

CLIA ID # 99D1030993

CAP ID # 7186701

Patient : Patient X
 Date of birth : 04/23/1953
 Specimen ID : HP11-2269
 Specimen type : Splenectomy

Collected : 05/13/2011
 Received : 05/14/2011
 Physician : Dr. X
 Institution : Wilshire Oncology

Clinical

58-year-old female with a diagnosis of stage 3 ovarian cancer since 01/2006. Previously treated in 2006 with Taxol, Carboplatin. Resulted in CR.

Recommendation

Based on the results of the MiCK assay either topotecan or doxorubicin would be expected to give the best clinical results with the patient. The combination of doxorubicin with Cytoxan should be avoided because the combination gave lower results than doxorubicin alone.

MiCK Assay Results

Drug tested	Max. Resp. (KU)	Resp. level	Drug tested	Max. Resp. (KU)	Resp. level
Topotecan	5.1	Sensitive	Carboplatin+Gemcitabine	1.3	Low
Doxorubicin	5.1		Irinotecan	1.0	
4HC(cytoxan)+Doxorubicin	3.8	Moderate	Caelyx(Doxil)	1.0	
4HC(cytoxan)	3.8		Carboplatin+Taxotere	1.0	
Cisplatin	3.8		Carboplatin	1.0	
Melphalan	3.5		Nonsensitive	Alimta	0.6
Oxaliplatin	3.2			Hexamethylmelamine	0.6
4HI(ifosfamide)	2.9	Vincristine		0.6	
Cisplatin+Gemcitabine	2.9	Etoposide		0.6	
Cisplatin+Taxotere	2.9	Gemcitabine		0.6	
Gemcitabine+Cisplatin	2.9	5-Fluorouracil		0.0	
Vinorelbine	2.2	Taxotere		0.0	
Carboplatin+Taxol	2.2	Taxol		0.0	

Interpretation

Primary ovarian carcinoma :

1. A population of cytologically malignant cells is present.
2. In the MiCK assay the malignant cells were equally sensitive to topotecan and doxorubicin as single drugs. Each gave 5.1 KUs of apoptosis.
3. The responses to the additional drugs/drug combinations which were tested were lower and are shown in the Graph and Table below.

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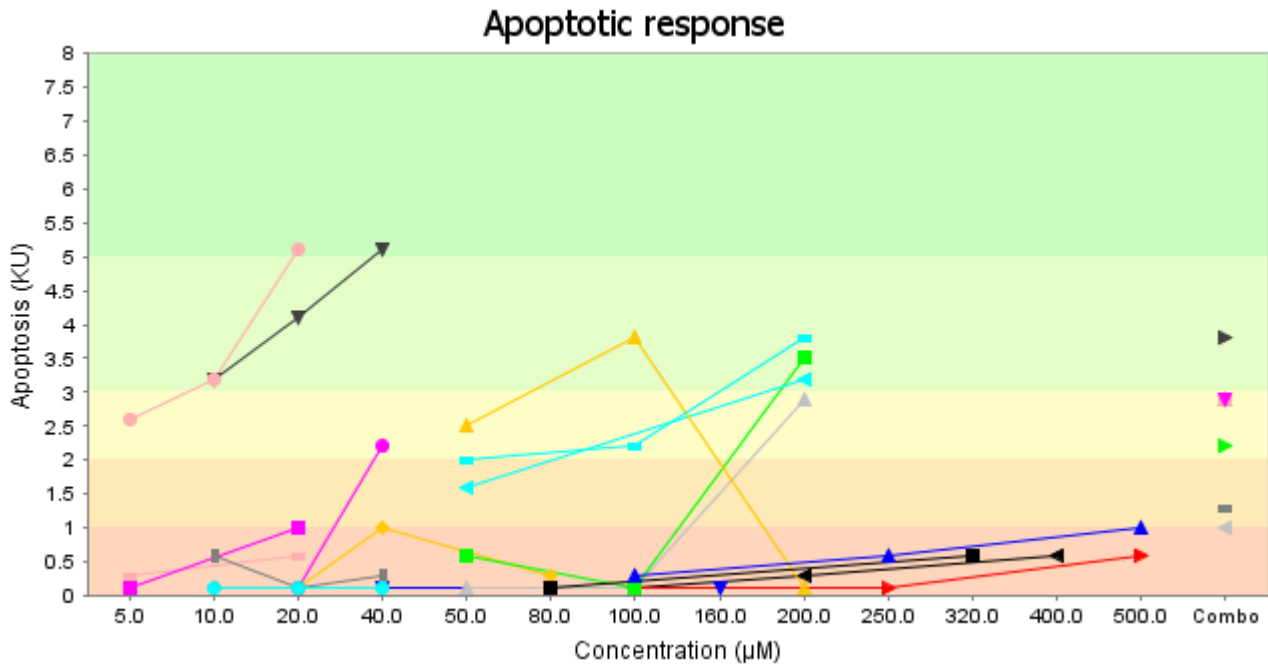
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Legend:		ND: data not displayed	NS: not sensitive
▼ Topotecan	5.1	◻ Cisplatin+Taxotere	2.9
◻ Doxorubicin	5.1	▼ Gemcitabine+Cisplatin	2.9
▲ 4HC(cytoxan)+Doxorubicin	3.8	◻ Vinorelbine	2.2
▲ 4HC(cytoxan)	3.8	▲ Carboplatin+Taxol	2.2
◻ Cisplatin	3.8	◻ Carboplatin+Gemcitabine	1.3
◻ Melphalan	3.5	◻ Irinotecan	1.0
◻ Oxaliplatin	3.2	◻ Caelyx(Doxil)	1.0
◻ 4HI(ifosfamide)	2.9	◻ Carboplatin+Taxotere	1.0
▲ Cisplatin+Gemcitabine	2.9	▲ Carboplatin	1.0
		◻ Alimta	0.6
		▲ Hexamethylmelamine	0.6
		◻ Vincristine	0.6
		◻ Etoposide	0.6
		◻ Gemcitabine	0.6
		▼ 5-Fluorouracil	0.0
		◻ Taxotere	0.0
		◻ Taxol	0.0

Comments

Viable malignant cells were tested for their sensitivity to multiple single drugs and drug combinations at three concentrations of each. Of note, the alkylating agents cyclophosphamide and ifosfamide require hepatic metabolic transformation to their active metabolite, 4HC and 4HI respectively and therefore cannot be tested directly in vitro. For the MiCK assay their active metabolites, 4HC and 4HI respectively were used. The MiCK assay identifies chemotherapy drugs that are effective in inducing apoptosis in a patient's tumor. The MiCK assay quantitates apoptosis and reports the level of apoptosis in units of measure referred to as kinetic units (KUs).

All tested drugs/drug combinations induced apoptosis in appropriate cell lines.

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Microscopic/Immunophenotypic studies

The final H&E stained cytospin preparation contains a near pure population of cytologically malignant cells with prominent anisocytosis. There is generally abundant cytoplasm with an increase N/C ratio. Nuclei are rounded and hyperchromatic with an irregular chromatin distribution. Occasional nucleoli are present.

Attending pathologist

Medical Director

DiaTech Oncology, LLC

Electronically signed on 11-30-2011

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.