

# Gemcitabine plus *nab*-Paclitaxel in metastatic or locally advanced inoperable pancreatic cancer – a single center experience

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Pancreatic cancer  
P-179

## Objectives

Metastatic or inoperable pancreatic cancer has a dismal prognosis with a median survival time of less than a year. FOLFIRINOX (5-FU, Calciumfolinate, Irinotecan, Oxaliplatin) has improved the outcome as first-line therapy. The choice of second-line treatment for patients who have progressed on FOLFIRINOX and the first-line treatment for unfit patients is still unclear. The use of *nab*-Paclitaxel in combination with Gemcitabine is an efficient and safe option in this setting. We present the outcome and safety with the use of *nab*-Paclitaxel and Gemcitabine mainly in second-line treatment at our center.

## Methods

Thirty-seven patients (median age: 70 years, range (46-92), 60% male) with metastatic (65%) or locally advanced inoperable pancreatic cancer (35%) were treated with *nab*-Paclitaxel and Gemcitabine in at least second-line (73%) or first-line (27%) from April 2012 to June 2015. Two-thirds of patients presented with a good performance status (ECOG  $\leq$  1). 22% received local radiation therapy. The application of Gemcitabine (1000 mg/m<sup>2</sup>) and *nab*-Paclitaxel (125 mg/m<sup>2</sup>) was modified to a 14 day schedule in two-thirds of patients due to the high incidence of grade 2 or 3 hematologic toxicities under the standard day 1,8,15 q28 schedule.

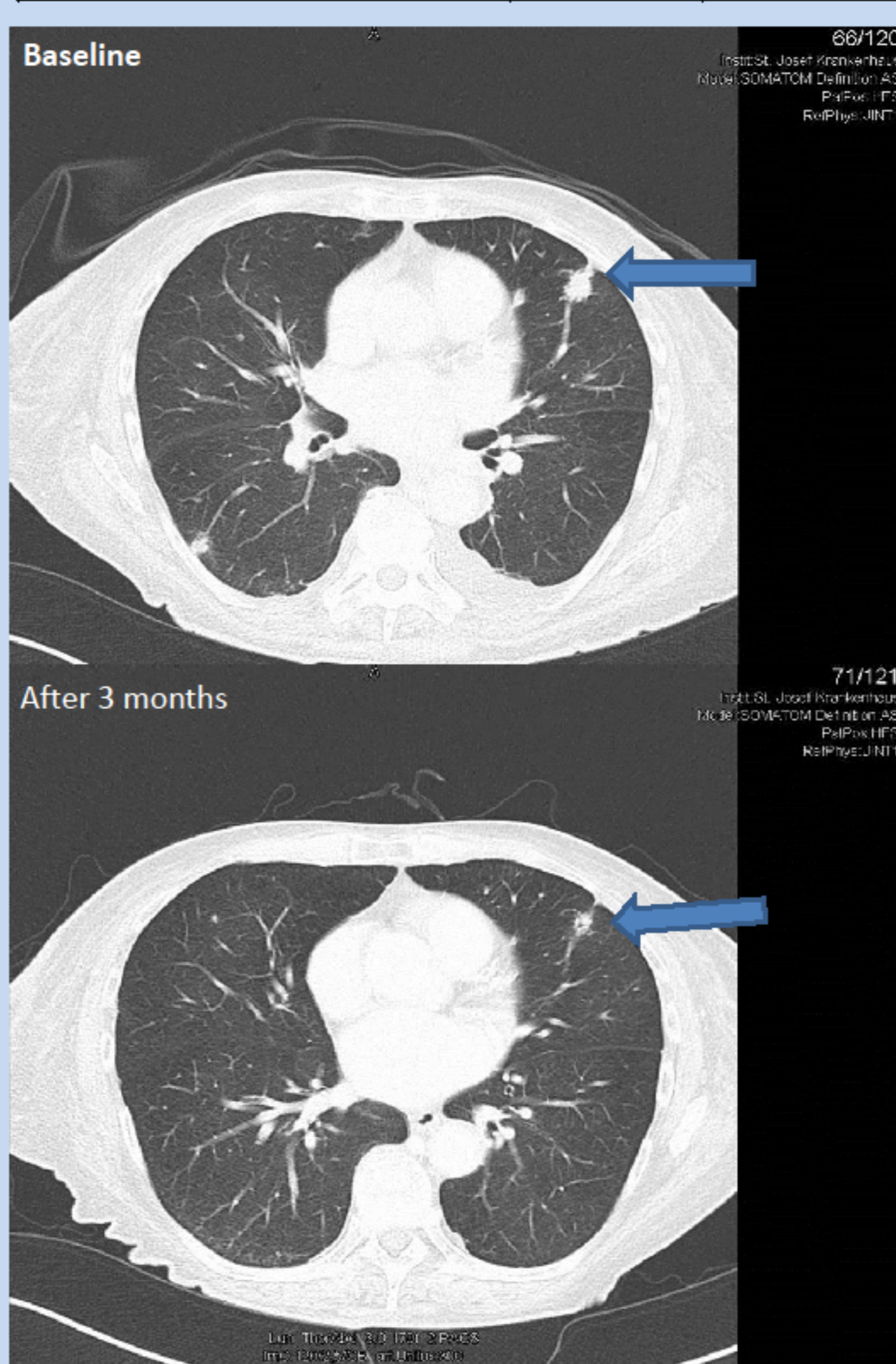
## Results

- The combination of *nab*-Paclitaxel and Gemcitabine is effective in patients with metastatic or locally advanced inoperable pancreatic cancer with manageable side effects especially when administered every two weeks.
- Adverse events were observed as follows: neutropenia (all grades: 38%, grade 3: 10.8%), thrombopenia (all grades: 40.5%, grade 3: 13.5%), alopecia (76%), nausea (all grades: 32.4%, grade 3: 5.4%), polyneuropathy (all grades: 27%, grade 3: 5.4%) and infection (7%).
- The **median progression-free survival** and **overall survival time** for patients treated with *nab*-Paclitaxel and Gemcitabine was **3.2 months** (95% CI: 0.8 – 5.7) and **8.3 months** (7-9.6 months), respectively.
- More than half of the patients (55%) received one or more **treatment lines after *nab*-Paclitaxel/Gemcitabine**.
- The **overall survival time from the start of the first chemotherapy for metastatic or locally advanced disease** was **30.2 months** (95% CI: 16-44.5).

## Tables and Graphs

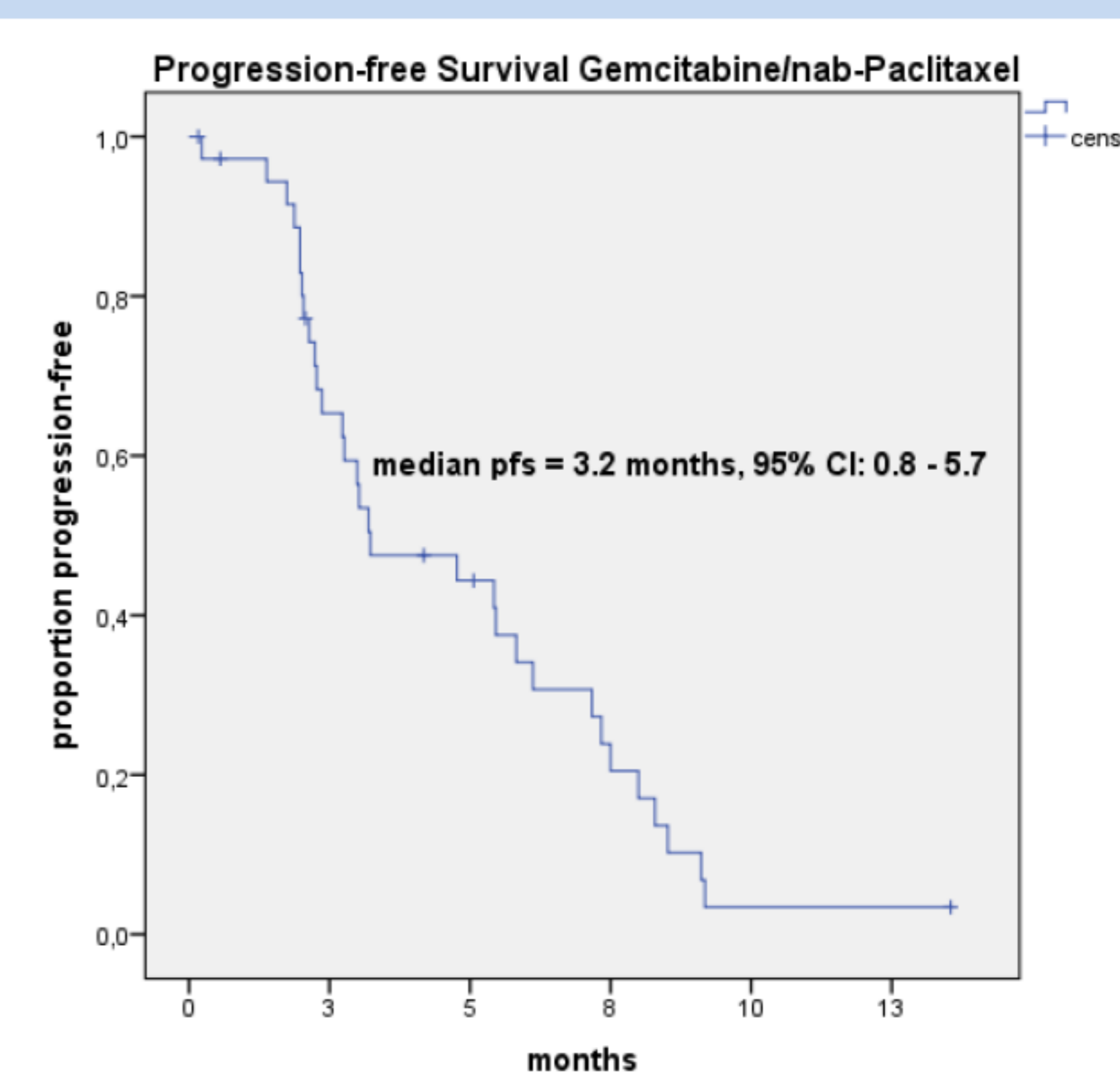
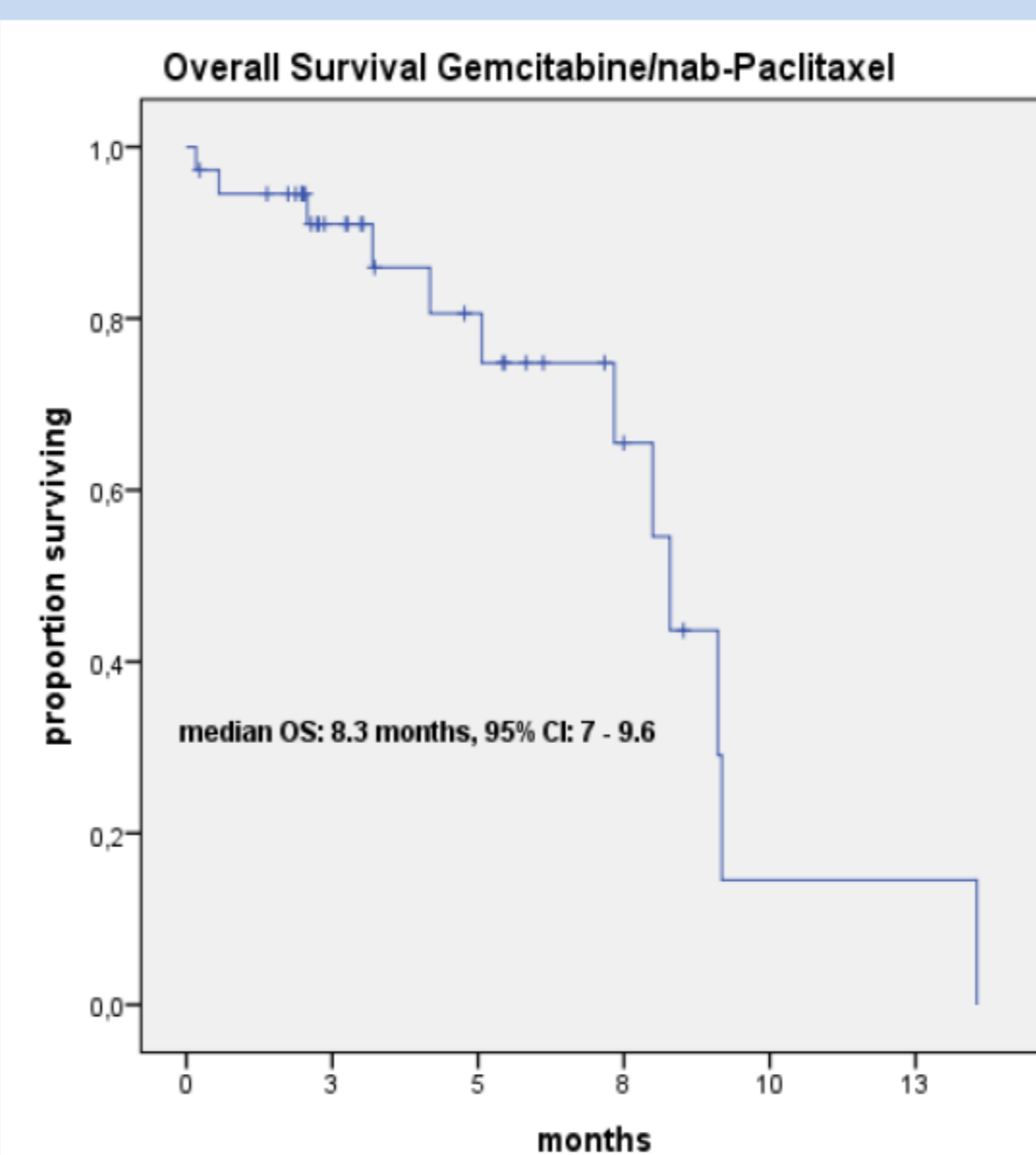
variable	patients	
	n	%
total number of patients	37	100
male	22	60
female	15	40
median age (range) years	70 (46-92)	
ECOG		
- 0	18	49
- $\geq$ 1	19	51
Stage, Grade		
- III	13	35
- IV	24	65
- G1	2	5
- G2	5	14
- G3	30	81
line Gemcitabine/ <i>nab</i> -Paclitaxel		
- first-line	10	37
- > second-line	27	73
prior treatment protocols		
- FOLFIRINOX	20	54
- Gemcitabine/Erlotinib	5	14
- GEMOX	2	5
local radiation therapy		
- yes	8	22
- no	29	78

Response (RECIST)		
- PR	8	22
- SD	13	35
- PD	14	38
- too early	2	5
Tumor marker response (CA19-9)		
- yes	23	62.5
- no	12	32.5
- too early	2	5
dose reduction / dose delay		
- Yes	12/13	32/35
biweekly schedule		
- yes	25	68
- no (day 1,8,15 q21)	12	32



Cycle number	CA 19-9 (U/ml)
Baseline	1359
Cycle 3	556.7
Cycle 5	151
Cycle 7	34.2
Cycle 9	36.4

Age	Sex	TX line	Pfs (months)	OS (months)	Response	CA19-9 decline	Dose scheme
76	femal e	2nd	7.4	10.2	PR	yes	q14



## Conclusion

The combination of *nab*-Paclitaxel and Gemcitabine in second-line treatment after FOLFIRINOX for patients with good performance status can extend the median survival time to 30 months and should be viewed as the new standard for these patients. For elderly or FOLFIRINOX unfit patients this combination should be considered as first-line treatment.

### References:

- Goldstein, D et al. Nab-Paclitaxel plus gemcitabine for metastatic pancreatic cancer: long-term survival from a phase III trial. *J Natl Cancer Inst*, 2015 Jan 31;107(2).
- Von Hoff, DD et al. Increased survival in pancreatic cancer with nab-paclitaxel plus gemcitabine. *N Engl J Med*, 2013 Oct 31;369(18):1691-703
- Von Hoff, DD et al. Gemcitabine plus nab-paclitaxel is an active regimen in patients with advanced pancreatic cancer: a phase I/II trial. *J Clin Oncol*, 2011 Dec 1;29(34):4548-54

