

METASTATIC PANCREATIC CANCER TREATMENT WITH NAB-PACLITAXEL: EFFECTIVENESS AND SAFETY.

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BACKGROUND:

In a phase 1, 2, 3 clinical trial of nab-paclitaxel, substantial clinical activity was noted in patients with advanced pancreatic cancer.
We conducted an observational study to assess the effectiveness and safety of this therapy in real clinical practice.

PURPOSE:

- To analyze the effectiveness and safety of the metastatic pancreatic cancer treated with Nab-paclitaxel.
- To compare our results in Overall Survival (OS) with the current evidence published in high impact journals.

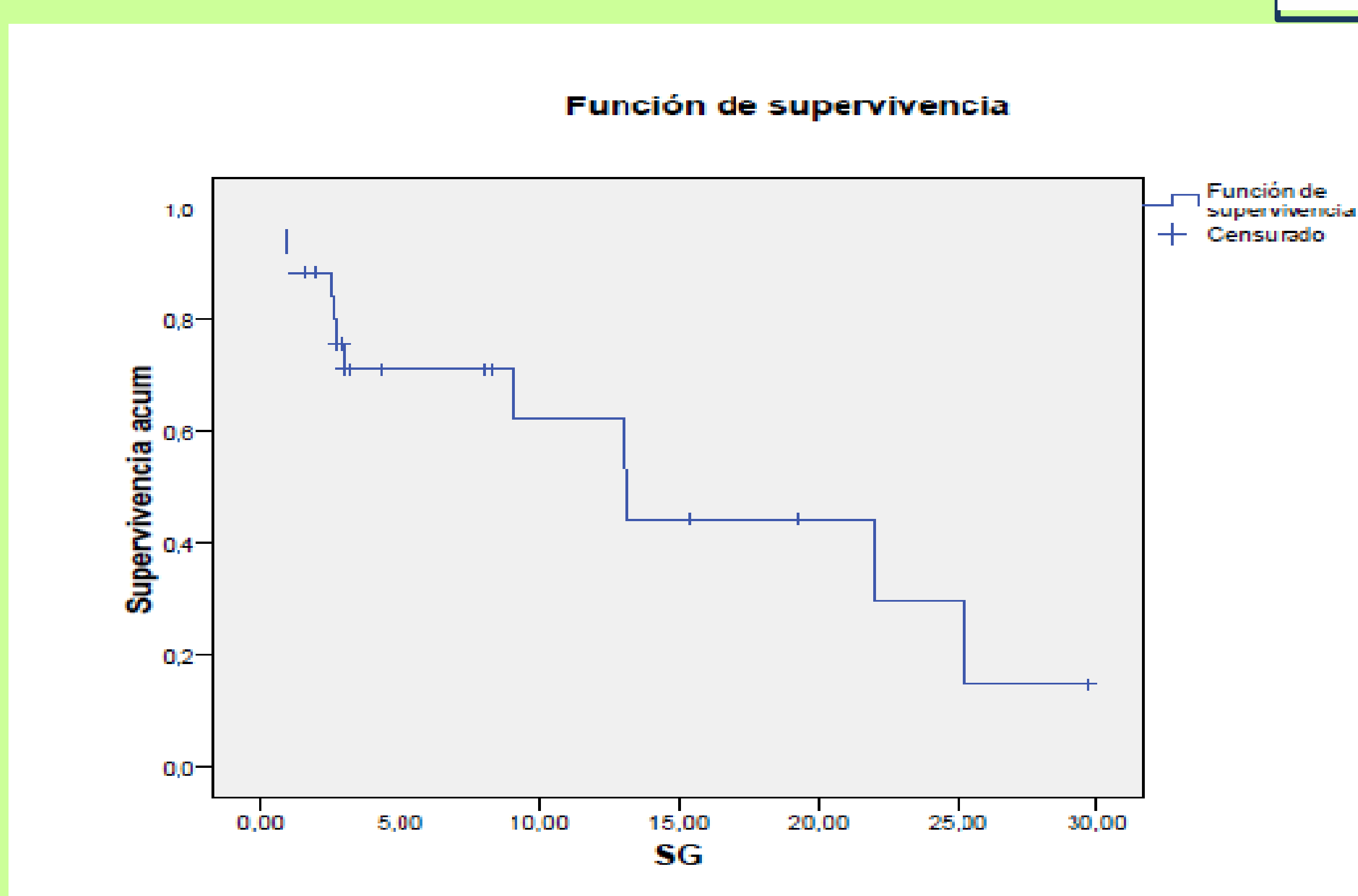
MATERIAL AND METHODS:

- An ambipective, multicentric and observational study was carried out in a third level hospital
- Inclusion criteria: patients diagnosed with metastatic pancreatic cancer treated with Nab-paclitaxel plus Gemcitabine since the use of this drug was included in the hospital formulary.
- Variables: age, sex, weight (kg), size (cm), body surface (m²), pancreatic tumor location, site of metastatic disease, number of metastatic disease, ECOG at baseline and after the CT examination, level of carbohydrate antigen 19,9 (CA 19,9), level of GPT, GOT, bilirubin and seric hemoglobine, neutrophils counts and adverse events grade 3 or higher.
- The principal effectiveness end-point was OS
- OS was analyzed with Kaplan– Meier method with the SPSS software.
- Data were obtained by pharmacy program (ATHOS®) and clinical charts.

RESULTS:

All demographic characteristics are detailed in the following table.

	N	Rango	Mínimo	Máximo	Media		Desv. típ.	Varianza
	Estadístico	Estadístico	Estadístico	Estadístico	Estadístico	Error típico	Estadístico	Estadístico
edad	28	28	48	76	62,18	1,623	8,590	73,782
Peso	27	46	38	84	64,96	2,325	12,083	146,004
Talla	25	35	144	179	163,00	1,647	8,236	67,833
SC	27	,70	1,30	2,00	1,6874	,03393	,17632	,031
Niveles de CCA19-9(0-37U/mL)	26	130102	1	130103	11250,41	5374,654	27405,464	7,5E+008
Neutrofilos (>1,5*10 ⁹ /l)	26	10,7	2,4	13,2	5,743	,5430	2,7690	7,667
Hemoglobina (>9g/dl)	27	48	101	149	122,19	2,623	13,630	185,772
GOT(0-37U/L)	24	84,00	10,00	94,00	32,5958	4,30356	21,08303	444,494
GPT(10-40 UI/L)	26	78	9	87	31,91	3,908	19,925	397,006
Bilirrubina(<1,2 mg/dl)	26	1,78	,12	1,90	,7142	,09344	,47646	,227



The mean of OS was 13,18 (IC 95% :7,1-19,3) months.

- Treatment-related adverse events of grade 3 or higher that were reported more often were: fatigue (2.4%), diarrhea (2.4%), sickness (2.4%) and alopecia (11%). 4.8% of patients have more than one adverse event.

CONCLUSION:

- Despite the poor prognosis in this disease, the results of OS in clinical practice are higher than those described in randomized clinical trials. Nab-paclitaxel was in general well tolerated.