologische Onkologie
AGO-GINECO OVAR7	Arbeitsgemeinschaft Gynakologische Onkologie - Group d'Investigateurs Nationaux pour l'Etude des Cancers Ovariens
AUC	area under the concentration - time curve
CAP	cyclophosphamide, doxorubicin (adriamycin) and cisplatin
cCR	clinical complete response
CJ	cyclophosphamide and JM-8 (carboplatin)
CP	cyclophosphamide and cisplatin
CR	complete response
CSF	colony stimulating factor
CT	computed tomography
DFI	disease-free interval
DJ	docetaxel and JM-8 (carboplatin)
ECOG	Eastern Cooperative Oncology Group
EORTC	European Organization Research of Treatment of Cancer
FIGO	International Federation of Gynecology and Obstetrics
FN	febrile neutropenia
Ga シンチグラム	gallium シンチグラム
G-CSF	granulocyte-colony stimulating factor
GFR	glomerular filtration rate
GINECO	Group d'Investigateurs Nationaux pour l'Etude des Cancers Ovariens
GOG	Gynecologic Oncology Group
GONO	Gruppo Oncologico Nord-Ouest
HSR	hypersensitive reaction
ICON	International Collaborative Ovarian Neoplasm Study
IDS	interval debulking surgery
ip	intraperitoneal
IRB	Institutional Review Board
iv	intravenous
IVP	intravenous pyelography
JP	JM-8 (carboplatin) and cisplatin
M-CSF	macrophage-colony stimulating factor
MRI	magnetic resonance imaging
MS	median survival
MST	median survival time
NAC	neo-adjuvant chemotherapy
NCCN	National Comprehensive Cancer Network
NIH	National Institutes of Health
NS	not significant
OS	overall survival

PALA	para-aortic lymphadenectomy
PBSCT	peripheral blood stem cell transplantation
pCR	pathological complete response
PFI	progression-free interval
PFS	progression-free survival
PLA	pelvic lymphadenectomy
PR	partial response
PS	performance status
PtFI	platinum-free interval
QOL	quality of life
RR	response rate
SCOTROC	Scottish Randomized Trial in Ovarian Cancer
SDS	secondary debulking surgery
SEER	Surveillance, Epidemiology, and End Results (National Cancer Institute)
SLO	second look operation
SLO/SDS	second look operation/secondary debulking surgery
SWOG	Southwest Oncology Group
TJ	taxol (paclitaxel) and JM-8 (carbopaltin)
TP	taxol (paclitaxel) and cisplatin
WHO	World Health Organization
51Cr EDTA	51Cr ethylenediaminetetraacetic acid
95%CI	95% confidential interval

Ⅲ 引用文献

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第2章 上皮性卵巣腫瘍

Ⅰ．概 論

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Ⅳ. 化学療法

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