

ASSESSING 2-MONTH CLINICAL PROGNOSIS IN PATIENTS WITH SOLID TUMORS : RESULTS OF PRONOPALL STUDY

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Observatory of Cancer - Brittany & Pays de la Loire

- Created in 2003 by Regional Representatives of French ministry of health
- Collects data from both private and public hospitals
- Provides a reflection on drug management aiming at optimizing health care

Presentation of the study

Palliative cancer therapy is a difficult medical practice, particularly in the advanced stages of the disease. **Relevance** puts repeatedly question to medical oncologists. The prognostic evaluation could be an aid to therapeutic decision, especially in a palliative context, where chemotherapy can degrade **quality of life of patients**.

Oncologists, caregivers and close relatives can be brought to challenge the risk of harmful or unnecessary chemotherapy. Indeed, a toxic death deprives patient, family and teams to do **preparatory work necessary in later life**.

The Palliative Care team from Poitiers's UHC validated a **prognostic score** in a **population of hospitalized patients** (Barbot et al, JCO 2008).

The Observatory dedicated to Cancer from Brittany and Pays de la Loire areas wants to validate this score in an **outpatient population** during consultation.

2 Phases :

- **PRONOPALL** : prognostic score validation (n=300)
- **PALLIACHIM** : prognostic score use and impact (n=300)

Purpose : The use of score should reduce by 15% the prescription palliative chemotherapy in the population included.

26 centers / 109 investigators

Eligibility criteria of patients:

- over 18 years
- with one of the seven eligible cancers
- involving only a palliative chemotherapy
- presenting at least one the **3 following criteria**:
 - ECOG, OMS, Performance Status (PS) ≥ 2 ,
 - and/or life expectancy < 6 months,
 - and/or progressive disease during previous palliative treatment

Scoring

PS	0-1 score = 0	2-3 score = 2	4 score = 4	=.../4
Number of metastatic site	≤ 1 score = 0	≥ 2 score = 2		=.../2
LDH (Uj/L)	< 600 score = 0	≥ 600 score = 1		=.../1
Albumin (g/L)	≥ 33 score = 0	<33 score = 3		=.../3
TOTAL SCORE :				=.../10

Pronopall Phase

October 2009- November 2010 : **302** patients included
 → **265** evaluable patients ; **37** patients not eligible

109 Males / 156 Females
 median age: **66** years [37-88]

80% of the patients had a previous palliative anticancer treatment

Inclusion criteria :
 1 criteria for 46% of patients
 2 criteria for 38% of patients
 3 criteria for 16% of patients

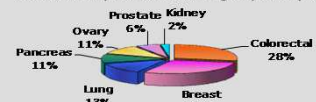
4 prognostic factors assessed at inclusion*:

Median LDH : **397** Uj/L [118-4314]

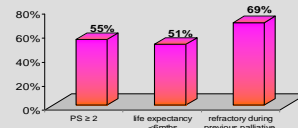
Median Albumin: **35** g/L [13-54]

* not calculated at the time of treatment contrary to the 2nd phase Palliachim

Distribution of patients according to primary tumor :



Percentage of patients per criteria:



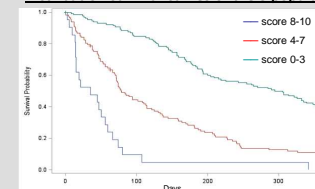
Number of metastatic site:

- no site : 2%
- 1 site : 32%; 2 site: 35%
- >2 sites : 31%

	% population	Survival 2 months	Survival 6 months	Median Overall Survival
Score 8-10	8%	24% (Barbot 8%)	5%	35 days [14 - 56]
Score 4-7	43%	64% (Barbot 43%)	26%	78 days [71 - 113]
Score 0-3	49%	92% (Barbot 92%)	66%	301 days [209 - 348]

Survival

Distribution survival curves of the 3 populations



$p < 0.001$ ⇨ In terms of survival, 3 statistically different populations

Statistically significant influence on the survival curve of ($p < 0.0001$) :

- Performance Status
- LDH rate
- Albumin rate

Oncogeriatry

62 patients over 75 years

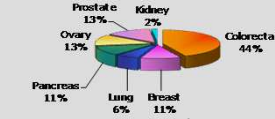
→ **Inclusion criteria** : no statistically significant between <75 and >75 years patients except for the distribution of the primary tumor

→ Same distribution of the score value

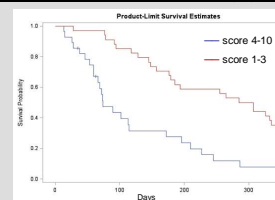
Survival for over 75 years patients :

	population	Survival 2 months	Median Overall Survival
Score 8-10	2		
Score 4-7	26	67%	74 days
Score 0-3	34	97%	296 days

Distribution of patients according to primary tumor



Distribution survival curves of the 2 populations



$p = 0.0002$ ⇨ statistically different

Palliachim Phase

Today, **293** patients included, 15 participating centers, 100 M / 193 F, median age : 67 years [35 - 90]

Pronopall study confirms the three prognostic profiles defined by the score.
Pronopall score is validated in an oncogeriatric subgroup (older than 75 years).
Results from Palliachim phase and validation in current practice coming soon...

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