



# SAFETY OF NAB-PACLITAXEL PLUS GEMCITABINE IN PATIENTS WITH METASTATIC PANCREATIC CANCER

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## BACKGROUND

PANCREATIC CANCER REMAINS A HIGHLY FATAL AND DIFFICULT TO-TREAT DISEASE.

NAB-PACLITAXEL (NAB-P), AN ALBUMIN-BOUND FORMULATION OF PACLITAXEL, APPEARS TO DECREASE LEVELS OF CYTIDINE DEAMINASE, WHICH IS THE PRIMARY GEMCITABINE CATABOLIC ENZYME, THIS LIKELY INCREASES SENSITIVITY TO GEMCITABINE (GEM) WHEN THESE AGENTS ARE COMBINED.

## PURPOSE

- ✓ TO EVALUATE THE SAFETY OF GEM PLUS NAB-P USED OFF LABEL IN PATIENTS WITH METASTATIC PANCREATIC DUCTAL ADENOCARCINOMA (PDA).
- ✓ TO COMPARE THE INCIDENCE OF ADVERSE EVENTS (AES) WITH CLINICAL TRIAL RESULTS.

## MATERIALS AND METHODS

- ✓ RETROSPECTIVE OBSERVATIONAL STUDY (JANUARY 2011-OCTOBER 2012)

### INCLUSION CRITERIA

ALL PATIENTS WITH PDA WHO RECEIVED GEM 1000 MG/M<sup>2</sup> FOLLOWED BY NAB-P AT 100 MG/M<sup>2</sup> WEEKLY FOR 3 WEEKS ON AN EVERY-4-WEEK CYCLE.

- ✓ THE INFORMATION WAS EXTRACTED FROM PATIENTS MEDICAL RECORDS AND FROM PHARMACY SERVICE RECORDS.

## VARIABLES

- ✓ DEMOGRAPHICS (sex-age)
- ✓ PREVIOUS TREATMENT
- ✓ DOSAGE REDUCTION AND TOXICITY
- ✓ AES WERE GRADED ACCORDING TO NCI-CTCAEV4.

## RESULTS

Median age (range)	63 years (41-80)	<b>SITE OF METASTASIS DISEASE</b>		<b>MOST COMMON TREATMENT-RELATED ADVERSE EVENTS</b>		
Male sex	61%	Liver	33%			
Median duration of treatment (range)	3,5 cycles (1-12)	Bone	33%			
		Abdomen/peritoneal	28%			
		Lung	17%			
		Liver only	11%			
<b>GRADE OF ADVERSE EVENTS</b>		<b>CAUSES OF DOSAGE REDUCTION</b>				
NO TOXICITY WITH GRADE 4						
TEN PATIENTS (56%) REQUIRED DOSAGE REDUCTION. THE CAUSES WERE THROMBOCYTOPENIA(50%), FATIGUE(30%), NEUTROPENIA(10%) AND PANCYTOPENIA(10%)						
					Our study	clinical trial
				fatigue	94%	94%
				anemia	66%	95%
				thrombocytopenia	56%	65%
				nausea	56%	45%
				diarrhea	50%	25%
				neutropenia	45%	85%
				vomiting	39%	15%
				leukopenia	33%	90%

## CONCLUSIONS

ALL ADVERSE EVENTS OBSERVED WERE REPORTED IN CLINICAL TRIAL. THESE PATIENTS REQUIRE CLOSE MONITORING DURING TREATMENT.

