

CLIA ID # 99D1030993

CAP ID # 7186701

Patient : Patient X
 Date of birth : 01/19/1959
 Specimen ID : HP11-2274
 Specimen type : Ascites

Collected : 05/16/2011
 Received : 05/17/2011
 Physician : Dr. X
 Institution : Walter Reed Medical Center

Clinical

52-year-old female with a diagnosis of ovarian cancer high grade since 12/2010, first presentation, no prior chemotherapy.

Recommendation

Based on the results of the MiCK assay there are several very good choices for the therapeutic regimen for this patient. The single drugs melphalan, cisplatin, topotecan, and doxorubicin each gave results that were in the highly effective range (>5.0KUs). Of note, Melphalan was effective only at the highest tested concentration while the other effective drugs also induced apoptosis of the tumor cells at lower concentrations. The combinations of carboplatin with gemcitabine and cisplatin with gemcitabine also were highly effective but it should be noted that the gemcitabine was only modestly effective(1.3KU) and added minimally to the combinations. The addition of gemcitabine added little to the cisplatin or carboplatin.

MiCK Assay Results

Drug tested	Max. Resp. (KU)	Resp. level	Drug tested	Max. Resp. (KU)	Resp. level
Melphalan	7.8	Sensitive	Mitoxantrone	2.1	Low to moderate
Cisplatin	5.8		Etoposide	2.1	
Carboplatin+Gemcitabine	5.6		Carboplatin+Taxotere	1.9	Low
Topotecan	5.1		Taxotere	1.9	
Gemcitabine+Cisplatin	5.1		Sorafenib	1.6	
Doxorubicin	5.0		Velcade	1.3	
Carboplatin	4.9	Gleevec(imatinib)	1.3		
Carboplatin+Taxol	4.2	Sunitinib	1.3		
4HC(cytoxan)+Doxorubicin	4.1	Moderate	Gemcitabine	1.3	
4HC(cytoxan)	3.8		Xeloda	1.2	
Oxaliplatin	3.4		Irinotecan	1.2	
Cisplatin+Taxotere	3.3		Hexamethylmelamine	1.1	
Vinorelbine	2.9	Low to moderate	Alimta	1.1	
4HI(ifosfamide)	2.9		Caelyx(Doxil)	1.0	
Taxol	2.8		Abraxane	0.9	Nonsensitive
Vinblastine	2.4		Tarceva	0.7	
Vincristine	2.2		Temozolomide	0.6	

Interpretation

Known ovarian carcinoma, ascites:

DiaTech Oncology

Patient Specific Cancer Testing

SAMPLE REPORT

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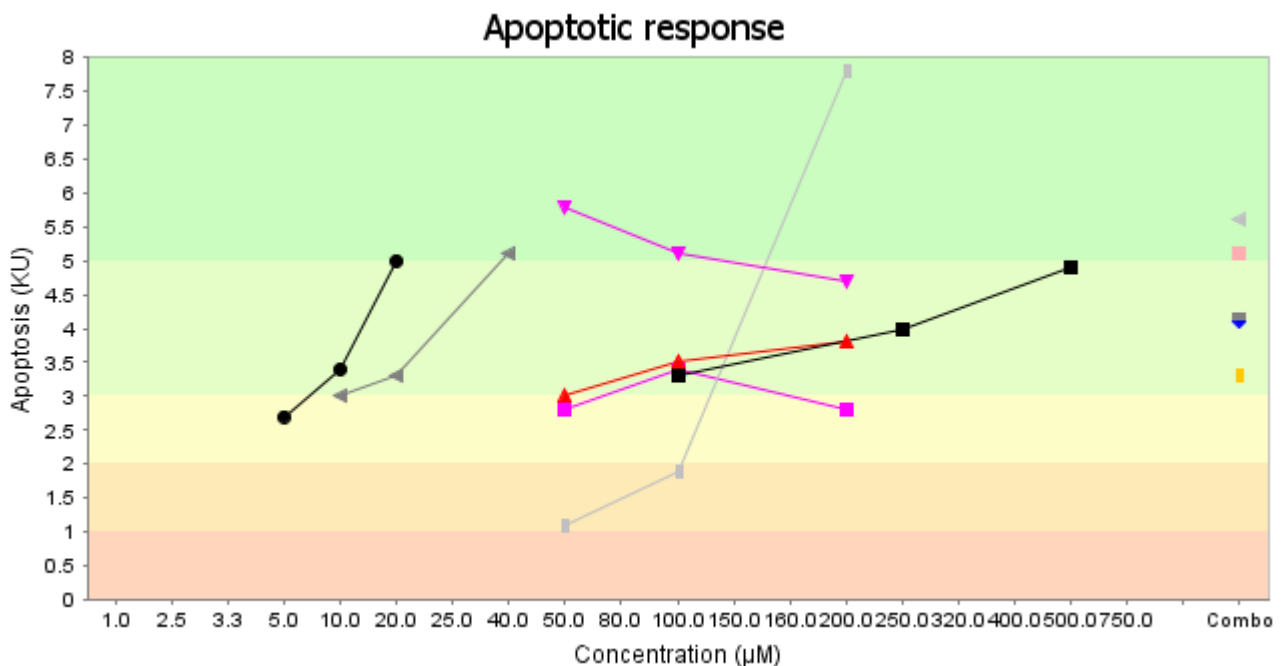
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1. There is a population of adenocarcinoma cells present in the cell suspension.
2. Multiple single drugs were highly effective against the tumor cells including melphalan, cisplatin, topotecan, and doxorubicin. Carboplatin was in the high moderate range of effectiveness.
3. The responses to the additional drugs/drug combinations that were tested are listed in the Table below.
4. The Graph indicates the results of the drugs/drug combinations that yielded kinetic unit (KU) values greater than 3.0, our moderate range of effectiveness.



Legend: ND: data not displayed NS: not sensitive

—	Melphalan	7.8	ND	Vinorelbine	2.9	ND	Sunitinib	1.3
—	Cisplatin	5.8	ND	4HI(ifosfamide)	2.9	ND	Gemcitabine	1.3
—	Carboplatin+Gemcitabine	5.6	ND	Taxol	2.8	ND	Xeloda	1.2
—	Topotecan	5.1	ND	Vinblastine	2.4	ND	Irinotecan	1.2
—	Gemcitabine+Cisplatin	5.1	ND	Vincristine	2.2	ND	Hexamethylmelamine	1.1
—	Doxorubicin	5.0	ND	Mitoxantrone	2.1	ND	Alimta	1.1
—	Carboplatin	4.9	ND	Etoposide	2.1	ND	Caelyx(Doxil)	1.0
—	Carboplatin+Taxol	4.2	ND	Carboplatin+Taxotere	1.9	ND	Abraxane	0.9
—	4HC(cytosine)+Doxorubicin	4.1	ND	Taxotere	1.9	ND	Tarceva	0.7
—	4HC(cytosine)	3.8	ND	Sorafenib	1.6	ND	Temozolomide	0.6
—	Oxaliplatin	3.4	ND	Velcade	1.3			
—	Cisplatin+Taxotere	3.3	ND	Gleevec(imatinib)	1.3			

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Comments

Viable malignant cells collected from the fluid were tested against the indicated drugs and drug combinations in the Table. Three concentrations of each were tested. The active metabolites 4HC and 4HI were used for cytoxan and ifosfamide.

The MiCK assay identifies chemotherapy drugs that are most effective in killing tumor cells by apoptosis and quantitates the amount of apoptosis in our units designated kinetic units (KUs). In this study melphalan yielded the greatest level of effectiveness (7.8KUs), however cisplatin, topotecan, and doxorubicin were all also highly effective. In relationship to the level of toxicity added for the added apoptosis, gemcitabine contributed little. Response greater than 5.0KUs are considered to be highly effective.

All tested chemotherapy agents induced apoptosis in an appropriate cell control.

Microscopic/Immunophenotypic studies

The H&E stained cytospin preparation contains many groups and individual cells of obvious adenocarcinoma. The cells are very large and cohesive. They contain 1-2 nuclei which are also large and hyperchromatic. Multiple nucleoli are present in virtually all nuclei. The cells are strongly positive with pancytokeratin.

The report was faxed to Dr. X on 05/20/2011.

Attending Pathologist

Medical Director

DiaTech Oncology, LLC

Electronically signed on 05-20-2011

The pathologist's signature on this report indicates that the case was personally reviewed and the findings confirmed by the attending pathologist. This test was performed at DiaTech Clinical Pathology Laboratory. This laboratory is certified under CAP and CLIA-88 and is qualified to perform high complexity clinical testings. The MiCK assay measures drug induced apoptosis and its performance characteristics were determined at Vanderbilt University and at DiaTech Oncology. Clinical use of the MiCK assay is based on a statistically significant increase in CR rate and overall survival of AML patients whose treatment protocol included a drug to which the patient's tumor cells were sensitive in the assay. When used with solid tumors, the MiCK assay is expected to identify drugs most effective in killing patient's tumor cells by apoptosis. This test has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such approval was not required.

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